

Knowledge, Attitude and Skills of Nurses of Delhi towards Adverse Drug Reaction Reporting

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ABSTRACT

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This study was aimed to determine the awareness of nurses of Delhi (India) about Adverse drug reaction (ADR) reporting and their involvement in activities related to pharmacovigilance.

A questionnaire was distributed and then collected from the nurses serving in Delhi. The response rate of the survey was 65%. The meaning of term pharmacovigilance was known to 68.27% of nurses. Surprisingly, only 51.92% of nurses understood the correct meaning of the term ADR. None of the nurses knew about the pharmacovigilance centers of India. Only 7.69% nurses knew the reporting centers of Delhi while just 2.88% nurses had their phone number, address. Nurses (93.27%) inform patients about the expected therapeutic effects of the prescribed drugs. Their interaction with the patients regarding side effects was significant. Nurses (90.38 %) said that they report observed ADRs. Majority of the nurses reported the ADRs to the physicians or hospital pharmacy. Nurses felt that, they need not report ADR either because ADR is well known (40.38%) or due to uncertainty about the causal drug (49.04%). About half of the nurses (47.12%) informed that they have existence of set procedure of reporting ADR in their organization. Most (75%) of the nurses did not have ADR reporting forms. Remaining 25% nurses had only localized ADR reporting forms.

Thus, we can conclude that nurses are not reporting ADRs to ADR monitoring centers of Central Drugs Standard Control Organization (CDSCO), New Delhi. Education and training is essential for enhancing ADR reporting by nurses to the ADR monitoring centers.

Keywords: ADR, ADR reporting, pharmacovigilance, nurses.

INTRODUCTION

Pharmacovigilance (PV) is defined by the World Health Organization (WHO) as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem"¹. Adverse drug reaction is a response to a medicine which is noxious and unintended and which occurs at a dose used in humans for prophylaxis, diagnosis, therapy or modification of physiological functions². ADRs are global problems because they have a significant pessimistic impact on both health and healthcare costs³. ADRs are cause for a substantial proportion of hospital admissions. ADRs account for 6.5% of all hospital admissions in the UK⁴. The percentage of adverse drug reactions leading to hospitalization in general population is 1.8% in the Netherlands⁵. ADRs are a cause of 6.89% of total admissions at medical emergency department of KEM hospital, Mumbai, India⁶. The economic burden of ADRs is massive. Data provided by Pirmohamed M. suggests that

admissions related to ADRs cost up to £466m annually to National Health Service in UK⁴. For patients suffering from ADRs, total medical costs have been increased by an average of 19.86%¹.

Need of pharmacovigilance in India: India is the second most populous country in the world with over 1.21 billion people (2011 census)⁸ and is now becoming favorable destination for conduct of clinical trials by various pharmaceutical companies. After successful clinical trials and permission from drug authorities, these drugs are launched into the market. Even after stringent scrutiny before launching, some drugs need to be withdrawn from the market due to ADRs. Hypoglycemic drug, Rimnabant is withdrawn from Indian market in 2008, due to serious side effects like depression, suicidal tendencies and seizures⁹. Rofecoxib, an analgesic, was withdrawn in 2004 due to high risk of myocardial infarction⁹. It is essential to recognize adverse drug reactions as soon as possible and prevent them if possible, to ensure the well-being of the patient. Up to 72% of the ADRs are avoidable⁴. Spontaneous reporting by healthcare professionals is critical for curtailing the ADRs. ADR reporting rate in India is below 1% as compared to the world

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rate of 5%¹⁰ and therefore it is the need of the hour to improve the awareness of healthcare providers regarding PV and ADR monitoring.

Pharmacovigilance program of India: National Pharmacovigilance Program (NPP) is revived by the Ministry of Health and Family Welfare in July 2010^{11,12} and it is overseen by CDSCO, New Delhi. The program is envisaged to be rolled out in three phases:

Phase I plans to include 40 ADR monitoring centers (AMCs).

Phase II plans to include 140 MCI recognized medical colleges by end of 2011.

Phase III would ultimately cover the total healthcare system by 2013.

ADR reports collected at the AMCs will be dispatched to the national co-ordinating centre. The coordinating centre will conduct causality assessment and upload the reports into the pharmacovigilance software. Lastly, the integrated ADR data will be transmitted through vigiflow software interface into the Uppsala Monitoring Center's ADR database where signal processing can be carried out¹².

Nurses and Pharmacovigilance: Nurses are the bedside caregivers. They can play a key role in ADR reporting because they can observe the adverse drug reactions first hand. It is important to motivate nurses to understand their role and responsibility in the detection, management, documentation, and reporting of ADRs, which are essential activities for optimizing patient safety.

The goal of our study was to determine the level of awareness of nurses regarding ADRs, their reporting and the extent of their involvement in pharmacovigilance activities.

MATERIALS AND METHODS

Research Design: This was a questionnaire based study involving nurses. A self prepared questionnaire was distributed to nurses working in various hospitals and clinics of Delhi, the National Capital of India. The prospective study was conducted, over a period of 10 months from December 2009 to September 2010. Entire area of Delhi was covered, which included North, West, South and Central zones of Delhi. We personally presented the questionnaire to the nurses and collected the duly filled questionnaire on the same day.

Material used: A questionnaire containing 23 questions was formulated to assess the knowledge, attitude and skills of the nurses regarding pharmacovigilance and ADR reporting. The questionnaire contained 7 questions related to knowledge, 6

questions related each to attitude and skills. The remaining 4 questions were designed to generate demographic data like name, qualification, sector and experience.

Subjects: The study included 160 nurses practicing in various government or private sector hospitals/clinics of Delhi.

Study setting: The study covered 8 government hospitals, 4 government dispensaries, 10 private hospitals and 3 private clinics of Delhi, namely

Government sector hospitals

1. Safdarjung Hospital (SJH).
2. Guru Gobind Singh Government Hospital (GGSGH).
3. Charak Palika Hospital (CPH), Moti Bagh.
4. Lok Nayak Jaiprakash Hospital (LNJP).
5. Deen Dayal Upadhaya Government Hospital (DDU).
6. Pt. Madan Mohan Malaviya Hospital, Malviya Nagar.
7. Primary Health Centre (PHC), Mehrauli.
8. ESI Hospital, Rohini.

Government sector Dispensaries

1. C.G.H.S Dispensary, R.K. Puram.
2. MCD Dispensary, Ber Sarai.
3. Delhi Government Dispensary, Khanpur.
4. Delhi Government Dispensary, Raghubir Nagar.

Private sector hospitals

1. Park Hospital, khyala.
2. Batra Hospital and Medical Research Centre, Tughlakabad.
3. Yogmaya Hospital, Mehrauli.
4. Neelu Angels Hospital, Saket.
5. Vikas Hospital, Mehrauli.
6. Bhagwati Hospital, Mehrauli.
7. Sitaram Bhartiya Hospital, Qutab Institutional Area.
8. Majeedia Hospital, Tughlakabad.
9. Rockland Hospital, Katwaria Sarai.
10. G M Modi Hospital, Saket.

Private clinics

1. Tayal Nursing Home, Mehrauli.
2. Bakaya Clinic, Mehrauli.
3. Sanjivani Nursing Home, Kamla Nagar.

RESULTS

Out of 160 nurses approached to participate in study, 104 nurses responded, giving response rate of 65%. The demographic profile of respondents is presented in Table 1. Maximum participation was from the nurses (24.04%) working in Safdarjung Hospital, New Delhi.

Table 1: Demographic profile of respondents.

DEMOGRAPHICS	NUMBER	PERCENTAGE
Qualification		
Diploma	73	70.19
B. Sc nursing	20	19.23
Un-qualified	11	10.58
Gender		
Male	02	1.92
Female	102	98.08
Sector		
Government	56	53.85
Private	48	46.15
Experience		
0-5 yrs.	52	50
5-15 yrs.	33	31.73
15-25 yrs.	11	10.58
25 or more	8	7.69

Assessment of Knowledge:

Out of the 104 nurses, 71 (68.27%) were aware of the term pharmacovigilance, 26 (25%) nurses did not know the term pharmacovigilance and 7 (6.73%) nurses did not respond, indicating that total, $26+7=33$ (31.73%) nurses did not know the term pharmacovigilance. Majority (92.31%) of the nurses were aware of the expected therapeutic effects of the prescribed drugs, 3 (2.88%) nurses did not know and 5 (4.81%) nurses did not respond to this query. The correct meaning of the term ADR was known to about half of the nurses (54, 51.92%). Thirty four (32.69%) nurses had hazy idea of the term ADR while 16 (15.38%) nurses did not respond. This shows that total 50 (48.08%) nurses, did not know the correct meaning of the term ADR. Most of the nurses (91.35%) said that they were aware about possible side effects of the drugs, 8 (7.69%) nurses responded negatively, one (0.96%) nurse did not respond.

None of the nurses had idea that reporting can be done at National Monitoring Center (NMC) and/or Regional monitoring centers (RMC). They responded that ADRs can be reported to physicians (79.81%), hospital pharmacy (7.69%),

Director of health services (0.96%), Senior supervisor (0.96%), Pharmacy in-charge and Director medical services (0.96%). Six (5.77%) nurses gave mixed response and four (3.85%) nurses did not respond. Total eight nurses (7.69%) knew correct reporting centers of Delhi. Out of these eight nurses, four voted for All India Institute of Medical Sciences, two voted for DGHS (Ministry of health and Family welfare), one each for Lady Hardinge Medical College and Maulana Azad Medical College, as reporting centers of Delhi. Only 3 (2.88%) nurses had the phone number and address of the reporting centers. This indicates that 101 (97.12%) nurses report ADRs at places other than official ADR monitoring centers designated by CDSCO.

Assessment of Skill:

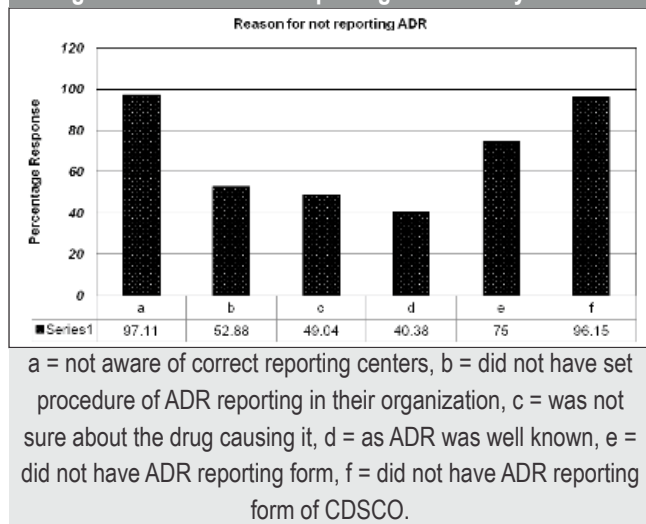
Majority of nurses 97(93.27%) said that they inform the patients about the expected therapeutic effects of the prescribed drugs while 7(6.73%) nurses did not inform. Significant number of nurses 95(91.35%) inform patients about the possible side effects, while 9(8.65%) nurses did not tell about possible side effects. Ninety three (89.42%) nurses responded that patients inform them about the discomfort experienced by them during or after the drug treatment, 7(6.73%) nurses responded negatively and 4(3.85%) nurses did not respond. Ninety four (90.38%) nurses said that they report ADR while 7(6.73%) did not report ADR and 3(2.88%) did not respond. Thus, $7+3=10$ (9.61%) nurses did not report the ADRs. Forty nine (47.12%) nurses reported to have set procedure of reporting ADRs in their organization. Forty three (41.35%) nurses agreed that their organization does not have set procedure of reporting ADR while 5 (4.81%) nurses said that they did not know answer to this question and 7 (6.73%) nurses did not respond. So, it shows that $5+7=12$ (11.54%) nurses were doubtful about the existence of set procedure for ADR reporting in their organization. Surprisingly, 67 (64.42%) nurses said they do not have ADR reporting forms and 11 (10.58%) nurses did not respond. Thus total, 78 (75%) nurses did not have either hospital generated ADR reporting form or CDSCO prescribed ADR reporting form. Only 26 (25%) nurses had ADR reporting form. Out of these 26 (25%) nurses, 22 (84.61%) nurses had their in-built organizational ADR reporting form and 4 (15.38%) nurses were unwilling to show the form.

Assessment of Attitude:

One hundred one (97.11%) nurses felt that ADR monitoring is essential. One (0.96%) nurse responded negatively and 2 (1.92%) nurses did not respond. The reasons of not reporting ADRs given by nurses were – uncertainty about causal drug (49.04%), ADR is well known (40.38%), unawareness of ADR reporting centers (83.65%).

Fifty seven (54.81%) nurses undergo continuing education program, 38 (36.54%) nurses did not undergo education program and 9 (8.65%) nurses did not respond to this question. Large number of nurses 96 (92.31%) were of the opinion that education and training is essential for increasing the ADR reporting rate while 1 (0.96%) nurse disapproved and 7 (6.73%) nurses did not respond. The overall reasons for not reporting ADRs are presented in Figure 1.

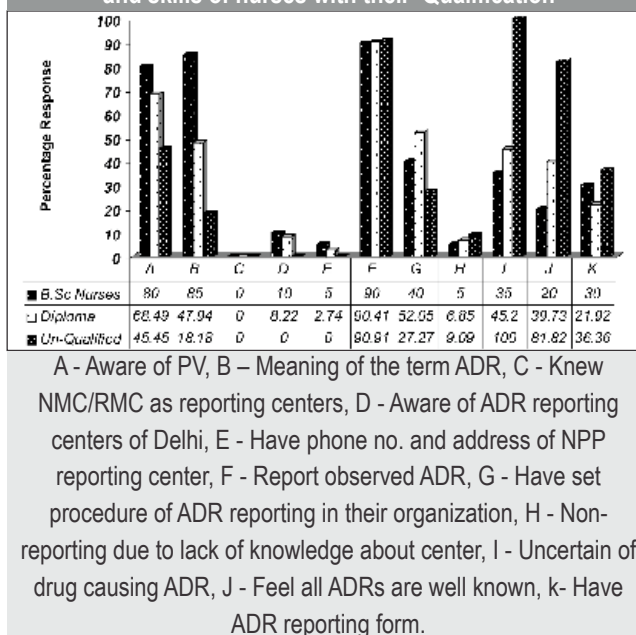
Fig. 1: Reasons for not reporting the ADRs by nurses.



Correlation between knowledge, attitude and skills of nurses with their qualification (Figure 2):

The knowledge of Pharmacovigilance was better in Graduate nurses (80%) than Diploma nurses (68.49%). Graduate nurses (85%) had better understanding of the term ADR as compared to Diploma nurses (47.94%). Graduate nurses (10%) were more aware of the ADR reporting centers of Delhi as compared to Diploma nurses (8.22%). Awareness of the phone number and address of these reporting centers was more of Graduate nurses (5%) than Diploma nurses (2.74%). Uncertainty about the drug causing ADR and the feeling that ADRs need not be reported as they are well known was maximum among un-qualified nurses (100%, 81.82%) followed by Diploma nurses (45.20%, 39.73%) and then Graduate nurses (35%, 20%). No association was observed between qualification and extent of ADR reporting.

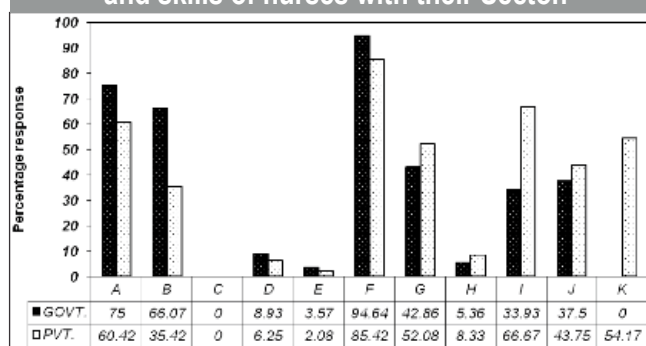
Fig. 2: Correlation between knowledge, attitude and skills of nurses with their Qualification



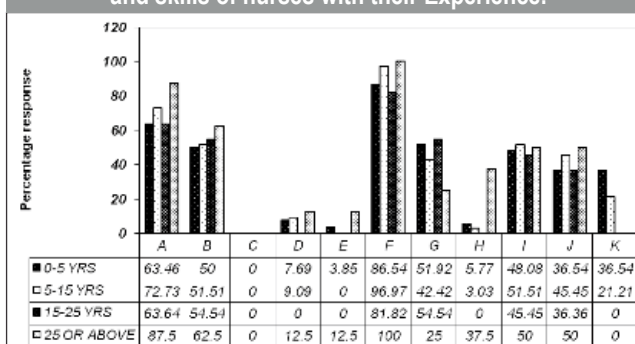
Correlation between knowledge, attitude and skills of nurses with their sector (Figure 3):

The nurses were grouped as per their sector of working as: Government sector nurses (53.85%) and Private sector nurses (46.15%). Awareness about Pharmacovigilance and ADR was better of the nurses from government sector (75%, 66.07%) as compared to private sector (60.42%, 35.42%). Knowledge of phone number and address of pharmacovigilance centers of Delhi was poor among both government sector nurses (3.57%) and private sector nurses (2.08%). Reporting by nurses from government sector (94.64%) was better than private sector (85.42%) nurses but none of the government nurses had ADR reporting form. Twenty six (25%) Private sector nurses had either organizational or CDSCO prescribed ADR reporting form.

Further the nurses were probed sector wise for reasons of underreporting. Major reasons for underreporting in private sector were lack of knowledge about centers of Delhi (93.75%), uncertainty about the drug causing ADR (66.67%), lack of set procedure of ADR reporting (47.92%), non availability of reporting form (45.83%), feeling that ADRs are well known and hence need not be reported (43.75%). Underreporting in Government sector was mainly due to non availability of reporting form (100%), lack of knowledge about centers of Delhi (91.07%), lack of set procedure of ADR reporting (57.14%), feeling that ADRs are well known hence need not be reported (37.5%) and uncertainty about the drug causing ADR (33.93%).

Fig. 3: Correlation between knowledge, attitude and skills of nurses with their Sector.

A - Aware of PV, B - Meaning of the term ADR, C - Knew NMC/RMC as reporting centers, D - Aware of ADR reporting centers of Delhi, E - Have phone no. and address of NPP reporting center, F - Report observed ADR, G - Have set procedure of ADR reporting in their organization, H - Non-reporting due to lack of knowledge about center, I - Uncertain of drug causing ADR, J - Feel all ADRs are well known, k- Have ADR reporting form.

Fig. 4: Correlation between knowledge, attitude and skills of nurses with their Experience.

A - Aware of PV, B - Meaning of the term ADR, C - Knew NMC/RMC as reporting centers, D - Aware of ADR reporting centers of Delhi, E - Have phone no. and address of NPP reporting center, F - Report observed ADR, G - Have set procedure of ADR reporting in their organization, H - Non-reporting due to lack of knowledge about center, I - Uncertain of drug causing ADR, J - Feel all ADRs are well known, k- Have ADR reporting form.

Correlation between knowledge, attitude and skills of nurses with their experience (Figure 4):

The nurses were grouped as per their experience as: Junior (0-5 years, 50%), Middle (5-15years, 31.73%), Senior (15-25years, 10.58%) and senior most (more than 25 years, 7.69%). Senior most nurses were found to be most aware of pharmacovigilance (87.5%) and ADR (62.5%). ADR reporting forms were not available with senior and senior most nurses. The availability of ADR reporting forms was found to be maximum (36.54%) with junior nurses. Senior most nurses were most aware about reporting centers in Delhi (12.5%) and their phone number and address (12.5%). Reporting of observed ADRs was best by senior most nurses (100%). This indicates that reporting is done orally, within the organization. Non-reporting of ADRs due to lack of knowledge of reporting centers (37.5%) as well as due to the feeling that ADRs are well known and need not be reported (50%) was maximum in senior-most nurses. The uncertainty about the drug causing the ADR was highest in middle nurses (51.51%).

DISCUSSION

For seeking health care facilities, majority of the Indian population favors government hospitals. This means a good ADR database can be generated from these hospitals. The daunting task is to foster a culture of ADR reporting among nurses who are in constant contact with hospitalized patients. Reasons for the low level of ADR reporting include lack of awareness, training and low understanding of significance of reporting.

An additional factor is that the government has not made it mandatory for health care providers to report ADRs unlike some countries such as Spain and Sweden¹³. Hence, there is definite need for spontaneous ADR reporting from the nurses in addition to physicians and pharmacists. Moreover, only few studies have been conducted on ADR reporting by nurses. Therefore this study was conducted to ascertain the actual participation of nurses of Delhi in ADR reporting to ADR monitoring centers.

The response rate of our survey was 65% against the 36% response rate of a study conducted in Iran¹⁴. In our study about half of the nurses (51.92%) knew the correct meaning of the term ADR. The knowledge of ADR was found to be much higher (75%) in a study conducted by Giti Hazebi in Iran¹⁴ while the finding of Li Q in china shows that only 1.6% of the nurses correctly define the term ADR¹⁵. Most of the nurses (91.35%) said that they were aware about possible side effects of the drugs. It seems that nurses were more familiar with the word side effect rather than adverse drug reaction. Possibly, there is lack of clarity in their knowledge regarding ADR and side effect.

In our study, nurse's proficiency in informing patients about expected side effects (91.35%) and therapeutic effects (93.27%) was very good. Nurses (89.42%) said that patients freely communicate the discomfort experienced by them. It indicates that the interaction of nurses with patients and vice versa was good. Nurses shared the relevant drug related information with patients. Eight respondents (7.69%) knew

correct reporting centers of Delhi which is much lower than an Iranian study, which states that 48% nurses were aware of ADR center. But study of Li Q in china observed that just 2.2% nurses knew the correct reporting center¹⁵. In our study, only 2.88% nurses had the phone number address of the reporting centers. Similar observations were found in studies conducted in Iran and China. Only 3.4% nurses of Iran and 2.9% nurses of China knew the phone number and address of the ADR reporting centers of their countries.

According to our study, 90.38% nurses report ADR, analogous to 92% reporting in case of a study in Iran¹⁴. National Pharmacovigilance program (NPP) of India states that ADR should be reported to ADR monitoring centers^{11,12}. But our nurses report ADRs mainly to the physicians (79.81%) and hospital pharmacy (7.69%) which is in congruence with the study in Iran indicating nurses report to physicians in the ward (56%), head nurse (26%), and pharmacy (13%)¹⁴. Hospital pharmacies, pharmaceutical companies and drug centers within the area are the responses given by nurses of a study in China as the main places for reporting ADRs¹⁵.

As per our study, total 75% nurses reported that they did not have ADR reporting form. Out of remaining 26 (25%) nurses, 22 (84.61%) nurses had in-built organizational ADR reporting form and 4 (15.38%) nurses were unwilling to show the form. These nurses were unqualified and thus it seems that they have given fake response regarding availability of the form. Thus we can say, none of the nurses had CDSCO ADR form. Moreover, the results show that nurses were devoid of the knowledge about the reporting centers in Delhi as well as India which confirms that reporting by nurses is not reaching the AMCs. The reason may be that nurses consider that once they report the ADR to physician or Pharmacy, their duty is completed. This restricts ADR reporting to their organization without further communication to ADR monitoring centers for the larger benefit of the society.

Essentiality of education and training, for increasing the ADR reporting rate, was expressed vehemently by nurses. Our study shows, 92.31% of nurses strongly felt that education and training is important for enhancing ADR reporting rate by nurses. It has been shown in the studies of Sweis¹⁶ and Green¹⁷ conducted in UK and study of I. Ribeiro Vaz¹⁸ in Portugal, that education and/or training improves ADR reporting.

Suggestions for Improvement in ADR Reporting:

1. Each hospital should establish local 'Pharmacovigilance Unit' for disbursement and collection of ADR reporting forms.

2. Conducting pharmacovigilance workshops to provide guidance to nurses for recognizing and reporting ADRs.
3. Providing a separate space for ADR reporting in patient chart.
4. Associate ADR reporting with rewards.25. Felicitation of nurses for maximum ADR reporting in a year.
6. Periodical meetings of experts from NPP with nurses should be arranged to boost reporting.
7. The NPP should periodically collect ADR forms from hospitals by sending representatives.
8. ADR drop boxes should be introduced at strategic sites in hospitals.
9. Facilitate ADR reporting by e-mail, fax and phone.
10. Incorporation of pharmacovigilance in the nursing syllabus.
11. Assurance of non-involvement in legal matters, if they arise.
12. Making ADR reporting mandatory for nurses.
13. Each hospital should have data-base on ADRs, easily accessible by nurses.
14. Periodic meetings between nurses, physicians and pharmacists for effective co-ordination.
15. Positively changing the mindset, so that ADR reporting becomes an accepted and understood routine.

CONCLUSIONS

Even though all nurses felt ADR monitoring to be essential and are willing to report, they are unaware about the national pharmacovigilance program. They lack the knowledge of ADR reporting centers. The availability of CDSCO ADR reporting forms and reporting to ADR monitoring centers of Delhi was extremely poor. None of the hospitals had effective set procedure of ADR reporting. Education and training regarding noticing, reporting of ADRs to nurses is essential. ADR reporting by nurses would significantly improve after implementing the suggestions. Proactive participation of nurses would certainly enhance spontaneous reporting of ADRs to ADR monitoring centers.

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