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Knowledge andAttitude among Health care professionals aboutPharmacovigilance in a Tertiary Care Teaching hospital RVS institute of medical sciences Andhrapradesh.

Dr. Madhav .P[1],Dr.Sankara Babu Gorle[2]
[1](Department of Pharmacology , RVS Institute of Medical Sciences, Andhra Pradesh)
[2](Department of Pharmacology, NRI Institute of Medical Sciences, Andhra Pradesh)
Corresponding authors: Dr.Sankara babu Gorle,Dr.Madhav .P)

Abstract: *Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects of drugs, or any other drug-related problems. Awareness of the impact of ADRs on individual patients is important for Health care professionals' perspectives on safety issues. The stories of patients who have experienced ADRs will elucidate the impact of ADRs to Health care professionals. Both serious and non-serious ADRs may negatively influence patients' quality of life and treatment satisfaction and hamper drug compliance. The Ministry of Health and Family Welfare, Government of India has set up National Pharmacovigilance Programme (NPP) in 2004 with the goal to ensure the benefits of use of medicine and outweighs the risks and thus safeguards the health of the Indian population. We performed a cross sectional questionnaire survey to assess knowledge, awareness and practices of health care professionals about pharmacovigilance and ADR reporting in RSV institute of medical sciences. After observing the Pharmacovigilance programme of our institution we found that doctors have better knowledge regarding pharmacovigilance in comparison to nurses and students. But their practice and attitude regarding ADR reporting has to be improved. We have to increase awareness of doctors that ADR reporting will not hamper their image as the name of doctors prescribing the causative drugs are kept confidential.We have to frequently conduct seminars and workshop to improve knowledge of nurse and students.*

Key Words- *Pharmacovigilance,Current Scenario, Knowledge, Attitude And Practice*

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I. Introduction

The drugs besides producing desirable or beneficial effects can also cause undesirable adverse effects due to drug factors or some non drug factors..the aim of pharmacotherapy is to provide maximum benefits with minimal risk adverse effects The safety of patients and the safe use of medicines are high priorities in the modern world. The first practical international co-operation in drug monitoring started in 1968. The ideas came up as a consequence of the so-called thalidomide tragedy. In the 1960s it was discovered limb deformities in babies may occur if thalidomide, ingested by mothers during pregnancy. This incident became the modern starting point of a science focusing on patient problems caused by the use of medicines. This science, and activities associated with it, is now most commonly called pharmacovigilance.

According to WHO,Pharmacovigilance is defined as the science and activities relating to the detection, assessment,understanding, and prevention of adverse effects of drugs, or any other drug-related problems[1].Pharmacovigilance starts from the clinical stage and continues throughout the product life cycle of the drug, mainly divided as pharmacovigilance during pre-marketing (that is clinical trial phase) and post-marketing. Pharmacovigilance is particularly concerned with the adverse drug reactions (ADRs) which are defined as an unintended and noxious response to a drug that occurs at doses normally used for the prophylaxis, diagnosis, or therapy of diseases, or for the modification of physiological function [2].

The Ministry of Health and Family Welfare, Government of India has set up national Pharmacovigilance Programme (NPP) in 2004 with the goal to ensure the benefits of use of medicine and outweighs the risks and thus safe guard the health of the Indian population. As India is now emerging as the 'Global hub for Generic Drugs, Clinical trials and Drug Discovery and Development', a vast number of new drugs are being introduced into the country which throws up the challenges of monitoring ADRs over large population base. All medicines (pharmaceuticals and vaccines) as a rule have known or unknown side effects. However many adverse drug reactions (ADRs) are preventable but it demands a good knowledge of pharmacology and good prescribing practices [3].

It is important to monitor every undesirable effect of medicines in order to determine any new information available in relation to their safety profile. In a vast country like India with a population of over 1.3

billion with vast ethnic variability, different disease prevalence patterns, practice of different systems of medicines, different socioeconomic status, it is important to have a standardized and robust pharmacovigilance and drug safety monitoring programme for the nation. Collection of this information and analysis of this data to reach a meaningful conclusion on the continued use of these medicines is the rationale of pharmacovigilance. The results thus obtained will be useful in changing the labeling of medicines indicating restriction in use or issue of statuary warning, precautions, or even withdrawal of the drug from the market. This also helps in educating doctors about ADRs and in the official regulations of drug.

In India the national coordinating center for Pharmacovigilance Programme is located at AIIMS with two zonal, five regional and a number of ADRs monitoring center (AMC). The whole programme is under the Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Government of India with the objectives of:

1. To monitor Adverse Drug Reactions (ADRs)
2. To create awareness amongst health care professionals about the importance of ADR reporting in India
3. To monitor benefit-risk profile of medicines
4. Generate independent, evidence based recommendations
5. Support the CDSCO for formulating safety related regulatory decisions for medicines

Spontaneous reporting is the core data-generating system of international pharmacovigilance, relying on healthcare professionals (and in some places consumers) to identify and report any suspected ADRs to their national pharmacovigilance center or to the manufacturer. Spontaneous reports are almost always submitted voluntarily. However, reporting of serious ADRs rarely exceeds 10% though the figures vary greatly between countries and in relation to minor and serious ADRs. Overall underreporting of ADRs is a common problem in pharmacovigilance programs. [4-6]

Major challenge ahead is to develop awareness among healthcare providers of the potential risks of medicines while also understanding the extent of their benefits. Often neglected, If the symptoms are not serious, they may not notice them at all. And even if the symptoms are serious, they may not be recognized as the effect of a particular drug. After observing the Pharmacovigilance programme of our institution we found that the problems of underreporting and lack of awareness were prevalent in the community of health professionals. Pharmacologists can make a major contribution toward making medicines safer for all patients by reporting their suspicions of ADRs to Local Adverse monitoring centres and also by monitoring pharmacovigilance cell in tertiary care hospitals. Ultimately, these interventions are intended to make medicines safer to use. Health professionals who care for patients' drug therapy are taught to consider as well the benefit as the risk when making therapeutic choices. To recognize and properly manage ADRs, careful observation and high index of clinical suspicion are of crucial importance. So undertaking all this consideration we plan to conduct a study to know the awareness of Pharmacovigilance among health professionals of our institute. Aim of our study is to create awareness of pharmacovigilance among health professionals and to uncover the causes of underreporting. In this study we also aimed to know the suggestions to improve the ADRs reporting. Since, there are considerable social and economic consequences of ADRs there is a need to engage health-care professionals, in a well structured programme to build synergies for monitoring ADRs. Moreover, it is also possible to detect an unusual adverse reaction associated with an old drug that is widely used and with known side effects profile. All such efforts will lead to better ADR management and increased patients' safety[7].

II. Material and Methods

This was a randomized, cross-sectional, observational, questionnaire-based study, conducted at a tertiary care teaching hospital in Vizianagaram, Andhra pradesh. This questionnaire survey was conducted during june 2013 and approval from Institutional Ethical Committee was obtained prior to administering the questionnaire survey. The questionnaire, contains 23 questions regarding knowledge, attitude and practices of Pharmacovigilance along with suggestions to improve ADR reporting, was designed based on similar previous studies. [8,9] Structured pretested questionnaire contained 7 items to check knowledge, 11 for attitude, and 5 to study practices. Participants were explained the purpose of study and were requested to complete and return the questionnaire immediately. Data were analyzed using SPSS 17 software. Study was done on health professionals (doctors, nursing staff and undergraduate students) working in the medical college and hospital.

Pretesting of questionnaire was done with Pharmacovigilance committee and on 10 randomized selected health professionals of the institute to identify any potential bias and mistakes. asked. The aim of study and questionnaire were discussed among the members of Pharmacovigilance committee and then personally briefed to the participants.

The information was recorded and analyzed using SPSS 17 software and the ANOVA test followed by Fisher test. The **p** value less than 0.05 was considered to be statistically significant.

III. Result

All the doctors (n=150), nurses (n=50) and undergraduate students(n=100) enrolled from different medical and surgical disciplines, *viz* medicine, surgery, obstetrics and gynecology, pediatrics, ophthalmology, oto-rhinolaryngology, and dermatology completed the questionnaire.

Majority of the doctors (97.6%), students (85.1%) and 62.5% of nurses chose the correct definition of ADR. Doctors had significantly (P <0.0001) better knowledge on the elements of Pharmacovigilance and regarding what to report **,** what is SAE.The yellow color depicts the comparison between doctors, nurses and students and the trend is that doctors score over nurses and nurses score over students. The red color depicts areas where students have scored over nurses.(Table/Figure No -1)

Table/Figure No -1

S.No	QUESTIONS	DOCTORS		NURSES		STUDENTS	
		Correct %	Incorrect %	Correct %	Incorrect %	Correct %	Incorrect %
1.	**DEFINITION OF ADR**: An adverse drug reaction (ADR) is "a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man"	97.6	1.5	62.5	37.5	85.1	14.8
2.	**KNOWLEDGE ABOUT NATIONAL ADR REPORTING SYSTEMS**	93.7	5.4	62.5	37.5	40.51	59.45
3.	**KNOWLEDGE ABOUT ELEMENTS OF PhV** (detection, assessment, understanding, prevention)	91.4	8.5	62.5	37.5	43.75	56.25
4.	**ADR REPORTING TO BE DONE FOR** :						
	a) Allopathic medicine	12.5		12.5		10.65	
	b) Indian system of medicine	2.3				9.25	
	c) Medical advices	0				5.15	
	d) All	84.3		75		74.35	
5.	**WHAT IS A SERIOUS ADVERSE EVENT (SAE)**?: A SAE is any event that is fatal, life-threatening, permanently/significantly disabling, requires or prolongs hospitalization, causes a congenital anomaly or requires intervention to prevent permanent impairment or damage	96.8	3.12	62.5	37.5	91.25	9.75
6.	**WHAT TO REPORT**:						
	a) SAE					6.03	
	b) Adverse event: An adverse event or experience is defined as "any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a casual relationship with the treatment"					5.72	
	c) ADRs					5.75	
	d) Side effect					6.28	
	e) All	86.7	13.2	75	25	76.25	
7.	**WHOM TO REPORT ADRS**:						
	a) National PhV center	0.7				12.29	
	b) ADR monitoring center of institution	41.4		40		13.65	
	c) Treating physician (in case of nurses)	21		21.8		7.26	
	d) Any of the above	35.9		31.2		42.7	
	e) Kept personally for future references					11.2	
	f) Do not know		0.7		6.25	11.6	

Regarding the practice, From question number 2 we can see that almost all students(99.25%) told to report ADRs but only 60% of doctors and nurses told to report. From question number 5 we can observe that majority of the students(69.2%) reported to write the ADRs on patient`s case sheet whereas in case of doctors only 42.1% reported to write on case sheet All highlighted values were compared by Fisher's exact test and p value < 0.0001.The yellow color depicts the comparison between doctors, nurses and students and the trend is that doctors score over nurses and nurses score over students. The red color depicts areas where students have scored over nurses.(Table/Figure No -2)

Table/Figure No -2

S.No	QUESTIONS	DOCTORS		NURSES		STUDENTS	
		Correct %	Incorrect %	Correct %	Incorrect %	Correct %	Incorrect %
1.	**TO FIND ADRs?**						
	a) Only ask from patients	33.5		31.2		10.52	
	b) Only ask from patient's relative	2.3				5.26	
	c) Only monitor the patient's reports	1.5				0	
	d) All of the above	80		68.7		84.21	
2.	**WHAT YOU DO WITH ADRs?**						
	a) Report to center/treating physician (nurse)	60		60		99.25	
	b) Do not inform to anybody as it is routine part of the treatment	39.8		40		0.75	
3.	**WHICH SEVERITY OF ADRs DO YOU REPORT?**						
	a) Minor: no therapy required	----		3.1		0	
	b) Moderate: required therapy	1.5				14.28	
	c) Severe: life-threatening	2.5		96.8		14.28	
	d) All	73.4				73.80	
4.	**IS THERE ANY ROUTINE DISCUSSION ON ADRs**	75	25	68.7	31.2	29.72	70.27
5.	**DO YOU MENTION THE ADRs ON THE PATIENT'S RECORD?**						
	a) Always	42.1		53.1		69.2	
	b) Once in a while	4.6				15.3	
	c) Never	51.5		46.8		10.25	
	d) Managed it without mentioning	1.5				5.12	

Regarding attitude, From question number 3 we can observe that only 15.78%of students told that ADR reporting will damage the professional image whereas majority of the doctors(86.7%) reported that ADR reporting will damage their professional image. Regarding reporting system of ADR only 15% of the students told it should be voluntary whereas majority of the doctors(55.4%) report that this should be voluntary. only 46.2% of the students told to report new drugs for ADR but majority of the doctors(68.7%) to report new drugs for ADR. Regarding conductance of workshop for pharmacovigilance majority of the students told to conduct more frequently and also they have stressed the importance of workshop in improving knowledge regarding pharmacovigilance(97.29%).majority of doctors (63.8%)reported that preferred mode of reporting ADR is drop box where as only 42.6% of nurses and 35.7% of students reported drop box as the preferred mode of reporting. Regarding location of drop box 92% of nurses told it should be in OPD where as only 59.25% of doctors ant 52.63% of students told the location to be OPD. All highlighted values were compared by Fisher's exact test and p value < 0.0001.The yellow color depicts the comparison between doctors, nurses and students and the trend is that doctors score over nurses and nurses score over students. The red color depicts areas where students have scored over nurses.(Table/Figure No -3)

Table/Figure No -3

S.No	QUESTIONS	DOCTORS		NURSES		STUDENTS	
		Correct %	Incorrect %	Correct %	Incorrect %	Correct%	Incorrect %
1.	**IS ADR REPORTING NECESSARY?**	100		100		99.28	
2.	**WHO BENEFITS FROM ADR REPORTING?**						
	a) HCPs	----		---		0	
	b) Patients	3.12		9.3		23.68	
	c) Health regulatory authorities	0.7		3.1		2.6	
	d) All	96		87.5		73.68	
3.	**DOES ADR REPORTING DAMAGE PROFESSIONAL IMAGE?**	86.7	13.2	12.5	87.5	15.78	84.2
4.	**IS THERE NEED OF INFORMATION ON DRUG CAUSING ADRs AND THEIR RISK MANAGEMENT**	92.9	7.0	96.8	3.12	92.1	7.8

	STRATEGIES?						
5.	**PREFERRED ADRs REPORTING SYSTEM**						
	a) Voluntary	55.4		13.4		15	
	b) Mandatory	44.5		56.3		72.5	
	c) Need base	---		3.1		12.5	
6.	**PHARMACEUTICAL PRODUCTS TO BE MONITORED FOR ADRs?**						
	a) New drug	68.7		40		46.2	
	b) Old drug	28.9		43		14.9	
	c) Medical devices	1.5		3.12		10.4	
	d) Vaccines	0.7		12.5		28.3	
7.	**DO CONFERENCE/WORKSHOPS ON PhV IMPROVE REPORTING?**	86.7	13.2	90.6	9.3	97.29	2.71
8.	**SUGGESTED FREQUENCY OF ADR CONFERENCE/WORKSHOPS**						
	a) Three monthly	28		25		37.83	
	b) Six monthly	36.7		34.3		35.13	
	c) Once in a year	31.2		40.6		27.02	
	d) Once in 3 years	3.9		---	---	0	
9.	**EXPECTATIONS FROM THE SUBMITTED ADRs?**						
	a) Feed back	54.6		68.7		85.01	
	b) Publication	34.3		18.7		15.0	
	c) Nothing	10.9		12.5		0	
10.	**PREFERRED MODE TO REPORT ADRs**						
	a) Phone	25.7		56.2		16.66	
	b) Drop box	63.8		40.6		35.7	
	c) E-mail	1.5		----		14.28	
	d) Personal visit	8.5		3.1		35.7	
11.	**IF OPTED DROP BOX ITS PREFERRED LOCATION**						
	a) Ward/OPD	59.2		92		52.63	
	b) AMC	40.7		7.6		5.2	
	c) Nearby chemist					21.05	
	d) Office of medical association					21.05	

IV. Discussion

In this study we involved the Doctors(n=150), nurses(n=50) and undergraduate students(n=100) regarding knowledge practice and attitude of Pharmacovigilance.

Regarding knowledge the doctors have better knowledge about elements of pharmacovigilance in comparision to nurses and students .Also they have better knowledge regarding what is SAE and what to report. This is because the doctors have already completed their MBBS study and the students yet to complete their study. So we have to improve the knowledge of students by teaching them regarding the importance of pharamacovigilance .Also we can improve their and nurses knowledge regarding pharmacovigilance by conducting workshops and seminars. This results can be compared to study conducted by Rehan et al where he also got similar results.[11] .But this is contrary to a study conducted by Hardeep et al where he got that doctors have poor knowledge regarding pharmacovigilance[J Clin Diagn Resv.7(1); Jan 2013

Regarding practice we can see that majority of students in comparision to doctors told to report ADRs . This may be due to fear of doctors that reporting ADR will hamper their professional image. Also students told to write the ADRs on patient`s case sheet . This shows the lack of knowledge regarding practice of ADRs in students. We have to increase awareness of doctors that this will not hamper their image as the name of doctors prescribing the causative drugs are kept confidential.We have to frequently conduct seminars and workshop to improve knowledge regarding practice of ADRs.

Regarding attitude majority of doctors reported that reporting ADR will hamper their professional image. About what to report and whether it should be voluntary or not doctors out scored nurses and students. Also about preferred mode of reporting of ADRs as drop box doctors outscored nurses and students. Majority of the Students told that frequent conductance of seminars and workshop will improve their knowledge regarding pharmacovigilance. From these we can conclude that doctors have a better knowledge regarding ADR reporting but they have fear of hampering their professional image. We have to improve knowledge of Students by conducting seminars and workshop.

So there is lack practice and attitude of ADRS in Doctor. .This results can be compared to study conducted by Rehan et al where he also got similar results.[10] This was also in agreement with the results of Li Qing et al., [6]. But this is contrary to a study conducted by Subish PALAIAN et al where he got that doctors have poor knowledge but relatively better practice and attitude towards pharmacovigilance (Palaian S, Ibrahim MI, Mishra P. Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. Pharmacy Practice (Internet) 2011 Oct-Dec;9(4):228-235.)

The paramedical staff(nurses) could play an important role in ADRs reporting, because they are close to the patient and are responsible for drug administration and recording side effects. They can alert the responsible physician about possible ADRs without time gap. Thus it is crucial to encourage the paramedical staff towards ADR reporting [9].

V. Conclusion

From this study we can conclude that doctors have better knowledge regarding pharmacovigilance in comparison to nurses and students. But their practice and attitude regarding ADR reporting has to be improved.We have to increase awareness of doctors that ADR reporting will not hamper their image as the name of doctors prescribing the causative drugs are kept confidential. Motivating doctors to report ADRs is not easy. Many attempts have to make to encourage ADR reporting by frequently conducting seminars and arranging workshops,or implying an educational program of lectures to improve knowledge of nurse and students.

References

[1]. World Health Organization (2002) Safety of Medicines: A guide to detecting and reporting adverse drug reactions. Geneva, Switzerland
[2]. International drug monitoring: the role of national centres. Report of a WHO meeting. World Health Organ Tech Rep Ser 498: 1-25.
[3]. World Health Organization (2002) The importance of pharmacovigilance - Safety monitoring of medicinal products. Geneva, Switzerland.
[4]. Green CF, Mottram DR, Rowe PH, Pirmohamed M (2001) Attitudes and knowledge of hospital pharmacists to adverse drug reaction reporting. Br J Clin Pharmacol 51: 81-86.
[5]. Subish P, Izham MM, Mishra P (2008) Evaluation of the knowledge, attitude and practices on adverse drug reactions and pharmacovigilance among healthcare professionals in a Nepalese hospital: a preliminary study. The Internet Journal of Pharmacology 6(1)
[6]. Ulfvarson J, Mejyr S, Bergman U (2007) Nurses are increasingly involved in pharmacovigilance in Sweden. Pharmacoepidemiol Drug Saf 16: 532-537.
[7]. Awareness among tertiary care doctors about Pharmacovigilance Programme of India: Do endocrinologists differ from others? Indian . J endocrine and metabolism 2016 May-Jun; 20(3): 343–347.
[8]. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK (2011) An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspect Clin Res 2: 129-136.
[9]. Ramesh M, Parthasarathi G (2009) Adverse drug reactions reporting: attitudes and perceptions of medical practitioners. Asian J Pharm Clin Res 2: 10-4.
[10]. Bäckström M, Ekman E, Mjörndal T (2007) Adverse drug reaction reporting by nurses in Sweden. Eur J Clin Pharmacol 63: 613-618.
[11]. Inman WH (1996) Attitudes to adverse drug reaction reporting. Br J Clin Pharmacol 41: 434-435.

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