International Journal of Allied Medical Sciences and Clinical Research (IJAMSCR)

ISSN:2347-6567

IJAMSCR |Volume 7 | Issue 2 | Apr - Jun - 2019
www.ijamscr.com

Research article *Medical research*

To study the awareness about the pharmacovigilance in the postgraduate residents at a tertiary care hospital- a kap study

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ABSTRACT

Background

Pharmacovigilance is the science related to detection, evaluation and prevention of Adverse drug reactions (ADRs). Safety of patients and safe use of medicines are high requisition that has emerged practice of Pharmacovigilance. Pharmacovigilance system is established to report suspected ADRs encountered during practice. Lack of knowledge, awareness, complacency and training are factors responsible for underreporting.

Methodology

We assessed awareness of Pharmacovigilance in Postgraduate residents in a hospital set up after ethical approval. The questionnaire of 26 questions (knowledge-15, attitude-5 and practice -6) was designed based on the precedence and was standardised. It was distributed among 120 post-graduate students and the data was analysed accordingly.

Result

Out of 120 postgraduate doctors, 100 participated in the study. Response rate was 83% Regarding knowledge, Only, 41% could retort the meaning of ADR, 52% could make a prospective relation for the meaning of pharmacovigilance, 88% had acquaintances for which ADR has to be reported. 89% had apprehension in recording important elements in ADR.

About attitude, residents were vivid in their outlook for ADR reporting as on catechising 100% felt necessity to report and 90% were affirmative about starting a Pharmacovigilance training program.

While trying to eloquent the practice, 87% have never seen ADR reporting form, 89% never reported it, 73% experienced ADR in patients. 98% opined to strengthen the Pharmacovigilance system.

Overall, 55% had knowledge, 87.6% had positive attitude whereas practice is only 45%

Conclusion

We recommend Pharmacovigilance should be made integral training program in healthcare curriculum to strengthen it.

Keywords: Adverse drug reactions (ADRs), Pharmacovigilance, Knowledge, Awareness

INTRODUCTION

The term Pharmacovigilance was coined from two Greek terms “Pharmakon”-drug and “vigilare”-to keep watch. A number of Adverse Drug Reactions related to drugs prompted the development of the science of “Pharmacovigilance”. Thalidomide disaster in 1961 is one of the incidences when thousands of congenitally deformed infants were born. This prompted WHO for systematic study of ADR of Drugs, which is the beginning of Pharmacovigilance [1]. According to Barker, there are three possible actions of drug: The one you want, the one you don’t want, and the one you don’t know about [2].

According to WHO, Pharmacovigilance is defined as the science and activities relating to the detection, evaluation, understanding and prevention of ADR’s or any other drug related problems [3]. The safety of patients and the safe use of medicines are high requisitions in the modern world, this emerged the practice and science of Pharmacovigilance [4].

Death due to a disease is often unavoidable, but death from a medicine is unacceptable. In USA, ADRs are among the top 10 causes of mortality [6] and in UK, it is suggested that ADRs may cause 5700 deaths per year [7]. The percentage of hospital admissions due to drug-related events in some countries is around 10 percent. In an effort to strengthen the Pharmacovigilance in India, government has initiated Pharmacovigilance program of India (PvPI). Similarly, the Drug Controller General of India and Indian Council of Medical Research have established ADR monitoring centres in many hospitals in major cities of India [8]. In a country like India with vast ethnic variability, different socioeconomic status, different disease prevalence and practice of different systems of medicines these types of studies are more important. But in India, these types of studies are very scanty. A study which was conducted in Mysore recommended that several studies of a similar kind, especially in the community setup, needed to be conducted, to know the attitudes of health care professionals towards the ADR reporting [9].

Presently the PvPI program has more than 200 Adverse Drug Monitoring Centres (AMCs) involving all states and Union Territories throughout India. 1,81,656 ADR reports have been received at NCC-PvPI during April 2011 - March 2016 but still ADR reporting in India is low.

AIM & OBJECTIVES

AIM

To study the awareness about the Pharmacovigilance in the postgraduate residents at a tertiary care hospital- A KAP STUDY.

OBJECTIVES

Primary

1. To evaluate knowledge, attitude and practice (KAP) about Pharmacovigilance.
2. To assess the awareness of Pharmacovigilance programme of India.
3. To assess the status of reporting of adverse drug reaction(s) ADR.

Secondary

1. To study the limitations & problems in reporting of ADR.
2. To promote awareness towards Pharmacovigilance.

METHODOLOGY

Study design

The study was a non-interventional, observational, questionnaire based study.

Study site

The study was carried out in Grant Govt. Medical College and Sir J.J Group of Hospital, Mumbai after the institutional ethics committee approval over a period of 4 months from December 2017-March 2018.

Study Population

Post-graduate residents of our hospital were selected as the sample population.

Study conduct

A total of 120 questionnaires were distributed among the residents in wards and OPDs. Study purpose was explained to them and duration of 45 minutes was given to fill the questionnaire. The complete filled questionnaires were analysed and partially filled questionnaires were discarded. Out

of 120, the total completely filled forms were 100 giving a response rate of 83%.

RESULTS

Pharmacovigilance awareness was tested in three domains of knowledge, attitude and practice by distributing a questionnaire to participants containing 26 questions, after obtaining permission from institutional ethics committee.

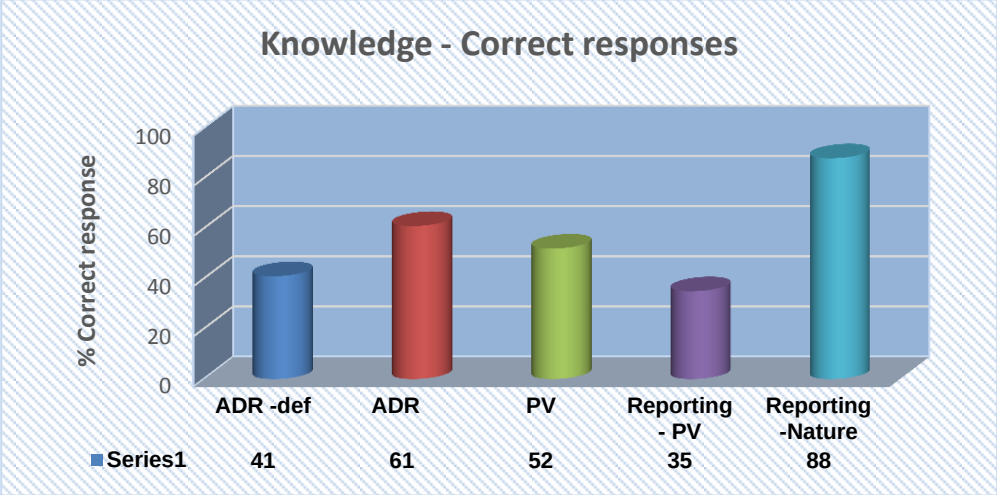
Assessment of Knowledge

Their pool of knowledge was tested beginning with the definition of ADR, we figured out that only 41% population knew the literal meaning. 61% participants could differentiate that side effects and untoward effects are not same. To know regarding orientation about pharmacovigilance study is related to it was found that only half of the population 52% could make a prospective relation. Knowledge regarding, who can report ADR, we got a downfall in their perspective where only 35% could answer correctly. Acquaintances of case in which ADR to be reported 88% participants opted for all known, unknown and serious life-threatening side effects.

On testing enlightenment in serious life-threatening ADR 55% felt it is important to report to ADR monitoring centre after stopping the drug and treating the patients. Surprisingly, 63% participants knew about existing National Pharmacovigilance programme and 74% knew that it is CDSCO as the regulatory body. But as the awareness lack regarding reporting only 63% have seen ADR reporting form. Wisdom of time, 48% felt that ADR can be reported within 24 hours. Important elements to be recorded during ADR, 89% had the apprehension that it should include Identifiable patient details, Identifiable reporter details and suspected medicinal products.71% opined that Drug related problems, Herbal products, Blood related products and Medical devices and vaccines are included in Pharmacovigilance. Regarding, reporting ADR by a non-medical person 64% agreed out of which 52% felt that it can be done by various means like orally, telephonically or via E-mail.

Table No. 1(a) – Appropriate knowledge about Pharmacovigilance in sample population

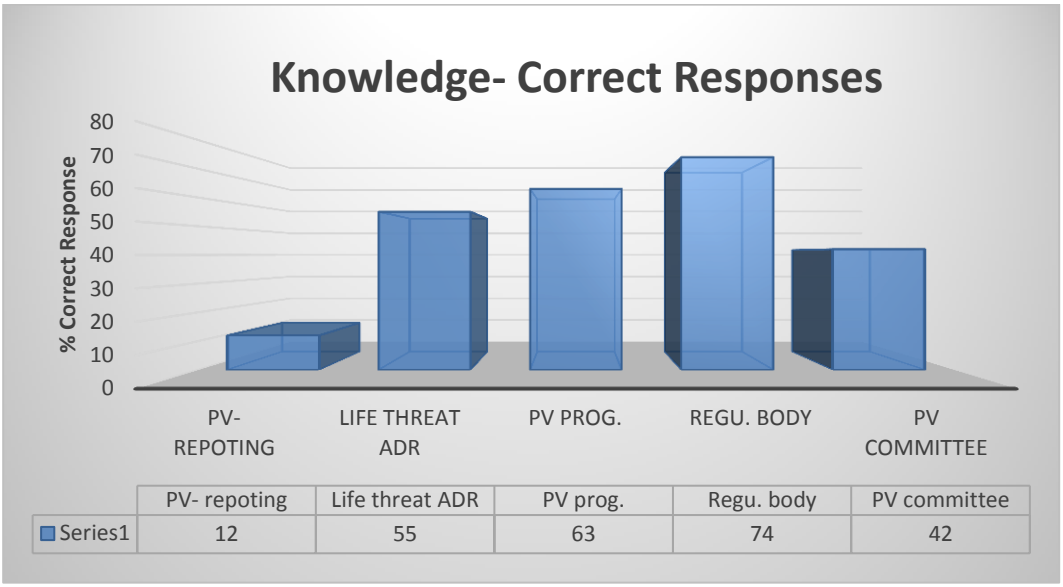
Sr. No.	Knowledge related Questions	Correct Response (%)	Incorrect Response (%)	Don't know (%)
1	Meaning of ADR	41	53	6
2	Are side effect and Untoward effects same	61	17	22
3	Pharmacovigilance is related to	52	28	20
4	ADR can be reported by	35	18	53
5	Cases in which ADR should be reported	88	10	2



Graph No. 1(a) – Appropriate knowledge about Pharmacovigilance in sample population

Table No. 1(b) – Appropriate knowledge about Pharmacovigilance in sample population

Sr. No.	Knowledge related Questions	Correct Response (%)	Incorrect Response (%)	Don't know (%)
6	Whom can ADR be reported	53	16	31
7	Measures in life-threatening ADR	55	29	16
8	National Pharmacovigilance program	63	24	13
9	Regulatory body for Monitoring ADR	74	20	6
10	Pharmacovigilance Committee in our institute	42	9	49



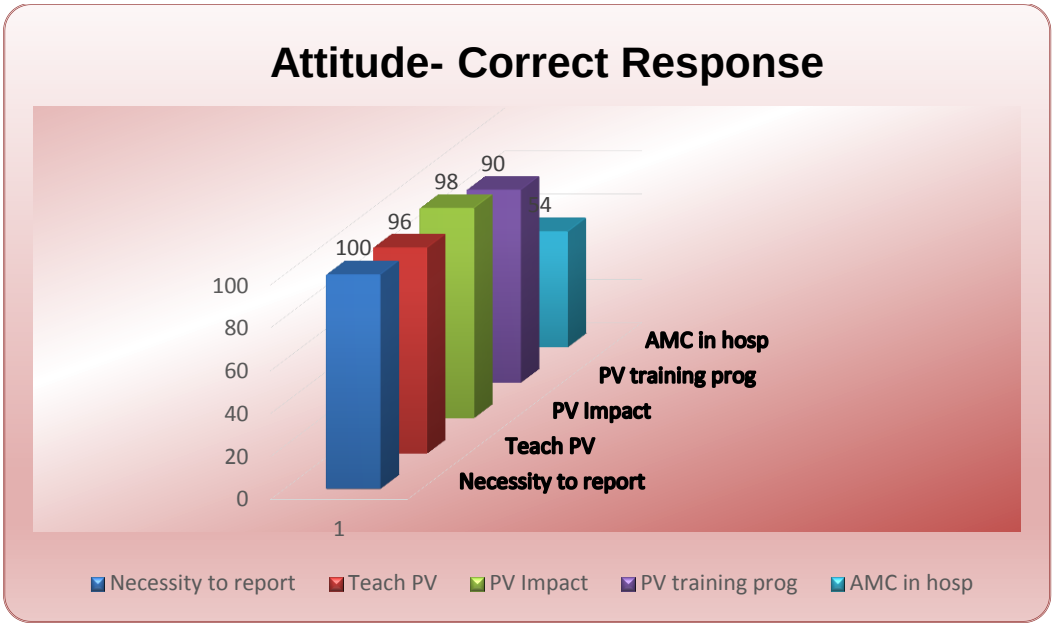
Graph No. 1(b) – Appropriate knowledge about Pharmacovigilance in sample population

Assessment of Attitude

Participants were vivid in their outlook and attitude for ADR reporting as on catechizing 100% felt it is necessary to report ADR. A positive attitude was observed among participants for teaching Pharmacovigilance in detail and will reporting have any impact on health care system responses were 96% and 98% respectively, and to start a separate Pharmacovigilance training program, 90% were affirmative about it. An average response was observed where only 54% were positive about establishing ADR monitoring centre in every Govt./Private hospital whereas 13% felt that one in city is sufficient. Rest of them 23% perceives that it should depend on number of bed size in hospitals.

Table. No. 2 - Appropriate attitude about Pharmacovigilance in sample population

Sr. No	Attitude related questions	Correct responses (%)	Incorrect responses (%)	Don't know (%)
1	Necessity of reporting ADR	100	0	0
2	Detailed teaching of Pharmacovigilance	96	1	3
3	Impact of reporting on healthcare	98	0	2
4	Separate Pharmacovigilance program in academics	90	3	7
5	Establishing AMC in every hospital	54	46	0



Graph No. 2 - Appropriate attitude about Pharmacovigilance in sample population

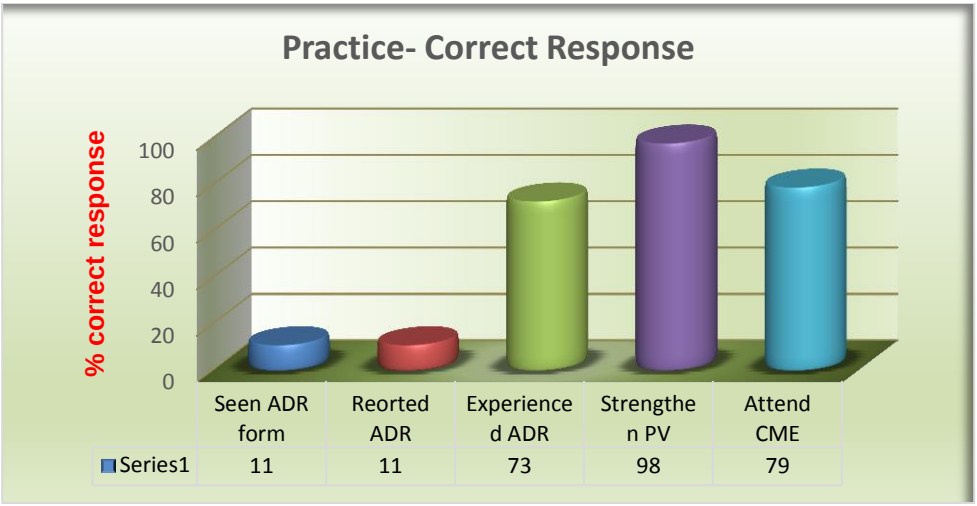
Assessment of Practice

Sadly, the scale tipped on the opposite side while knowing the current execution. As, 89% never saw the ADR reporting form and with 25% have no idea how to report and 13% dint know where to report, 89% participants have never reported any ADR on the contrary 73% have experienced ADR in their patients.

A very variegated response was established while knowing the factors for less reporting of ADR, where 12% felt that managing patient was more important than reporting, the others 9% had legal liability issues and 18% had concerns about professional liability. On knowing regarding the implementation of workshop 79% supported it and 98% would like to strengthen Pharmacovigilance system of our country by becoming part of it.

Table No. 3 – Appropriate practice of Pharmacovigilance in sample population

Sr. No.	Practice related Questions	Yes (%)	No (%)
1	Seen ADR reporting form	11	89
2	Ever reported ADR to Pharmacovigilance center	11	89
3	Experienced ADR in patient	73	27
4	Would like to strengthen Pharmacovigilance	98	2
5	Attend lecture on Pharmacovigilance in conference/workshop	79	19



Graph No. 3 – Appropriate practice of Pharmacovigilance in sample population

DISCUSSION

Our study aimed at studying the awareness about pharmacovigilance in post-graduate residents for which questionnaire were distributed among 120 participants.

The safety of patients and the safe use of medicines are high requisite to the modern world, this emerged the practice and science of Pharmacovigilance. For a successful Pharmacovigilance program, proper co-ordination is required among healthcare-professionals and institution. With this background perceiving the importance of Pharmacovigilance program and contribution of each ADR, it can bring change to the overall statistics ADR database and knowing the adverse effect related mortality. It becomes necessary to survey the current knowledge, attitude and practice of healthcare professionals in terms of reporting an ADR or becoming a part of Pharmacovigilance system of India.

To validate it, we did a study structured with 26 questions in three different domains (Knowledge - 15, attitude-5, practice-6). Questionnaire were distributed to participants and responses obtained were analysed. The results reflected very divergent responses in all the domains.

Analysing the knowledge of participants about purpose of Pharmacovigilance 52% could answer it correctly, similar study conducted in 2017 by Torwane et al [14]. Regarding, the existence of Pharmacovigilance program in India 63% could match up the correct answer. These finding are in co-relation with findings of the study conducted by Gupta et al [15]. 74% knew that CDSCO is the regulatory body governing Pharmacovigilance program. Elements mandatory to record, 6% felt that Identifiable patient and reporter details and 5% for suspected medicinal products whereas 89% felt that all the elements are necessary.

Although, knowledge being average, Interestingly, attitude of the participants was found to be quite positive as 100% felt the necessity of reporting ADR and 98% realized the contribution of each ADR. 96% also felt that PV program should be taught in detail. These findings co-related well with studies by Gupta et al and Torwane et al [14].

Surprisingly, on procuring the practice of the participants a huge gap was obtained as 73% of them have experienced ADR and only 11% of them have reported it. This raises a matter of huge concern because presence of an immense gap between experiencing and reporting, makes us realize that great number of ADR are going unreported. The similar results were obtained and can be co-related with study done by Torwane et al [14]. Important factors that generated concern was the practical hindrances healthcare-professionals face for reporting ADR. 9% don't think it is important, 12% think managing patient is more important than reporting ADR, 9% of them have legal liability issues and concern about professional liability. Out of 89% who have never reported an ADR, is due to the factors that 25% don't know how to report and 13% don't know where to report.

It is quite disheartening to perceive the average knowledge being 55%, 87.6% have an approach

and positive outlook but overall practicing and reporting of ADR just remained 38%. Outcomes of the study prompt us the significance of educating and accustoming healthcare professional of practicing Pharmacovigilance and making it as an integral part of practice.

Nwokike [16] study suggested shift from spontaneous report to self -report or reporting of ADR by patients, and thus motivating them to engage in Pharmacovigilance activities.

Various factors were encountered are held responsible for under-reporting. These included unawareness of reporting ADR, unware whom to report, how to report and where to report, occupied in handling patients, lack of knowledge regarding Pharmacovigilance program, perceive that one ADR doesn't make a huge difference. Similar factors were identified in a study by Torwane et al [14].

Comparing the results of our study with previous studies conducted, similarities were found regarding improving knowledge and positive attitude but lack in practicing and reporting of ADR but deficient in becoming part of Pharmacovigilance system.

Limitation

The major limitation was being a single-centric with limited number of participants.

Suggestion

- Increase awareness about Pharmacovigilance program.
- Make ADR forms available at the Nurses counter and making it as a part of daily routine reporting and handing over to other staff.
- Encourage doctors, nurse, pharmacist to report all suggested ADR's serious, non-serious, known, unknown, uncommon, life-threatening
- Educating doctors, nurses, pharmacists on How to report, where and whom to report an ADR.
- Providing remuneration
- Organizing Workshops and CME's on Pharmacovigilance and ADR reporting
- Incorporating Pharmacovigilance program in Undergraduate and Post graduate syllabus.
- Organizing and making compulsory 1 or 2 days certification course providing general information of ADR form and its reporting process.

CONCLUSION

The study revealed the lack of knowledge, awareness, indifference, complacency responsible for under-reporting. Perhaps, the immense difference was observed between the ADR's experienced and ADR's reported. Thus, it is recommended Pharmacovigilance system should be made integral training program in health curriculum to strengthen it. Additionally, starting up of workshops and organizing compulsory CME's for regular updates.

REFERENCES

[1]. Mandal S.C, Mandal M. Evolution of Pharmacovigilance programme: Present status in India. Pharma times, May 49(5), 2017, 31.
[2]. Hema N, Bhuvana K. Pharmacovigilance: The extent of awareness among the final year students, interns and postgraduates in a government teaching hospital. J Clin Diagn Res 6(7), 2012, 1248-53.
[3]. The Safety of Medicines in Public Health Programmes: Pharmacovigilance an essential tool, World Health Organizations, 2006, 7. –Accessed on 30/11/2017.
[4]. Bankowski Z, Dunne JF. Drug surveillance: International co-operation past, present and future. (2013)Proceedings of the XXVIIth CIOMS Conference, Geneva, Switzerland.
[5]. World Health Organization. Requirements for adverse reactionreporting. Geneva, Switzerland: World Health Organization; 1975.
[6]. Lazarou J, Pomeranz BH, Corey PN., Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. JAMA. 15, 279 (15), 1998, 1200-5.
[7]. Pirmohamed M. et.al, Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients, BMJ. 2004; 329 (7456): 15–19.
[8]. Patil A,Gurav YA,Thorat MB, Walsangikar SD. Survey of pharmacovigilance awareness among healthcare professionals. Int J Pharmacol Ther; 4, 2014, 31-4.

[9]. Ramesh M, Parthasarathi G. Adverse drug reaction reporting: the attitudes and the perceptions of the medical practitioners. Asian Journal of Pharmaceutical and Clinical Research. April-June 2(2), 2009, 10-14.
[10]. Oshikoya KA, Awobusuyi JO. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. BMC Clin Pharmacol. 9, 2009, 14
[11]. Yadav S. Status of adverse drug reaction monitoring and pharmacovigilance in selected countries. Indian J Pharmacol. 40(1), 2008, S4–9.
[12]. Smith CC, Bennett PM, Pearce HM, Harrison PI, Reynolds DJ, Aronson JK, et al. Adverse drug reaction in a hospital general medical unit meriting notification to the Committee on Safety of Medicines. Br J Clin Pharmacol. 42, 1996, 423–9.
[13]. Moride Y, Haramburu F, Requejo AA, Bégaud B. Under-reporting of adverse drug reactions in general practice. Br J Clin Pharmacol. 43, 1997, 177–81.
[14]. Torwane NA, Hongal S, Gouraha A, Saxena E, Chavan K. Awareness related to reporting of adverse drug reactions among health caregivers: A cross-sectional questionnaire survey. J Nat Accred Board Hosp Healthcare Providers 2, 2015, 23-9.
[15]. Gupta SK, Nayak RP, Shivaranjani R, Vidyarthi SK. A questionnaire study on the knowledge, attitude, and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in South India. Perspect Clin Res 6, 2015, 45-52.
[16]. Nwokike J. Monitoring Adverse Drug Reaction in the Public Health Programs: The Case of the Nigeria TB Program; 2008. Available from: http://www.apps.who.int/medicinedocs/documents/s18400en/ s18400en.pdf.

How to cite this article: AD Joshi, Femina Dawer. To study the awareness about the pharmacovigilance in the postgraduate residents at a tertiary care hospital- a kap study. Int J of Allied Med Sci and Clin Res 2019; 7(2): 351-358.
Source of Support: Nil. **Conflict of Interest:** None declared.