Status of spontaneous reporting of adverse drug reaction by physicians in Delhi

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ABSTRACT

Adverse drug reaction (ADR) monitoring and reporting activity is in its infancy in India. Physicians being frontline caregivers, a study was conducted to determine the level of awareness of physicians about ADR reporting and the extent of their involvement in pharmacovigilance activities. A study of physicians was conducted among various government hospitals, private hospitals and private clinics of Delhi (INDIA) from Dec 2009 to July 2010. A questionnaire containing 19 questions was distributed to 200 physicians. Only 124 physicians completed the questionnaire giving response rate of 62%. Out of these, only 70.97% physicians were aware of the term Pharmacovigilance. Majority of the respondents (99.19%) consider ADR monitoring to be essential. However, 96.77% physicians noticed ADRs in patients but only 34.68% physicians reported them. Only 8.87% of the physicians knew the pharmacovigilance centers of Delhi. Out of these only 2.42% had phone number and address of these centers and they reported ADRs at these centers. The major reasons for not reporting ADR were: not aware of reporting centers (97.58%), non-availability of ADR reporting form (90.32%), adverse drug reaction already well known (57.26%), uncertainty about drug causing it (47.58%) and lack of set procedure of ADR reporting in their organization (42.74%). Most of physicians (87.90%) consider ADR monitoring should be made mandatory on doctors. Despite good observation and knowledge of ADR among doctors the rate of reporting to ADR monitoring centers is very low.

Keywords: ADR, ADR reporting, Pharmacovigilance, Physicians.

INTRODUCTION

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 functions.[1] ADRs are global problem of major concern.

Impact of ADR on Health:

ADRs are the cause of hospital admission in 3% to 6% of patients of all ages.[2,3] While the incidence of hospital admissions due to ADR in elderly patients is 3% to 24% .[4] ADR incidence has been reported to range from 5.9 to 22.3% of all emergency department admissions.[5] According to a study carried out in a tertiary referral center in South India the admissions due to ADRs accounted for 0.7% of total admissions and deaths due to ADRs accounted for 1.8% of total ADRs.[6] The study of Bord et al indicated that, in patients who experience ADRs, death rates were 19.18% higher and the length of hospital stay is 8.25% higher.[7] ADRs are 4th-6th largest cause of death in USA. ADRs have been estimated to account for up to 106,000 deaths annually in the United States.[8,9]

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Impact of ADR on Healthcare Cost:

ADRs have a considerable negative impact on both health and healthcare costs.[10] In a study at Taiwan teaching hospital, the mean cost of an ADR associated with extended hospitalization was US $3489.[11]

Bordet's study shows that increase in the cost of hospitalization attributable to ADR was US $3200. He identified that longer hospital stays were directly contributing to increased ADR related costs.[12] Dormann's study found that the mean additional cost of hospitalization for an ADR was US $1400.[13]

Need of ADR Reporting and Scenario of ADR Reporting in India:

India is a developing country with large drug consuming population, with per capita income of only $ 1031.[14] It is fourth largest producer of pharmaceuticals in the world with more than 6,000 licensed drug manufacturers and over 60,000

branded formulations.[15] It is also emerging as a clinical trial hub exposing larger population to newer drug treatments. Thus it is essential that the drug treatment should be safe, efficacious and cost effective. It is the need of the hour to identify adverse drug reactions as early as possible and to prevent them if possible, to ensure the well-being of the patient at reasonable cost.

Spontaneous reporting of ADRs would enhance monitoring and evaluation activities related to drug safety.

To improve the pharmacovigilance activities in India, the Ministry of Health and Family Welfare had initiated the National Pharmacovigilance Program (NPP) on 1 January 2005 which was further revived in July 2010.[15,16] This program is overseen by Central Drugs Standard Control Organization (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 will be collected at the AMCs which will then be dispatched to the coordinating centre as per the standard operating procedures. 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 out.[16]

Physicians and Pharmacovigilance:

In India, physicians are frontline healthcare givers in a community. They play a pivotal role in maintaining the well being of society. Preventing ADRs is an integral part of routine clinical work of any physician. Their active involvement in spontaneous reporting of ADRs is essential for the effective implementation of National Pharmacovigilance Program.

Objectives:

The primary objectives of this study were:

1. To assess the knowledge, attitude and skills of physicians regarding pharmacovigilance and spontaneous reporting of ADR.
2. To identify the reasons for under-reporting.
3. To suggest methods for improvement in the current spontaneous ADR reporting system.

METHODOLOGY

***Research Design*:** This was a questionnaire based study involving physicians, who were surveyed with a questionnaire. The study was conducted in Delhi, the National capital of India, over a period of 8 months from December 2009 to July 2010. Entire area of Delhi was covered which included North, East, West, South and Central zones of Delhi. We visited the physicians personally, distributed the questionnaire and collected the duly filled questionnaire on same day.

Material used: A questionnaire containing 19 questions was prepared. First four questions were designed to generate demographic information about the name, qualification, specialization, sector and experience. The remaining questions were designed to evaluate knowledge (3 questions), to assess their attitude (3 questions) and to judge their skills (9 questions) about pharmacovigilance and ADR reporting.

- Questions on knowledge revealed information regarding their knowledge about pharmacovigilance, awareness about ADR reporting, phone number and address of pharmacovigilance centers in Delhi. Further they were asked to choose the place of ADR reporting from given multiple choice of - hospital pharmacy, senior/fellow physician, manufacturing industry, regional monitoring centre and national monitoring centre.
- Questions on attitude regarding pharmacovigilance helps to know their opinion on essentiality of ADR monitoring and possible reasons for non- reporting of an encountered ADR such as ADR is well known, not sure about the drug causing ADR. Further their perception about 'whether ADR monitoring should be made mandatory' was probed.
- Questions on skills covered various activities or inputs given by physicians 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, availability of ADR form, reporting/non-reporting of observed ADR, existence of set procedure of reporting ADR in their organization.

***Subjects*:** The study included 200 physicians practicing in government or private sector hospitals/clinics of Delhi.

***Study setting*:** The study covered 10 government hospitals, 3 private hospitals and 6 private clinics of Delhi. Following hospitals were included in the study.

Government sector hospitals

1. All India Institute of Medical Sciences and Research (AIIMS)
2. Guru Gobind Singh Government Hospital (GGSGH)
3. Safdarjung Hospital (SJH)
4. Deen Dayal Upadhaya Government Hospital (DDU)
5. Charak Palika Hospital (CPH)
6. Govind Ballabh Pant Hospital (G B Pant)
7. Lok Nayak Jaiprakash Hospital (LNJP)
8. Primary Health Centre (PHC), Mehrauli.
9. Pt. Madan Mohan Malaviya Hospital
10. Chacha Nehru Bal Chikitsalaya

Private sector hospitals

1. Park Hospital
2. Batra Hospital and Medical Research Centre
3. Tirathram Shah Hospital

RESULTS

Out of 200 physicians approached to participate in study, 124 physicians completed and returned the questionnaire, giving response rate of 62%. The participation of physicians from various hospitals is represented in Fig.1. The demographic profile of respondents is represented in Table No.1. Maximum participants (27, 21.77%) were from All India Institute of Medical Sciences and Research, New Delhi.

Fig.1: Participation of physicians from various hospitals

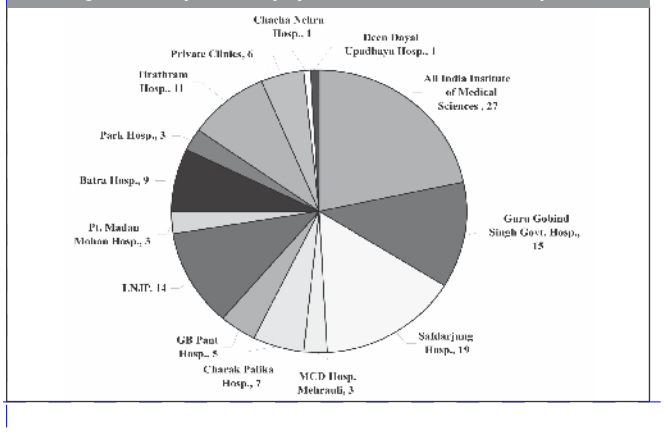


Table 1: Demographic profile of respondents

Demographics	Number	Percentage
Qualification		
Post graduate	92	74.19
Under graduate	32	25.81
Gender		
Male	95	76.61
Female	29	23.39
Sector		
Government	95	76.61
Private	29	23.39
Experience		
0-5 yrs.	52	41.93
5-15yrs.	53	42.74
15-25yrs.	12	9.68
25 or more	7	5.64

Knowledge of physicians:

Out of the total (124) physicians, 88 (70.97%) reported that they were aware of the term pharmacovigilance, 29 (23.39%) physicians did not know the term pharmacovigilance and 7 (5.64%) physicians did not respond indicating that total 29+7 =36 (29.03%) physicians, did not know the term pharmacovigilance. The results show considerable variability regarding physicians' knowledge about the possible reporting centers in India. Six (4.84%) physicians had faint idea that reporting can be done at National Monitoring Center (NMC) and/or Regional monitoring centers (RMC) because NMC and RMC were one of the many options chosen by them for place of ADR reporting. The percentage response to other options was senior/fellow physicians (16.93%), hospital pharmacy (11.29%) and manufacturing industry (3.22%). Two (1.61%) physicians gave mixed response. Physician's responses for reporting centers other than those provided in the multiple choices were Medical Superintendent, Hospital pharmacy, Hospital laboratory, Hospital committee, Journal, OPD card, Director Health Services and Drugs controller. Eleven (8.87%) physicians knew that AIIMS and LHMC are the reporting centers of Delhi but Surprisingly only 3 (2.42%) physicians had the phone number, address of the reporting centers. It indicates that 97.58% physicians report ADRs at places other than NMC and RMC.

Skills of physicians:

Majority of physicians (120, 96.77%) reported that they inform the patients about the possible side effects of the prescribed drug and thereafter notice ADRs in patients. One hundred twenty two (98.39%) physicians said that patients

inform them about the discomfort /side effects/adverse effects experienced by them during or after the drug treatment. One (0.81%) physician said that patients do not interact with them about discomfort /side effects/adverse effects observed after and during the drug treatment. One (0.81%) physician did not respond. Only 43 (34.68%) physicians said that they report observed ADR while 73 (58.87%) do not report ADR and 8 (6.45%) did not respond. Thus, 73+8= 81 (65.32%) physicians did not report the ADRs which they had come across. Only 23 (18.55%) physicians said to have set procedure of reporting ADR in their organization. Most respondents 53 (42.74%) agreed that their organization do not have set procedure of reporting ADR while other 23 (18.55%) physicians said that they did not know answer to this question and 25 (20.16%) physicians did not respond. So we can state that 23+25=48 (38.71%) physicians were doubtful about the existence of set procedure for ADR reporting in their organization. The hospital wise response of physicians towards existence of set procedure in their organization is given in Table No.2. Twenty eight (22.58%) physicians did not report ADRs because they were not sure of the drug causing the ADR while 31 (25.0%) physicians did not respond to this query. So, total 28+31=59 (47.58%) physicians were uncertain about drug causing ADR. Half of the physicians did not report the observed ADR because they did not know the center of reporting. Surprisingly only 12 (9.68%) physicians had ADR reporting form while 98 (79.03%) physicians said they do not have this form and 14 (11.29%) physicians did not respond. Thus total, 112 (90.32%) physicians did not have ADR reporting form.

Table 2: Response for existence of set procedure of ADR reporting in different hospitals

Hospitals	Total Physician	Yes	No	Don't Know	No Response
AIIMS	27	7	7	12	1
GGSGH	15	1	11	2	1
SJH	19	1	13	2	3
PHC	3	0	3	0	0
CPH	7	1	4	0	2
GB Pant	5	2	0	2	1
LNJP	14	1	5	4	4
Pt. Madan Mohan	3	1	2	0	0
Batra	9	5	0	1	3
Park	3	1	2	0	0
Tirathram	11	0	2	0	9
Chacha Nehru	1	1	0	0	0
DDU	1	1	0	0	0
Pvt. clinics	6	1	4	0	1

Attitude of physicians:

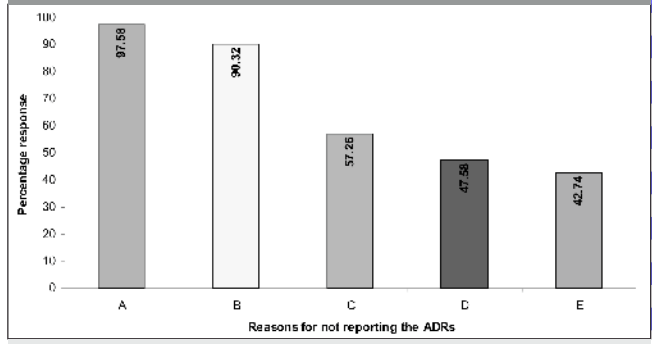
One hundred twenty three (99.19%) physicians felt that the ADR monitoring is essential. One (0.81%) physician did not respond. It may be possible that he did not understand the meaning of ADR monitoring.

Forty two (33.87%) physicians felt that there is no need to report the ADR as it is well known. Fifty three (42.74%) physicians responded negatively while 29 (23.39%) physicians did not respond. So, total 42+29=71 (57.26%) physicians do not report the ADR with the feeling that it is well known. Good number of physicians (109 , 87.90%) were of the opinion that ADR reporting should be mandatory on doctors while 8 (6.45%) physicians considered that ADR reporting should not be mandatory and 7 (5.64%) physicians did not respond.

Summary of results:

Fig.2 represents the major reasons for not reporting of ADR by physicians. They were - unawareness of reporting centers (97.58%), non-availability of ADR reporting form (90.32%), do not have set procedure of reporting in their organization (42.74%), adverse drug reaction already well known (57.26%) and uncertainty about drug causing ADR (22.58%).

Fig. 2: Reasons for not reporting the ADRs

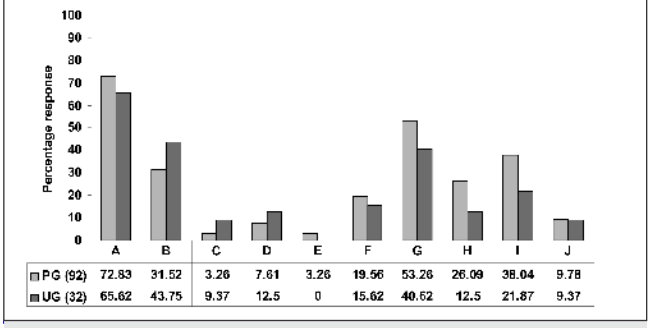


A-Not aware of correct reporting centers, B- Did not have ADR reporting form, C- Feeling that ADR was well known, D- Was not sure about the drug causing ADR, E- Did not have set procedure of ADR reporting in their organization.

Correlation between knowledge, attitude and skills of physicians with their qualification (Fig.3):

The physicians were grouped as per their qualification as: post graduate (PG) physicians (74.19%), undergraduate (UG) physicians (25.81%). The awareness of UG physicians (65.62%) about pharmacovigilance was less than PG physicians (72.83%). Involvement of undergraduates in ADR reporting was more (43.75%) as compared to that of 31.52% of PG physicians but none of the UG physician had phone

Fig. 3: Correlation between knowledge, attitude and skills of physicians with their qualification



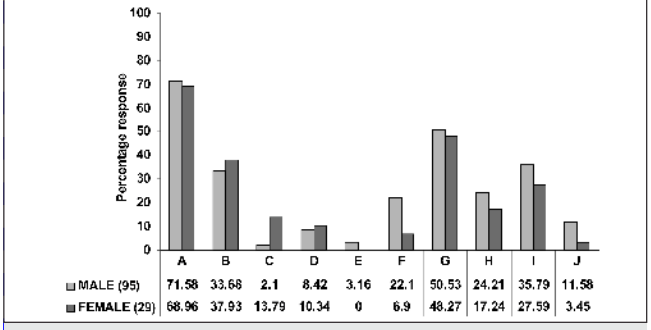
A - Aware of pharmacovigilance, B - Report observed ADR, C - Knew NMC/RMC as reporting centers, D - Aware of ADR reporting centers of Delhi, E - Have phone number and address of NPP reporting center, F - Have set procedure of ADR reporting in their organization, G - Non-reporting due to lack of knowledge about center, H - Uncertain of drug causing ADR, I - Feel all ADRs are well known, J - Have ADR reporting form

number and address of pharmacovigilance centers in Delhi while 3.26% of PG physicians had this information. It seems that undergraduates report ADRs to senior physicians and not to ADR monitoring centers. Uncertainty about the drug causing ADR was more among PG physicians (26.09%). The feeling that ADRs are well known and thus need not be reported was also more in PG physicians (38.04%).

Correlation between knowledge, attitude and skills of physicians with their gender (Fig.4):

The participation of male physicians and female physicians in the study was 76.61% and 23.39% respectively. Awareness about pharmacovigilance of male physicians (71.58%) was better than female physicians (68.96%). The knowledge of NMC/RMC as reporting centers was better of female physicians (13.79%) as compared to 2.10% of males. Male

Fig. 4: Correlation between knowledge, attitude and skills of physicians with their gender



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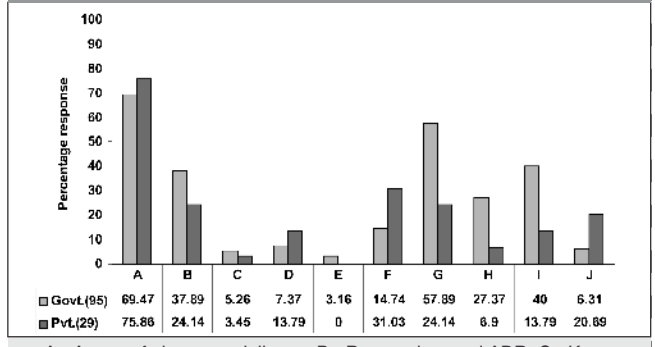
physicians were more aware about phone number and address of pharmacovigilance centre of Delhi (3.16%) and set procedure of ADR reporting in their organization (22.10%). Availability of ADR reporting forms was more with male physicians (11.58%). Reporting of ADR by female physicians (37.93%) was more than male physicians (33.68%). Uncertainty about drug causing ADR was more in males (24.21%) as compared to 17.24% of females. The feeling that ADRs are well known and thus need not be reported was more in males (35.79%).

Correlation between knowledge, attitude and skills of physicians with their sector (Fig.5):

The physicians were grouped as per their sector of working as: Government sector physician (76.61%), Private sector physician (23.39%). Awareness about pharmacovigilance of

Fig. 5: Correlation between knowledge, attitude and skills of physicians with their sector



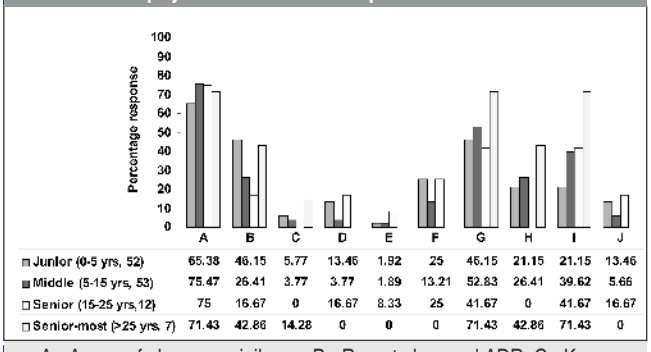
A - Aware of pharmacovigilance, B - Report observed ADR, C - Knew NMC/RMC as reporting centers, D - Aware of ADR reporting centers of Delhi, E - Have phone number and address of NPP reporting center, F - Have set procedure of ADR reporting in their organization, G - Non-reporting due to lack of knowledge about center, H - Uncertain of drug causing ADR, I - Feel all ADRs are well known, J - Have ADR reporting form.

physicians from private sector (75.86%) was better than government sector (69.47%). Knowledge of phone number and address of pharmacovigilance centre of Delhi was better of government sector physicians (3.16%). Actual reporting by physicians from government sector was better than private sector physicians. The reason may be that hierarchy is observed in reporting from Junior doctors to Senior doctors to Consultants within private organization but further communication to ADR monitoring centers does not occur. Major reasons for underreporting in government sector were – Lack of knowledge about centre (57.89%); uncertainty about the drug causing ADR (27.37%); feeling that ADRs are well known hence need not be reported (40.0%). Major reason for underreporting in private sector was non availability of reporting form (79.31%).

Correlation between knowledge, attitude and skills of physicians with their experience (Fig.6):

The physicians were grouped as per their experience as: Juniors (0-5 years, 41.93%), Middle (5-15years, 42.74%), Senior (15-25years, 9.68%) and Senior most (more than 25 years, 5.64%). Juniors were found to be least aware of pharmacovigilance (65.38%). However, no significant difference was found regarding awareness of pharmacovigilance among physicians having experience more than 5years. Senior-most physicians were most aware about NMC/RMC as reporting centers (14.28%) followed by junior (5.77%) and senior physicians (3.77%) while none of the middle physicians had this information. The availability of ADR reporting forms was maximum (16.67%) with senior doctors. Senior physicians were most aware about reporting centers in Delhi (16.67%) and their phone number and address (8.33%). Reporting of observed ADRs was best by junior doctors (46.15%). But the availability of ADR reporting forms was low, it seems that junior doctors are reporting to senior doctors and senior most doctors are discussing ADRs in physician forums. Non-reporting of ADRs due to lack of knowledge of reporting centers (71.43%) as well as the uncertainty about the drug causing the ADR (42.86%) was maximum in senior-most doctors. The feeling that ADR is well known and thus need not be reported went on increasing with experience.

Fig. 6:Correlation between knowledge, attitude and skills of physicians with their experience



	A	B	C	D	E	F	G	H	I	J
Junior (0-5 yrs, 52)	65.38	46.15	5.77	13.46	1.92	25	46.15	21.15	21.15	13.46
Middle (5-15 yrs, 53)	75.47	26.41	3.77	3.77	1.89	13.21	52.83	26.41	39.62	5.66
Senior (15-25 yrs,12)	75	16.67	0	16.67	8.33	25	41.67	0	41.67	16.67
Senior-most (>25 yrs, 7)	71.43	42.86	14.28	0	0	0	71.43	42.86	71.43	0

A - Aware of pharmacovigilance, B - Report observed ADR, C - Knew NMC/RMC as reporting centers, D - Aware of ADR reporting centers of Delhi, E - Have phone number and address of NPP reporting center, F - Have set procedure of ADR reporting in their organization, G - Non-reporting due to lack of knowledge about center, H - Uncertain of drug causing ADR, I - Feel all ADRs are well known, J - Have ADR reporting form.

DISCUSSION

The countries like Australia, Brazil have well established spontaneous ADR reporting systems with participation from all healthcare professionals.[17] In India, very few studies have looked at ADRs as the cause of hospital admissions and fewer still have looked at costs associated with ADRs.[18] ADR monitoring and reporting activity is in its nascent stage in India.[19] This survey helps in knowing the actual participation of physicians of Delhi in spontaneous reporting to ADR monitoring centers. The overall response rate of this survey was (62.0%) which is somewhat higher than the 50% response rate reported by Hasford et al in his study.[20] Physician's expertise in informing patient about expected side effects and noticing ADRs in patient was very good (96.77%). Physicians have extended their role beyond diagnosing and prescribing. The physicians are informing patients about the expected therapeutic effects, dosage regimen, directions for use and possible side effects. Patient's feedback to doctors about experienced discomfort was also good (98.39%). Such data indicates that physicians have good communication skills and they have been successful in developing healthy relationship with patients which is essential for patient safety. Significant percentage (90.32%) of physicians was devoid of ADR reporting form. This is against the finding of Cosentino M that only 16% of physicians of Northern Italian district were devoid of ADR reporting form.[21] As per NPP, adverse drug reactions should be reported to national or regional centers,[15,16] but in our study fellow physicians (16.93%) and hospital pharmacy (11.29%) were found to be the most common recipients of ADR reports. Surprisingly 65.32% physicians did not report the ADRs which they had come across which is almost similar with the study of J. Hasford et al., which found that 68.2% physicians did not report the suspected adverse drug reaction.[20] But our percentage is much higher than the finding of Cosentino M that 50% medical practitioners did not report observed ADRs.[21]

In a study conducted by J. Hasford et al. in 2002, 66.3% physicians were found to be uncertain of definite causality thereby not reporting it[20] while in our study 47.58% physicians were found to be uncertain about drug causing the ADR. The reason for such finding can be enhancement in physician's ADR assessment ability over the period of 8 years. Although the NPP states that all suspected reactions to any drug in the market must be reported, 57.26% physicians felt that the observed ADR need not be reported as it is well known. This is lower than the findings of J. Hasford et al. which state that 75.6% of suspected ADR went unreported by physicians as they were considered to be well known.[20] The set procedure of reporting ADR in their organization was

known to only 18.54% physicians. Remaining physicians were either doubtful or were of the opinion that such procedure does not exist in their organization. Further when the physicians responses were studied hospital wise (Table No.2), a clear fact came forward that; there is no dissemination of the information regarding existence of a set procedure for reporting of ADRs in their organizations. There was a mixed response from the physicians of the same hospital setting. For example, in prime hospital of Delhi like AIIMS, where pharmacovigilance centre exists, out of 27 physicians who participated in the study, 7 physicians were of the opinion that they have set procedure of ADR reporting while 7 other physicians totally disagreed and 12 physicians said that they did not know answer to this question. One physician did not respond to this query. So, conclusive results could not be drawn whether the said hospital setting has a set procedure for reporting ADR. This may be due to:

1. Lack of importance given to the ADR reporting and Pharmacovigilance.

2. Inappropriate dissemination of information and inadequate co-ordination.

3. Communication gap between the NPP representatives, hospital administration and physicians.

Similar pattern was observed in other hospitals of Delhi.

Almost all physicians felt that the ADR monitoring is essential which is in alliance with study of Consentino M that, no doctor seemed to believe that ADR reporting is useless.[21] Though Physicians (99.19%) felt ADR monitoring is essential only 34.68% reported them, indicating that the attitude of physician's is not in sync with their skills. Sixty two (50.0%) physicians felt that they did not report ADR because they did not know where to report. This indirectly indicates that remaining 62 physicians knew where to report ADR but this is contradictory to the fact that only 9.68% physicians had ADR reporting forms and merely 2.42 % had phone number and address of reporting centers of Delhi. Thus we can say that majority of the physicians were ignorant about the existence of ADR monitoring centers, their phone number and address as well as the guidelines of NPP that ADRs should be reported in the ADR reporting form to the monitoring centers. Possibly these 34.68% reported ADRs are discussed in physician's forums or the junior doctors are reporting them to senior doctors. This is in congruence with study of J.Hasford, conducted in Germany, where only few physicians report directly to the German drug authority.[21] In addition, the ADRs reported by physicians may die silent death without any action for benefit of the society as the reporting is scattered and it does not reach the NMC. Thus we can say that the reporting by physicians of Delhi to ADR monitoring centers is extremely low. This is in congruence with study of Janaje et.al., with estimates of only around one in 20 serious ADRs are reported.[22] ADR reporting should be mandatory on doctors was of the opinion of 87.90% physicians. This shows their willingness to contribute in the pharmacovigilance program.

Suggestions for Improvement in ADR Reporting:

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

2. The NPP should periodically collect ADR forms from hospitals by sending representatives.

3. Periodical meetings of experts from NPP with doctors should be arranged to boost reporting.

4. ADR drop boxes should be introduced at strategic sites in hospitals.

5. Pharmacovigilance workshops for health care professionals should be initiated.

6. Facilitate ADR reporting by e-mail, fax and phone.

7. Incorporation of pharmacovigilance in the syllabus of UG and PG courses of medicine.

8. Associating ADR reporting with rewards.

9. Felicitation of physicians for maximum ADR reporting in a year.

10. Assurance of non-involvement in legal matters, if they arise.

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

12. The Government of India may pass a law for making ADR reporting mandatory for physicians.

CONCLUSION

Despite good observation and knowledge of ADR among doctors, the rate of reporting to AMC was low. The overall awareness of doctors about ADR reporting centers of Delhi, their phone number, address and availability of ADR reporting forms was very low. The actual reporting of ADRs by physicians to monitoring centers designated by national pharmacovigilance program was very low. Sensitization and orientation of physicians towards reporting of ADRs to

monitoring centers is essential to improve reporting rate. Implementing the suggestions would significantly improve ADR reporting. Proactive participation of physicians is a key to enhance spontaneous reporting.

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