AWARENESS ABOUT PHARMACOVIGILANCE AMONG RESIDENT DOCTORS IN A TERTIARY CARE HOSPITAL
Amit A. Bansode¹, Zad V. R², Sawant S. D³, Dudhal K. S⁴

HOW TO CITE THIS ARTICLE:
Amit A. Bansode, Zad V. R, Sawant S. D, Dudhal K. S. "Awareness about Pharmacovigilance among Resident Doctors in a Tertiary Care Hospital". Journal of Evolution of Medical and Dental Sciences 2015; Vol. 4, Issue 02, January 05; Page: 207-210, DOI: 10.14260/jemds/2015/33

ABSTRACT: BACKGROUND: Monitoring and evaluation of adverse drug reactions (ADRs) through a well-organized pharmacovigilance system is vital for safe use of medicines. ADR reporting by healthcare professionals forms the backbone of pharmacovigilance system. AIM: To assess the awareness of pharmacovigilance among resident doctors in a tertiary care hospital. MATERIAL AND METHODS: This is a cross sectional descriptive study, carried out in a total 160 resident doctors from various specialities in a government run tertiary care teaching hospital were administered a questionnaire to evaluate knowledge, attitude and practice of pharmacovigilance. The questionnaire consisted of open and closed ended questions. The study was conducted in January/February 2012. RESULTS: Most of the residents had heard the term 'pharmacovigilance’ but only 25% knew the actual meaning of it. About 84% of the residents did not know about Pharmacovigilance Programme of India (PvPI), 68% did not know about existence of any ADR reporting centers in the country. Most of them (75%) agreed that ADR reporting is responsibility of the doctors. So far none of the residents have reported an ADR under PvPI. CONCLUSION: The awareness of pharmacovigilance among resident doctors in teaching hospitals is very low. There is an urgent need to train health professionals in pharmacovigilance to improve the current sorry state. KEYWORDS: Pharmacovigilance, adverse drug reactions, PvPI.

INTRODUCTION: Adverse drug reactions (ADRs) due to drug are common yet often preventable and are associated with significant morbidity and mortality.¹² ADRs were responsible for increased length of stay in hospitals and increased economical burden.²³ Monitoring and evaluation of ADRs through a well-organized pharmacovigilance system is vital for safe use of medicines.

To accomplish this task government has initiated pharmacovigilance programme of India (PvPI). WHO defines pharmacovigilance as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problems.”⁴

Spontaneous ADR reporting by health care professionals forms the backbone of pharmacovigilance system. However, under-reporting is a major hurdle in achieving goal of pharmacovigilance. In order to improve the reporting rate, it is important to improve knowledge, attitude and practice (KAP) of the healthcare professionals regarding pharmacovigilance and its importance, we conducted a study in postgraduate residents in a tertiary care hospital and attached medical college. This will also help to build a useful database that will improve the quality of health care in our hospital.

AIM: To assess the awareness of pharmacovigilance amongst resident doctors in a tertiary care hospital.
MATERIAL AND METHODS:
- **Type of Study:** Cross-sectional, questionnaire based, descriptive study.
- **Place of Study:** At Govt. run tertiary care hospital and attached medical college.
- **Duration of Study:** Study was conducted from 10th January to 10th February 2012.
- **Sample Size:** the study was carried out in a total 160 resident doctors from various specialities.
- **Study Tools:** The pre-designed questionnaire based on KAP were given to resident doctors.

RESULTS: Out of 160 received filled questionnaire from resident doctors 10 was incompletely filled and were excluded from the study, giving response rate 93.75 %.

**KNOWLEDGE ABOUT PHARMACOVIGILANCE:** 74 % of resident doctors had heard the term ‘pharmacovigilance’, but 24.67% of resident doctors knew the actual meaning the term pharmacovigilance. 84% of resident doctors did not know about the the existence of “Pharmacovigilance programme of India (PvPI)”. 68% of resident doctors did not know the adverse drug reaction (ADR) reporting centres in India:
- **Attitudes regarding Pharmacovigilance:** 75% of the resident doctors believe that ADR reporting is only a duty of doctors, and only 8% of resident doctors believe that ADR reporting can be done by doctors, nurses as well as pharmacists.
  96% of resident doctors were willing to undergo pharmacovigilance training and all resident doctors believe that ADR reporting is necessary for safe use of medicines. All residents (100%) believe that ADR reporting is necessary.
- **Practice regarding Pharmacovigilance:** None of the residents have ever reported ADR under pharmacovigilance.

DISCUSSION: ADRs are a major clinical problem and it is truism that detection of common or uncommon ADRs requires vigilance. This led to development of pharmacovigilance system. The Uppsala Monitoring centre (UMC, WHO), Sweden is maintaining the international database of ADR reports (Currently about 4.7 million case reports) received from several national centre (96 member countries). However, still it is estimated that only 6- 10 % of all ADRs are reported. Contribution of India to UMC database is very little, this is due to lack of awareness among the healthcare professionals about pharmacovigilance system.

  Majority of residents responded to our study with response rate 93.75% which is higher than that of Hasford et al study in which response rate was 50%. 74% residents of our institute have heard the term pharmacovigilance however, only 24.66% of them knows actual meaning of pharmacovigilance which is much lower than study conducted by Olufunsho Awodele et al in which 79.3% knows the meaning of pharmacovigilance.

  Many factors are associated with ADR under-reporting among health care professionals. These factors have been broadly classified as personal and professional characteristics of health carers, their knowledge and attitude to reporting. Only 32% of residents knew the pharmacovigilance Centre’s, whereas 10% of residents knew that our institute has pharmacovigilance Centre. Which is similar to study conducted by Amrita P et al. in which 8.87% of doctors were aware that their institute has pharmacovigilance centre.
All residents (100%) have agreed the fact that ADR reporting is necessary which is similar to result obtained by Amrita P et al (99.19%)\(^8\) and higher than that of LI Qing et al study (94%).\(^9\)

None of the residents had ever reported ADR under PvPI, as they have low level of awareness of ADR reporting under PvPI (16%).

**CONCLUSION:** The awareness of pharmacovigilance among resident doctors in teaching hospital is very low. There is an urgent need to train resident doctors by health professional expert in pharmacovigilance to improve the current sorry state. This will not only lead to a better standard of reporting, but will also serve for safe and effective use of medicines and doctors would be more apt to consider ADRs as the cause of complaints at an early stage in their differential diagnosis.

**REFERENCES:**

1. Lazarou J, Pomeranz BH, Corey PN. Incidence of Adverse Drug Reactions in Hospitalized Patients-A Meta-Analysis Of Prospective. JAMA 1998; 279: 15; 1200-5.
2. Classen DC, Pestotnik SL, Evans RS et al. Adverse Drug Events in Hospitalized Patients. JAMA 1997; 277 (4): 301-6.
3. Bates DW, Spell N, Cullen DJ et al. (1997) the costs of adverse drug events in hospitalized patients. JAMA 277: 307–11.
4. “Safety of medicines: A guide to detecting & reporting adverse drug reactions” available from http://whqlibdoc.who.int/hq/2002/WHO_EDM_QSM_2002.2.pdf [last accessed on 18/12/2014].
5. Feely J, Moriarty S, O’ Connor P: Stimulating reporting of adverse drug reaction by using a fee. Br Med J 1990, 300: 22-23.
6. Hasford J, Goettler M, Munter KH, Muller-Oerlinghausen B. Physicians knowledge regarding the spontaneous reporting system for adverse drug reactions. J Clin Epidermol, 2002; 55: 9; 945-50.
7. Awodele O, Akinyede A, Adeyemi OA, Awodele DF. Pharmacovigilance Amongs Doctors in Private Hospital in Lagos West Sensational District, Nigeria. The International Journal of Risk and Safety in Medicine. 2011, 23: 4; 217-26.
8. Amrita P, singh SP. Status of Spontaneous Reporting of Adverse Drug Reactions by Physicians in Delhi. Indian Journal of Pharmacy Practice.2011, 4: 2; 29-36.
9. Qing, L, Su-min, Z, Hua-ting, C, Shi-ping, F, Xin, Y, Dong, L, et al. Awareness and attitudes of healthcare professional in Wuhan, China to the reporting of adverse drug reactions. Chinese Medical Journal. 2004, 117: 6; 856-61.

| Questions                                      | Yes (%) | No (%) |
|------------------------------------------------|---------|--------|
| Residents who heard the term pharmacovigilance | 74      | 26     |
| Residents who knew meaning of pharmacovigilance | 24.67   | 75.33  |
| Residents who knew about PvPI                  | 16      | 84     |
| Residents who knew ADR reporting centres       | 32      | 68     |

**Table 1: Knowledge about pharmacovigilance**
Fig. 1: Attitude of resident doctors towards ADR reporting

Fig. 2: Percentage of resident doctors willing to undergo pharmacovigilance training

AUTHORS:
1. Amit A. Bansode
2. Zad V. R.
3. Sawant S. D.
4. Dudhal K. S.

PARTICULARS OF CONTRIBUTORS:
1. Service Resident, Department of Pharmacology, Dr. V. M. G. M. C. Solapur.
2. Assistant Professor, Department of Pharmacology, Dr. V. M. G. M. C. Solapur.
3. Assistant Professor, Department of Biochemistry, Dr. V. M. G. M. C. Solapur.
4. Assistant Professor, Department of Pharmacology, L. T. M. M. C, Sion, Mumbai.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Amit A. Bansode,
# 7-B, Dr. K. B. Antrolkar Nagar-1,
Solapur-413003.
E-mail: amit_bansode12@hotmail.com

Date of Submission: 20/12/2014.
Date of Peer Review: 22/12/2014.
Date of Acceptance: 29/12/2014.
Date of Publishing: 02/01/2015.