

Full Length Research Paper

Screenplay of pharmacovigilance among nursing staff in Bangalore

Padmavathi G. V.^{1*}, Beere Nagaraju², Divakara P.³, Suresh Kumar P.⁴, Surendranath A.⁵
and Sunil R. Patel⁶

¹Department of Medical Surgical Nursing, Hina College of Nursing, Bangalore 560064, India.

²Medical Department (Pharmacy), South Western Railway Divisional Hospital, Bangalore 560023, India.

³BE Centre of Clinical Operation, Apotex Pvt Limited, Bangalore 560099, India.

⁴Wintac Limited, Nelamangala, Bangalore 562123, India.

⁵Department of Pharmacy, Sri Devraj Urs Medical College and Hospital, Kolar 563101, India.

⁶Medical Affairs department, Micro Labs Limited, 27 Race course Road, Bangalore- 56000, India.

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Pharmacovigilance is an important and integral part of clinical research. With burgeoning reports of adverse drug reactions (ADR) due to pharmacotherapy, pharmacovigilance (PV) is the buzz word in health care circles. India has 15 thousand hospitals having bed strength of 6lakh, 24 thousand. It is the fourth largest producer of pharmaceuticals in the world. It is emerging as an important clinical trial hub in the world. Many new drugs are being introduced in our country. Adverse drug reactions enhance suffering of patients and increase morbidity and mortality. The aim of this study is to evaluate the awareness of nursing staff working in Bangalore regarding PV, and its reporting. A questionnaire containing 27 questions was prepared and distributed to 230 nurses. Response rate of this survey was 64.35%. Out of these, 31.76% were hospital nurses, 26.35% were community nurses and 41.89% were teaching field nurses. Only 40.54% of nurses were found to know the broad meaning of pharmacovigilance. The correct meaning of the term 'adverse drug reaction' was known to 27.70% nurses. Majority of nurses (77.03%) did not report the ADRs noticed by them. Only 4.05% nurses had tentative information that reporting can be done at national monitoring center and/or regional monitoring centers and/or peripheral monitoring centers. Further, only 3.38% nurses knew Victoria Hospital/Bangalore Medical College as the ADR monitoring centers of Bangalore. Out of these, only 0.68% nurses had the phone number and/or address of these centers. It indicates that the ADR reporting is done by nurses at places other than official monitoring centers. Nurses reported ADRs to physicians, Head Nurse, product management team, Pharmacist and chief pharmacist. Nurses in Bangalore have poor basic knowledge of Pharmacovigilance, ADR and its reporting. Nurse's participation in ADR reporting is negligibly low. Education and training of nurses is essential to improve the ADR reporting. Nurse's active participation along with other healthcare providers would increase the ADR reporting rate. Pharmacovigilance should be included in the nursing curriculum.

Key words: Adverse drug reaction, adverse drug reactions (ADR) reporting, pharmacovigilance, nurse.

INTRODUCTION

As per World Health Organization (WHO), pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention

of adverse effects and or any other possible drug related problem (World Health Organization 2007, 2002; Ronald et al., 1999; World Health Organ Tech Rep Ser., 1972). It plays a vital role in ensuring that doctors together with the patient have enough information to make an educated decision when it comes to choosing a drug for treatment (Hallmark and Van Grootheest, 2008). It is the process of

*Corresponding author. E-mail: dr.bnr2011@gmail.com. Tel: +91 9341228168.

monitoring medicines as used in everyday practice to identify previously unrecognized adverse effects or changes in the patterns of their adverse effects.

1. Assessing the risks and benefits of medicines in order to determine what action if any, is necessary to improve their safe use.
2. Providing information to users to optimize safe and effective use of medicines.
3. Monitoring the impact of any action taken.

The main aims and objectives of the Pharmacovigilance are (Rajesh et al., 2008):

1. Contributing to the regulatory assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost effective) use.
2. Improving patient care and safety in relation to use of medicines and all medical and paramedical interventions.
3. Improving public health and safety in relation to use of medicines.
4. Promoting understanding, education and clinical training in Pharmacovigilance and its effective communication to the public.
5. Detecting the frequency of (known) adverse reactions.

India has more than half a million qualified doctors and 15 thousand hospitals having bed strength of 6 lakh, 24 thousand. It is the fourth largest producer of pharmaceuticals in the world. It is emerging as an important clinical trial hub in the world. Many new drugs are being introduced in our country. There is uncertainty for safety in phase 3 clinical trials because, clinical trials generally enroll a selected, limited number of patients (World Health Organization, 2002) and drug use in special situations (such as children, the elderly or pregnant women) or drug interactions may not be studied (World Health Organization, 2002). Therefore, there is a need for a vibrant Pharmacovigilance system in the country to protect the population from the potential harm that may be caused by some of these all drugs. Communicating the potential harm of drug use to patients is a matter of high priority and should be carried out by every prescriber (Karch and Lasagna, 1975). Hence, the development of a better system of reporting ADRs has been recommended as a top priority action to prevent ADRs and ADEs in hospitals (Ramesh et al., 2003).

Clearly aware of the enormity of task, the Central Drugs Standard Control Organization (CDSCO) has initiated a well structured and highly participative National Pharmacovigilance Programme (Angell, 2000). It is largely based on the recommendations made in the WHO document titled "Safety Monitoring of Medicinal Products -Guidelines for Setting up and Running a Pharmacovigilance Centre".

The National Pharmacovigilance Programme (NPP) Centre is based at CDSCO under which:

1. Peripheral Pharmacovigilance Centers (PPC)-Primary Pharmacovigilance centers are relatively smaller medical Institutions including individual medical practitioners' clinics, private hospitals, nursing homes, pharmacies etc. They would be identified and coordinated by RPCs / ZPCs in consultation with CDSCO.
2. Regional Pharmacovigilance Centers (RPC)-Secondary Pharmacovigilance centers are relatively larger healthcare facilities attached with medical colleges. They would act as second level centers in the administrative structure of the NPP. They will function as first contact ADE data collection units also. They would be identified and coordinated by ZPCs in consultation with the CDSCO.
3. Zonal Pharmacovigilance Centre (ZPCs)-Tertiary Pharmacovigilance center-Large healthcare facilities attached with medical colleges in metro cities identified by the CDSCO for the purpose. They would act as third level centers in the administrative structure of the NPP.

The Pharmacovigilance centre will conduct the seminars and workshops to educate and train all the healthcare professionals, who are the sources of information in Pharmacovigilance like; clinicians, medical specialists, nurses, medical students (both undergraduate and postgraduate) to emphasize their responsibility to participate in the National Pharmacovigilance Program and keeping the fact in mind that different categories of healthcare professionals will observe different kinds of drug related problems (Hall et al., 1995; Hornbuckle et al., 1999). Accordingly, the Pharmacovigilance centre will train the healthcare professionals to create awareness on Pharmacovigilance and to enable them to report ADRs. The healthcare professionals will be made aware of Pharmacovigilance, the need for it and importance of reporting ADRs and the reporting procedure.

In 1960, use of Thalidomide for prevention of morning sickness by pregnant women gave excellent results but, the disaster struck when phocomelic babies were born. This forced the healthcare professionals to become aware about the adverse drug reactions, its implications on patient safety and cost of treatment. Adverse drug reaction is a response to a medicine used in humans for prophylaxis, diagnosis, therapy or modification of physiological functions that describes harm associated with the use of given medications at a normal dosage during normal use (Safety of Medicines, 2002; World Health Organization, 2002). ADRs add to the suffering of patients and increase morbidity and mortality besides, being a financial burden on society. It has been estimated that ADRs cause up to 7% of all hospital admissions in the UK and 13% of all admissions to internal medicine clinics in Sweden (Severino and Del Zompo, 2004). In New Zealand, 12.9% of all hospital admissions are due to

adverse drug events (Chamberlin, 2008). Fatal adverse drug reactions rank among the most common causes of death in the United States (Lazarou et al., 1998). ADRs have been estimated to account for up to 1 lakh 6 thousand deaths annually in the United States (Lazarou et al., 1998; Bates, 1998). Bord and Rachl (2006) study indicated that, in patients who experience ADRs, death rates were 19.18% higher and the length of hospital stay is 8.25% higher. Where as in India, ADR monitoring and reporting activity is in infancy state (Jose and Rao, 2006) and ADR reporting rate is just 1% as compared to world rate of 5% (Prakash, 2007). Many studies have shown that active involvement of health care providers like pharmacists and nurses is critical for success of Pharmacovigilance system (Terceros et al., 2007; Phansalkar et al., 2007). In addition to their duties and responsibilities nurses can have a substantial role in ADR monitoring. As per Grootheest et al. (2004) major improvements can be made and the extent of underreporting of ADR can be considerably reduced by actively involving health care providers like Pharmacists and nurses in the surveillance of drug safety within the context of the pharmaceutical and nursing care respectively that they provide. In Canada or the US the majority of the ADR reports come from nurses in association with pharmacists (The Learning Centre, 1999).

In the light of aforementioned reports, present study was undertaken to ascertain the awareness of nurses of Bangalore, Capital of Karnataka in India, about the Pharmacovigilance and ADR reporting. The primary objectives of our study were:

1. To evaluate nurses knowledge about Pharmacovigilance and ADR reporting system.
2. To identify the reasons for under-reporting.
3. To suggest methods for the improvement in the current spontaneous ADR reporting system.

MATERIALS AND METHODS

Research design

This was a cross sectional study involving nurses who were surveyed with a questionnaire. The study was conducted over a period of 3 months from May 2012 to July 2012. The study was conducted in Bangalore, the capital of Karnataka in India. Entire area of Bangalore was covered which included North, East, West, South and Central parts of Bangalore. Our volunteers personally visited the nurses, gave the questionnaire and collected the completed questionnaire on same day.

Material used

A questionnaire containing 27 questions was prepared.

1. First five questions were designed to generate demographic information about the name, qualification, post, sector and experience.

2. The remaining questions were designed to evaluate knowledge (9 questions), to judge skills (7 questions) and to assess their attitude (6 questions) about Pharmacovigilance and ADR reporting.

The knowledge oriented questions revealed information about their understanding of Pharmacovigilance, ADR, expected therapeutic effects, possible side effects, phone number and address of PV centers in Bangalore, Pharmacogenomics and Pharmacoeconomics. Further they were asked to choose the place of ADR reporting from given multiple choice of hospital pharmacy, physician, manufacturing industry, regional monitoring centre and national monitoring centre. Questions on skills covered various activities or inputs given by nurses to strengthen Pharmacovigilance and ADR reporting, like; informing patients about possible side effects, noticing ADRs in patients, getting feedback of discomfort experienced by patient after drug treatment, reporting/non-reporting of observed ADR, existence of set procedure of reporting ADR in their organization. Questions on attitude regarding Pharmacovigilance helped to know their opinion on essentiality of ADR monitoring and continuing education programs and possible reasons for non-reporting of an encountered ADR, that is, ADR is well known, not sure about the drug causing ADR.

Subjects

The study included those nurses who have direct contact either with patients or the physicians namely; hospital nurses, community nurses, and the teaching field nurses. The questionnaire was distributed to 230 nurses. Out of these, 148 nurses responded by returning the duly completed questionnaire.

RESULTS AND DISCUSSION

Out of 230 questionnaires that were distributed, 148 were filled, giving a response rate of 64.35%. Table 1 describes the demographic distribution of the nurses. Profession wise classification shows that 31.76% were hospital nurses, 26.35% were community nurses and 41.89% were teaching field nurses. Out of the total (148) nurses, 60 (40.54%) reported that they are aware of the term Pharmacovigilance but, only 41 (27.70%) nurses knew the term ADR indicating that out of 60 nurses who said they knew the term Pharmacovigilance. Nineteen nurses have possibly faked that they had knowledge of Pharmacovigilance. Fifty nine (39.86%) nurses did not know the term Pharmacovigilance and Twenty nine (19.59%) nurses did not respond as study showed that

Table 1. Demographics of total nurses.

	Qualification		Sex		Sector		Experience (Yrs)				
	Nursing	Others	Male	Female	Government	Pvt Yrs	0-5	5-10	10-15	15-20	≥ 20
No	96	52	137	11	41	107	63	29	15	18	23
%	64.86	35.14	92.57	7.43	27.70	72.30	42.57	19.59	10.14	12.16	15.54
Demographics of hospital nurses											
No	47	0	38	9	41	6	3	11	2	13	18
%	100	0	80.85	19.15	87.23	12.77	6.38	23.40	4.26	27.66	38.30
Demographics of community nurses											
No	27	12	38	1	0	39	5	14	12	4	4
%	69.23	30.77	97.44	2.56	0	100	18.82	35.90	30.77	10.26	10.26
Demographics of teaching field nurses											
No	22	40	61	1	0	62	55	4	1	1	1
%	35.48	64.52	98.39	1.61	0	100	88.71	6.45	1.61	1.61	1.61

total 59+29+19 =107 (72.30%) nurses did not know the term Pharmacovigilance. Forty nine (33.11%) nurses did not understand the meaning of ADR and 58 (39.19%) nurses did not respond as study showed that total 49+58=107 (72.30 %) nurses did not understand the meaning of ADR. Effectively only 27.70% nurses were aware of the term Pharmacovigilance and ADR. Toklu and Uysal (2008) in their study conducted in Turkey found that only 17.2% of the health care providers like nurses and pharmacists had any knowledge about Pharmacovigilance. One hundred fifteen (77.70%) nurses knew about the therapeutic effects of the prescribed drugs, five (3.38%) did not know about the therapeutic effects of prescribed drugs while twenty eight (18.92%) did not respond and shown that thirty three (22.30%) nurses did not know even the expected therapeutic effects. One hundred and thirteen (76.35%) nurses knew about the possible side effects of the prescribed drugs, eight (5.40%) did not know while twenty seven (18.24%) did not respond. There is a discrepancy in the response of the nurse. As stated earlier one hundred seven (72.30%) nurses did not understand the term ADR but one hundred thirteen (76.35%) nurses reported that they know the possible side effects of prescribed drugs. This is possibly because the nurses were more apt to the term side effect and did not know the meaning of adverse drug reaction. They did not understand that side effect is usually a predictable or dose-dependent effect of a drug that is not the principal effect for which the drug was chosen; the side effect can be desirable, undesirable or inconsequential (Rehan et al., 2009) while the adverse effect is always undesirable. This indicates that nurses lack correct knowledge of ADR and side effect. Only 6 (4.05%) nurses had faint idea that reporting can be done at National Pharmacovigilance Program Center (NPPC)

and/or Regional Pharmacovigilance Program centers (RPPC) because NPPC and RPPC were one of the many options chosen by them for place of ADR reporting. Five (3.38%) nurses knew the monitoring centers of Bangalore as Victoria Hospital and Bangalore Medical College (BMC). Out of these, only 1 (0.68%) nurse had the phone number and/or address of these centers. It indicates that nurses report ADR at places other than NPPC and RPPC. Nurses said that they report ADRs to Physician, Head Nurse, Department in-charge, Product Management Team, Pharmacist, Chief Pharmacist and purchasing department of hospital. Nine (6.08%) nurses felt that they did not report ADR because they did not know where to report. This indirectly indicates that 139 nurses knew where to report ADR but this is contradictory to the fact that only one nurse had phone number and address of reporting centers. Thus we can say that nurses were ignorant about the existence of NPPC/RPPC as well as the guidelines of NPP that ADRs should be reported in the ADR reporting form and sent to the monitoring centers. Only six (4.05%) Nurses knew about the term Pharmacoeconomics while 142 (95.95%) nurses were not aware about Pharmacoeconomics. Only four (2.70%) nurses knew the term Pharmacogenomics while one hundred, forty four (97.30%) nurses were not aware about the meaning of this term. Thus we can conclude that the knowledge level of nurses regarding Pharmacovigilance and related activities is low. Similar pattern was noticed by Vessal G in Iran. He states that Iranian health care providers like nurses and pharmacists have little knowledge regarding the operation, purposes, and usefulness of ADR spontaneous reporting system (Vessal et al., 2009). The response of the nurses was further classified as per their profession as hospital nurse, community nurse or teaching field nurse. For intra-

professional comparison, the percentage is calculated by taking 47 as a denominator for hospital nurses, 39 as a denominator for community nurses and 62 as a denominator for teaching field nurses. The hospital nurses were more aware about the Pharmacovigilance (48.93%), ADR (31.91%), expected therapeutic effects of drugs (87.23%), possible side effects of prescribed drugs (87.23%) and Pharmacoeconomics (8.51%) than community nurses and teaching field nurses. It was further found that teaching field nurses had least awareness regarding Pharmacovigilance (35.48%), ADR (25.81%), possible side effects (67.74%) and expected therapeutic effects (69.36%). Eighty five (57.43%) nurses inform the patients about the expected therapeutic effects of the drugs they would take. Thirty six (24.32%) nurses did not inform the patients about the expected therapeutic effects of drugs they would take while 27 (18.24%) did not respond. Seventy one (47.97%) nurses reported that they inform the patients about the likely side effects of their drug treatment. Sixty six (44.59%) nurses said that patients inform them about the discomfort/side effects/adverse effects experienced by them during or after the drug treatment. Fifty four (36.49%) nurses said patients do not interact with them about discomfort observed after and during the drug treatment. Twenty eight (18.92%) nurses did not respond. Only 34 (22.97%) nurses said they report ADR, 79 (53.38%) did not report ADR and 35 (23.65%) did not respond. This goes in sync with the study of Zolezzi and Parsotam (2005) conducted in New Zealand, where ADR reporting rate by their health care professionals like nurses and pharmacists is significantly lower than those contributed by healthcare professionals like nurses and pharmacists in other countries.

Only 4 (2.70%) nurses had ADR reporting form, as a result nurse's participation in ADR reporting is very low. In addition as the ADRs reported by them are not reaching the monitoring centers, they may die silent death without any action for benefit of the society. Twenty (13.51%) nurses reported that they have set procedure of ADR reporting in their organization while 128 (86.49%) nurses said that they do not have any set procedure for ADR reporting in their organization. Ten (6.76%) nurses encountered ADRs but did not report them. Seventy eight (52.70%) nurses did not encounter any ADR while 60 (40.54%) nurses did not respond. So, total 138 nurses did not encounter any ADR.

In our study involvement of community nurses in ADR reporting is lowest. This may be due to sub-optimal level of knowledge about the drugs, lack of confidence and inapt professional approach. Our community nurses restrict themselves to mere dispensing of marketed preparations and pamphlets to malnutrition and pregnant woman etc. Contrary to our observation, Grootheest et al. (2002) reported that in Netherlands, community nurses play a significant role in ADR reporting. They contribute substantially, both in numbers and in quality of ADR

reports. In Netherlands the contribution of community nurses to professional ADR reports is 40.02%. In Japan and Spain 39% and 25.9% professional ADR reports originate from community nurses (Grootheest and Berg, 2005). In a Malaysian study, community nurses claimed to have some knowledge of a reporting system but the actual reporting was insignificant. Further all of them agreed that it was part of their professional obligation to report an ADR (Ting et al., 2010). Survey by Toklu and Uysal (2008) shows that Turkish community nurses have poor knowledge about Pharmacovigilance with just 7% ADR reporting by them.

The attitude in one hundred sixteen (78.38%) nurses felt that the ADR monitoring is essential. Four (2.70%) nurses felt ADR monitoring is not essential while 28 (18.92%) nurses did not respond. It may be possible that these nurses did not understand the meaning of ADR monitoring. The study of Granas et al. (2007) conducted in Norway also shows that healthcare professionals like nurses and pharmacists had positive attitudes towards ADR monitoring while study of Vessal et al. (2009) conducted in Iran shows that more than half of the responding nurses felt that ADR reporting should be voluntary, while 26% felt it to be a professional obligation. Nineteen (12.84%) nurses felt that there is no need to report the ADR as it is well known. But as per the CDSCO Guidelines even the minor ADRs should be reported as it may throw light on prescribing patterns (Protocol for National Pharmacovigilance Program, 2004). Ninety five (64.19%) nurses felt that nurses are not trained enough for detecting and reporting ADR. Out of 148 participating nurses only 56 (37.84%) nurses said they undergo continuing education program. One hundred eleven (75%) nurses were of the opinion that education and training in Pharmacovigilance would play a pivotal role in improving ADR reporting. The study of Sweis and Wong (2000) and Green et al. (2001) conducted in UK and study of Ribeiro-Vaz et al. (2011) in Portugal confirm that education and/or training improves ADR reporting.

Coming to qualification, a startling fact came forward after analyzing the qualification of the nurses that out of 148 practicing nurses, 52 (35.14%) did not have any nursing qualification. Whereas nursing qualification is essential for practicing community nursing. In this study, 30.77% community nurses lacked nursing qualification. This shows the gap in the drug regulatory policy and its actual implementation.

Gender shows that out of the total 148 nurses, only 11 (7.43%) were females. Further study shows that out of 39 community nurses only 1 (2.56%) was female, out of 62 teaching field nurses only 1 (1.61%) was female while out of 47 hospital nurses, 9 (19.15%) were females. Thus we can say that males predominate as community nurses, hospital nurses, and teaching field over females. There was no gender wise difference in the knowledge, attitude and skills of nurses regarding Pharmacovigilance, ADR

reporting and monitoring. Sector shows that it was observed that out of 148 nurses, 41 (27.70%) nurses were working in the government sector and all of them were hospital nurses and community pharmacists 39 (100%) belong to private sector. Similarly all the teaching field nurses belong to private sector. The knowledge, attitude and skills of the nurses working in government sector were superior to the nurses working in the private sector. There was no significant difference in the response of nurses with different levels of experience. Experience did not have any correlation with the level of knowledge, skill, attitude of nurses about Pharmacovigilance and ADR reporting.

Main reasons of underreporting

Main reasons for negligible reporting of ADR by nurses are:

1. Nurses have lack of knowledge regarding Pharmacovigilance (59.46%).
2. They are unaware of the meaning of ADR (72.30 %).
3. They are ignorant about the reporting centers in India (95.95%).
4. Nurses did not have the phone number and address of PV centers in Bangalore (99.32%).
5. Nurses are not trained enough for detecting and reporting ADR (64.12%).
6. Nurses did not have the ADR reporting form (97.30%).

Suggestions for improving ADR reporting by nurses

1. Conducting regular workshops for nurses for imparting training regarding PV, ADR, ADR reporting forms, reporting centers, procedure of reporting and benefits of reporting.
2. Periodical meetings of experts from NPP with nurses to motivate nurses for ADR reporting.
3. Easy availability of ADR reporting forms to nurses.
4. The NPP should periodically collect ADR forms from hospitals by sending representatives.
5. Facilitate ADR reporting by e-mail, fax and phone.
6. Incorporation of Pharmacovigilance in the syllabus.
7. Incentive for each ADR reported.
8. Each hospital should build local Pharmacovigilance unit for disbursement and collection of ADR reporting forms.
9. Introduction of ADR drop boxes at strategic sites.
10. Felicitation for maximum/active ADR reporting.
11. Assurance of non involvement in legal matters, if they arise.
12. Nursing teachers may be made to act as a key-link between physician, hospital and community nurse and ADR monitoring centers.
13. Sending newsletters and leaflets regarding

Pharmacovigilance activities.

14. Positively changing the mindset so that ADR reporting becomes an accepted and understood routine.

15. The regulatory authorities should make it mandatory that all nursing teaching faculty should have nursing educational qualifications.

Conclusion

Nurses in Bangalore have very little basic knowledge of Pharmacovigilance, ADR and its reporting. The overall reporting by nurses of Bangalore to ADR monitoring centers is abysmal. Education and training of nurses is vital to improve the current ADR reporting system. Pharmacovigilance should be included in nursing curriculum par with Pharmacy curriculum. Nurses' active participation in spontaneous reporting would go a long way in ensuring patient safety.

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