

Status of Adverse Drug Reaction Reporting by Health Care Professionals of Delhi

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ABSTRACT

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Objective: To evaluate the awareness of health care professionals (HCPs) regarding Pharmacovigilance, adverse drug reactions (ADRs) and its reporting. **Method:** A self-structured questionnaire was delivered by hand to a sample of 590 HCPs in Delhi. The filled questionnaire was collected on the same day. **Result:** The Response rate of this survey was 63.73%. The HCPs were Physicians (32.98%), pharmacists (39.36%) and nurses (27.66%). Only 58.24% HCPs were aware of the broad meaning of the Pharmacovigilance and ADR. Majority of HCPs (90.43%) felt that ADR monitoring is essential. Though 45.48% HCPs reported the ADRs encountered by them just 3.19% HCPs had faint information that reporting can be done at National Monitoring Centre (NMC) and/or Regional monitoring centres (RMC). All India Institute of Medical Sciences (AIIMS) and Lady Hardinge Medical College (LHMC) as ADR monitoring centres of Delhi were known to only 5.85% HCPs. Out of these, only 1.86% HCPs had the phone number and/or address of these centres. It indicates that the ADR reporting is done by HCPs at places other than NMC and RMC. **Conclusion:** Reporting of ADRs by HCPs is poor. Among the HCPs, the knowledge, skill & attitude towards pharmacovigilance and ADR reporting was highest of physicians followed by nurses and then pharmacists. Education and training is essential to increase ADR reporting rate by HCPs.

Keywords: Health Care Professionals, ADRs, Pharmacovigilance

INTRODUCTION

Pharmacovigilance 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 possible drug related problems.”¹ Most countries in the world have established ADR reporting systems.² But still ADRs have been a global problem of major concern, causing both morbidity and mortality,^{3,4,5,6} affecting both children and adults with varying magnitude. In US ADRs are responsible for 3% to 6% hospital admissions of patients of all ages.^{4,7} 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.⁸ In New Zealand, 12.9% of all hospital admissions are due to adverse drug events.⁹ 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.¹⁰

Not only health, ADRs have a considerable negative impact on healthcare costs.¹¹ In a study at Taiwan teaching hospital, the mean cost of an ADR associated with extended

hospitalization was US \$ 3489.¹² Bordet's study shows that increase in the cost of hospitalization attributable to ADR was US \$3200.¹³ Dormann's study found that the mean additional cost of hospitalization for an ADR was US \$1400.¹⁴

India is a developing country with per capita income of only \$ 3694.¹⁵ It is the fourth largest producer of pharmaceuticals in the world with more than 6,000 licensed drug manufacturers and over 60,000 branded formulations.^{16,17} It is also emerging as a clinical trial hub exposing larger population to newer drug treatments. Thus it is need of the hour to identify ADRs as early as possible and to prevent them, to ensure the well being of the patient at reasonable cost.

Pharmacovigilance is in its embryonic stage in India.¹⁷ ADR reporting rate in India is below 1 % as compared to world rate of 5 %.¹⁸ In view of this, the National Pharmacovigilance Program (NPP) which was introduced in 2005, was revived and re-launched in July 2010 by the Ministry of Health and Family Welfare.¹⁹ It is co-ordinated by the Central Drugs Standard Control Organization (CDSCO) of India. This new pharmacovigilance program for India (PVPI) has ambitious plan to start ADR Monitoring Centers (AMC) all over India by 2013.

The awareness about Pharmacovigilance program is essential for reporting of ADRs. It is essential that all healthcare professionals should be voluntarily involved in reporting of ADRs. There has to be a system approach to these ADRs.²⁰ The health care system stands on three pillars, namely:

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physicians, nurses and pharmacists. Only when all three pillars work hand in hand in detecting & reporting ADRs, pharmacovigilance program can grow into a fruit bearing tree. This is because ADR which is surpassed by a physician might be detected by nurses or if it is passed unnoticed by both, it may be trapped by pharmacist. Thus we can have series of barriers against failure as given by Swiss cheese model.²⁰ The failure will result only if individual barrier weaknesses align, permitting a hazard to pass through all of the holes in all of the barriers.

In the light of above reports, present study was undertaken to ascertain the awareness of HCPs working in Delhi (National Capital of India) regarding Pharmacovigilance, ADR and its reporting.

OBJECTIVES

The primary objectives of our study were:

1. To assess the knowledge, attitude, skills of HCPs regarding Pharmacovigilance & 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 HCPs, who were surveyed with a questionnaire. The study was conducted in Delhi, the National capital of India, over a period of 10 months from December 2009 to September 2010. Entire area of Delhi was covered which included North, East, West, South and Central zones of Delhi. We approached various HCPs personally, distributed the questionnaire and collected the duly filled questionnaire on same day.

Material design:

The questionnaire containing 22 questions was formulated to evaluate the Knowledge, Attitude & Skills of the HCPs regarding the Pharmacovigilance, ADR and its reporting. The questionnaire contained 7 questions related to knowledge, 8 questions related to skills and 3 questions related to attitude. The remaining 4 questions were designed to generate data like name, qualification, sector and experience.

- The knowledge based questions revealed information regarding their knowledge about the term pharmacovigilance, ADR, therapeutic effects and possible side effects of drug administered, Pharmacovigilance centres in Delhi and availability of phone number and address of these centres. Further they

were asked to choose the place of ADR reporting, from given multiple choice of - hospital pharmacy, physician, manufacturing industry, regional monitoring centre, national monitoring centre.

- Questions on skill covered various activities or inputs given by HCPs to strengthen pharmacovigilance & ADR reporting, like – informing patients about therapeutic effects and possible side effects of drug administered, 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, availability of ADR reporting form. It was further enquired whether they undergo any continuing education program to improve their professional skills.
- Questions on attitude regarding pharmacovigilance help to know their view on the essentiality of ADR monitoring. We further queried about the possible reasons for non-reporting of an encountered ADR. Their perception about “whether education and training on ADR reporting should be made mandatory on HCPs” was also probed.

Subjects:

The study included 590 HCPs which included physicians, nurses and pharmacists. Physicians and nurses were working in one of the 10 government hospitals or 13 private sector hospitals/clinics, or 4 government dispensaries. Pharmacists worked either in these hospitals or medical shops of Delhi or in pharmaceutical industry as medical representative, posted in Delhi.

RESULTS

Out of 590 HCPs approached to participate in study, 376 HCPs responded, giving response rate of 63.73%. Profession wise classification shows that 32.98% were Physicians, 39.36% were Pharmacists and 27.66% were Nurses (Fig.1). Affirmative response of HCPs to knowledge, skill & attitude related questions is depicted as percentage in Fig.2

Knowledge of HCPs:

Out of 376 HCPs, 219 (58.24%) were aware of the term Pharmacovigilance, while 114 (30.32%) HCPs did not know the term pharmacovigilance and 43 (11.44%) HCPs did not respond, indicating that total 114 + 43 = 157 (41.76%) HCPs, did not know the term pharmacovigilance.

The correct meaning of the term ADR was known to 219 (58.24%) HCPs. Eighty three (22.07%) HCPs did not know the term ADR and 74 (19.68%) HCPs did not respond, indicating that total 83 + 74 = 157 (41.76%) HCPs, did not know the correct meaning of the term ADR.

Therapeutic effects of the prescribed drugs were known to 335 (89.10%) HCPs. Eight (2.13%) HCPs did not know the therapeutic effects while 33(8.78%) did not respond indicating that 41(10.90%) HCPs did not know even the expected therapeutic effects.

Possible side effects of the prescribed drugs were known to 332 (88.30%) HCPs. Sixteen (4.26%) HCPs did not know while 28(7.45%) did not respond, indicating that 44 (11.70%) HCPs were not aware of the possible side effects of the prescribed drugs.

The result shows considerable variability regarding HCPs knowledge about the possible reporting centers in India. Out of all HCPs only 12 (3.19%) 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 as a place for ADR reporting. Other places of ADR reporting chosen by 299 (79.52%) HCPs included Physician, Hospital Pharmacy, Manufacturing Industry, Senior Supervisor, Department in-charge, Product Management Team, Chief Pharmacist, purchasing department of hospital, Medical Superintendent, Hospital laboratory, Hospital committee, Journal, OPD card, Director Health Services and Drugs controller. Sixty five (17.29%) HCPs did not respond to this question. When the HCPs were further probed regarding reporting centres of Delhi, Twenty two (5.85%) HCPs tentatively knew that AIIMS and LHMC are the reporting centers of Delhi but surprisingly only 7 (1.86%) HCPs had their phone number & address. Therefore total 369 (98.14%) HCPs report ADRs at places other than official ADR monitoring centers designated by CDSCO.

Above results make it clear that some of the HCPs knew AIIMS and LHMC as ADR reporting centres but they were unaware that AIIMS is NMC and LHMC is an RMC.

Intra professional response regarding knowledge

The response of the HCPs was further classified as per their profession as physician, pharmacist or nurse. For intra-professional comparison, the percentage is calculated by taking 124 as a denominator for physicians, 148 as a denominator for pharmacists and 104 as a denominator for nurses. Figure 3 depicts the comparison between knowledge level of physicians, pharmacists and nurses.

The physicians were more aware about the pharmacovigilance (70.96%), than nurses (68.27%) and pharmacists (40.54%).

Awareness of ADR and expected therapeutic effects was maximum among physicians (100%, 100%) followed by nurses (51.92%, 92.31%) and pharmacists (27.70%, 77.70%). Similar pattern of knowledge regarding possible side effects of the drug was found among HCPs.

Out of all HCPs who reported the observed ADRs, only 6 (4.84%) physicians, 6 (4.05%) pharmacists and none of the nurses had the knowledge about NMC and/or RMC.

The overall knowledge regarding places of reporting ADRs in Delhi was negligible but on comparison physician's knowledge was found better than nurses followed by pharmacists. The knowledge regarding phone number & address of ADR reporting centers in Delhi was very low but similar in nurses & physicians. Pharmacist's knowledge in this regard was poor.

Skill of HCPs:

Expected therapeutic effects of the prescribed drugs were informed to the patients by 306 (81.38%) HCPs. Forty three (11.44%) HCPs did not inform the expected therapeutic effects of drugs while 27 (7.18%) did not respond. Thus total $27 + 43 = 70$ (18.62%) HCPs did not inform the patients about the expected therapeutic effects of the drugs.

Two hundred eighty six (76.06%) HCPs inform the patients about the likely side effects of their drug treatment. Two hundred eighty one (74.73%) HCPs said that patients inform them about the discomfort experienced by them during or after the drug treatment. Sixty two (16.49%) HCPs said patients do not interact with them about discomfort observed after and during the drug treatment. Thirty three (8.78%) HCPs did not respond.

One hundred seventy one (45.48%) HCPs submitted reports when ADRs were encountered while 159 (42.29%) do not report observed ADR and 46 (12.23%) did not respond. Thus significant number of HCPs ($159 + 46 = 205$, 54.52%) did not report the ADRs which they encounter.

Only 92(24.47%) HCPs said that they have set procedure of ADR reporting in their organization. Most respondents (224, 59.57%) agreed that they do not have a set procedure of reporting ADR while 28 (7.45%) HCPs did not know answer to this question and 32 (8.51%) HCPs did not respond. So it is clear that $28+32= 60$ (15.96%) HCPs were doubtful about existence of set procedure for reporting ADRs in their organization.

Only 42 (11.17%) HCPs had ADR reporting form while 270 (71.81%) said they do not have this form and 64 (17.02%) did not respond. Thus, most of the HCPs ($270 + 64 = 334$, 88.83%) did not have ADR reporting form.

One hundred thirty five (35.90%) HCPs did not report the ADR because either they could not diagnose that the symptoms experienced by patients after taking drug was ADR and/or they could not point out the causal drug from the drug treatment. This indicates that HCPs are not trained enough to detect the ADRs, which was further proven by the fact that, out of 376 participating HCPs only 237 (63.03%) HCPs undergo continuing education program.

Intra professional response regarding skills

Figure-4 gives the comparison between skill level of physicians, pharmacists and nurses. It is clear that physicians (100%, 100%) are ahead of nurses (93.27%, 91.35%) and pharmacists (57.43%, 47.97%) in informing patients about the expected therapeutic effects and possible side effects of their drug treatment.

The interaction between physicians and patients was found to be best among the three. This is indicated from the response that 98.39% of physicians, 89.42% of nurses and 44.59% pharmacists were informed by the patients about the side effects experienced by them.

Involvement of nurses (90.38%) in reporting ADR was greater than the physicians (34.68%) and pharmacists (22.97%).

Nurses (47.12%), Physicians (18.55%) and pharmacists (13.51%) reported that they have set channel for reporting ADR in their organization.

Of the 42 (11.17%) HCPs who said to have ADR reporting form 26 (25.0%) were nurses, 12 (9.68%) were physicians and 4 (2.70%) were pharmacists.

Almost half of the physicians (47.58%) & nurses (49.04%) were uncertain about the drug causing the ADR and thus did not report it. While 16.89 % pharmacists did not report ADR due to uncertainty of drug causing ADR.

Among the groups, the participation in continuing education programs of physicians was highest (100%) followed by nurses (54.81%) and pharmacists (37.84%).

Attitude of HCPs:

Essentiality of ADR monitoring was felt by 340 (90.43%) HCPs. Five (1.33%) HCPs felt ADR monitoring is not essential while 31 (8.24%) HCPs did not respond. It may be possible that these HCPs did not understand the meaning of ADR monitoring.

The feeling that ADR need not be reported as it is well known was observed in 132 (35.11%) HCPs.

Most HCPs (331, 88.03%) were of the opinion that education and training would play a pivotal role in improving ADR reporting.

Intra professional response regarding attitude

The response of the HCPs for attitude related questions was further classified as per their professions. Figure-5 gives the comparison between attitude of Physicians, Pharmacists and Nurses. Among the groups, physician's response for essentiality of ADR monitoring was maximum (123, 99.19%) followed by nurses (101, 97.12%) and then pharmacists (116, 78.38%).

The need of education and training in ADR reporting was vehemently expressed by physicians (100%) who were trailed by nurses (92.31%) and pharmacists (75%).

The feeling that untoward symptoms experienced by the patients (ADR) are well known was more prominent in physicians (57.26%) than nurses (40.38%) and pharmacists (12.84%).

Major reasons of Underreporting of ADR:

Fig. 6 represents the reasons for under-reporting of ADRs by HCPs. Majority of HCPs lacked knowledge of the correct ADR reporting centres as well as their phone no. and address (96.81%, 98.14% respectively). ADR reporting forms were not available with 88.83% HCPs. Non existence of set procedure of reporting ADR in their organization (59.57%), lack of knowledge regarding pharmacovigilance and ADR (41.76%), uncertainty about causal drug (35.90%) and feeling that ADR is well known (35.11%) are the other reasons for non-reporting of ADR.

DISCUSSION

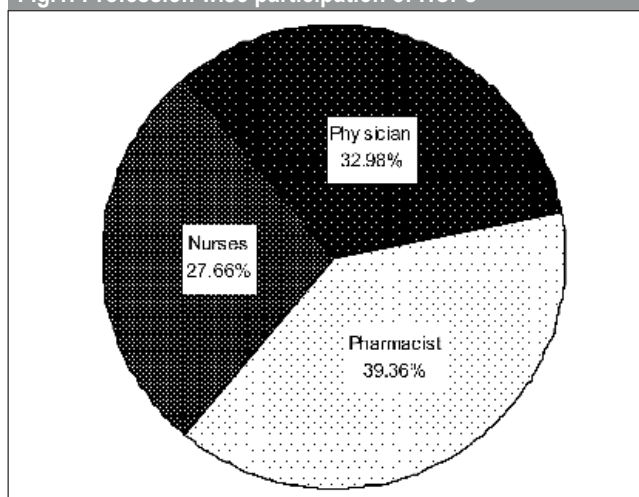
Spontaneous reporting of ADRs to the Regional Monitoring centre (RMC) or National monitoring Centre (NMC) via the ADR reporting form is crucial for safety surveillance of the marketed drugs.²¹ But, in India, very few studies have looked at ADRs as the cause of hospital admissions and fewer still have looked at costs associated with ADRs.²²

We could find only one study conducted by LI Qing et al in China in 2004, which has assessed the participation of HCPs in ADR reporting. In our study we included Physicians, Pharmacists & nurses as healthcare professionals while LI Qing et al²³ included Physicians, Pharmacists & administrators as healthcare professionals. The overall response rate of our survey was (63.73%) which is somewhat lower than the 85% response rate reported by Li Qing et al. According to WHO the definition of ADR is "any response to a drug which is noxious, unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function".¹ In this study 58.24% of the HCPs knew the correct meaning of ADR which is much better than the study in China which states that only 2.7% of HCPs knew the meaning of ADR. As stated above 157 (41.76%) HCPs did not understand the term ADR but 332 (88.30%) HCPs reported that they know the possible side effects of prescribed drugs. This is because the HCPs were more apt to the term side effect and did not know the meaning of adverse drug reaction. They did not understand that- A 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 inconsequential¹ while the adverse

effect is always undesirable. This indicates that HCPs could not differentiate between ADR and the side effect.

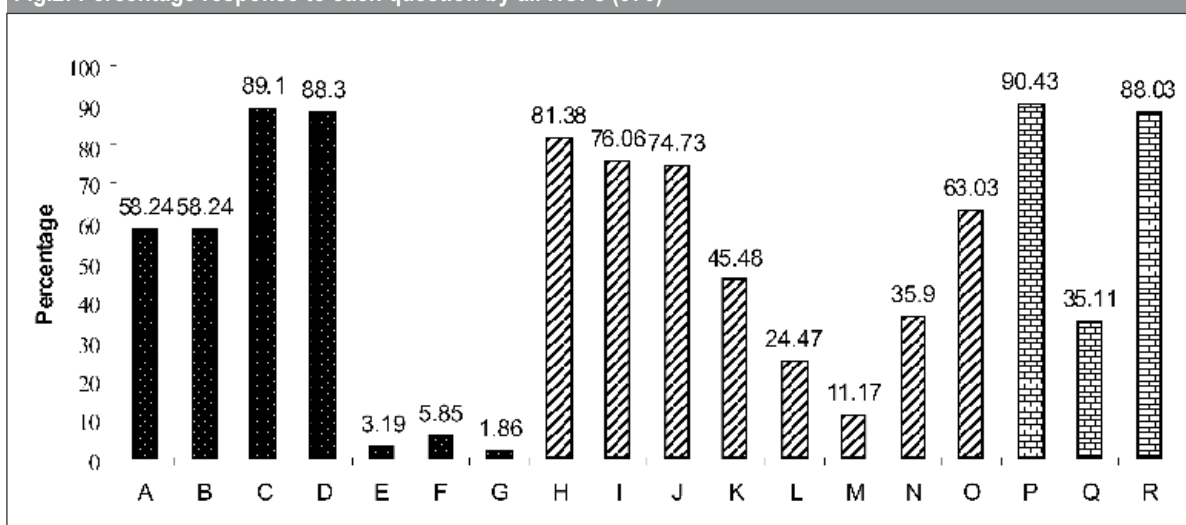
HCP's expertise in informing patient about expected side effects and receiving feed back from patient regarding discomfort felt after taking medication was fairly good (76.06%, 74.73%). But intra profession result indicates that problem lies in pharmacy sector, which is endorsed by the good percentage of physicians (100%), nurses (91.35%) and just average percentage of pharmacists (47.97%) informing patients about expected side effects while 98.39% of physicians, 89.42% of nurses, 44.59% of pharmacists are able to receive feedback from patient regarding discomfort they felt after taking medication. This indicates that pharmacist's interaction with patients is low and needs to be improved. Pharmacists should extend their role from just dispensing to a responsible pharmacist who is willing to inform patients about the expected therapeutic effects, dosage regimen, directions for use and possible side effects of drugs. In addition, he should be good listener to receive feedback from patients. However, Physicians and nurses have good communication skills and they have been successful in developing healthy relationship with patients which is essential for patient safety.

Fig.1: Profession wise participation of HCPs



As per NPP, adverse drug reactions should be reported to national or regional centres in the prescribed ADR reporting form.^{16,19} In our study, significant percentage (88.83%) of HCPs were devoid of ADR reporting form, which is much higher than the finding of Li Quing et al that only 60.4% HCPs were devoid of ADR reporting form. The knowledge of the

Fig.2: Percentage response to each question by all HCPs (376)



Knowledge related questions:

A- Awareness of pharmacovigilance, B- Awareness of ADR, C- Awareness of therapeutic effects, D- Awareness of possible side effects, E- Knew NMC or RMC as reporting centre, F- Knew places of reporting in Delhi, G- Have phone no. & address of NPP reporting centre.

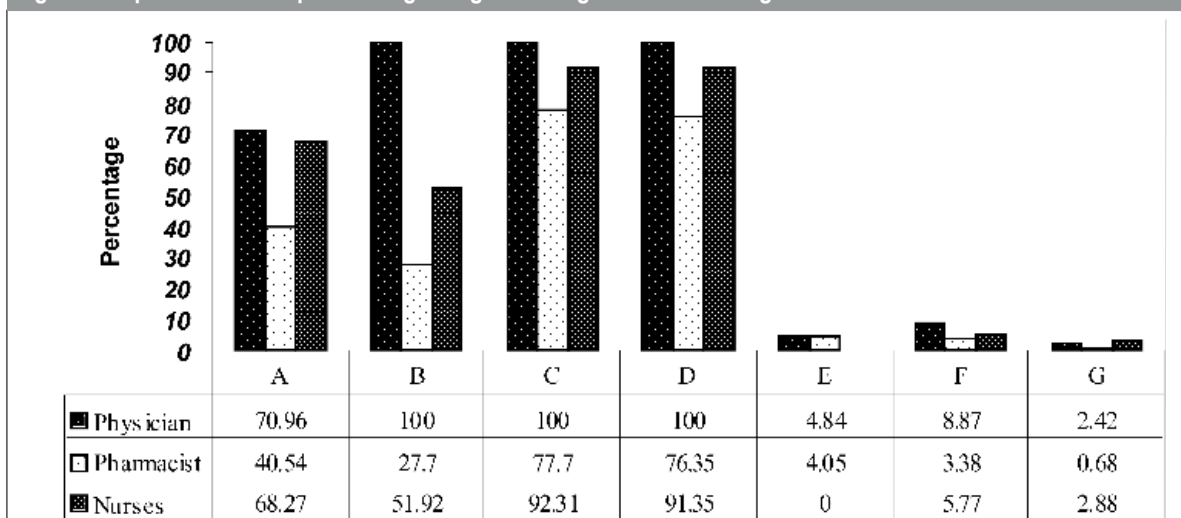
Skills related questions:

H- Inform patients about therapeutic effects, I- Inform patients about side effects, J- Do patient inform you about side effects, K- Do you report ADR, L- Have set procedure of reporting ADR in their organization, M- Have ADR reporting form, N- Underreporting due to uncertainty of drug causing it, O- Underwent continuing education program.

Attitude related questions:

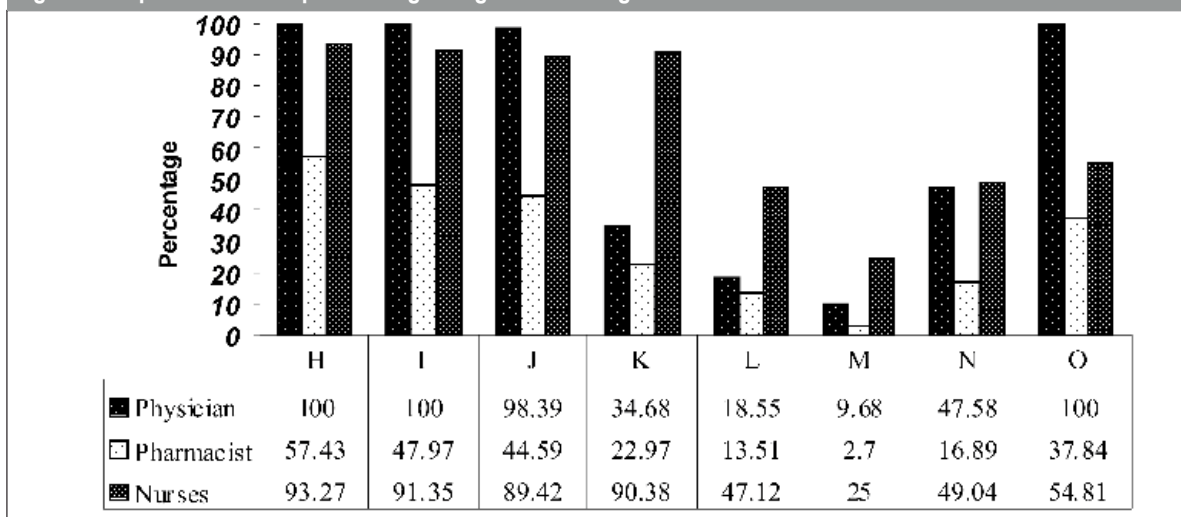
P- Essentiality of ADR monitoring, Q- Underreporting due to feeling that ADR is well known, R- Essentiality of education and training for increasing ADR reporting.

Fig.3: Intra-profession comparison regarding knowledge of Pharmacovigilance



A- Awareness of pharmacovigilance, B- Awareness of ADR, C- Awareness of therapeutic effects, D- Awareness of possible side effects, E- Knew NMC or RMC as reporting centre, F- Knew places of reporting in Delhi, G- Have phone no. & address of NPP reporting centre.

Fig. 4: Intra-profession comparison regarding Pharmacovigilance skills



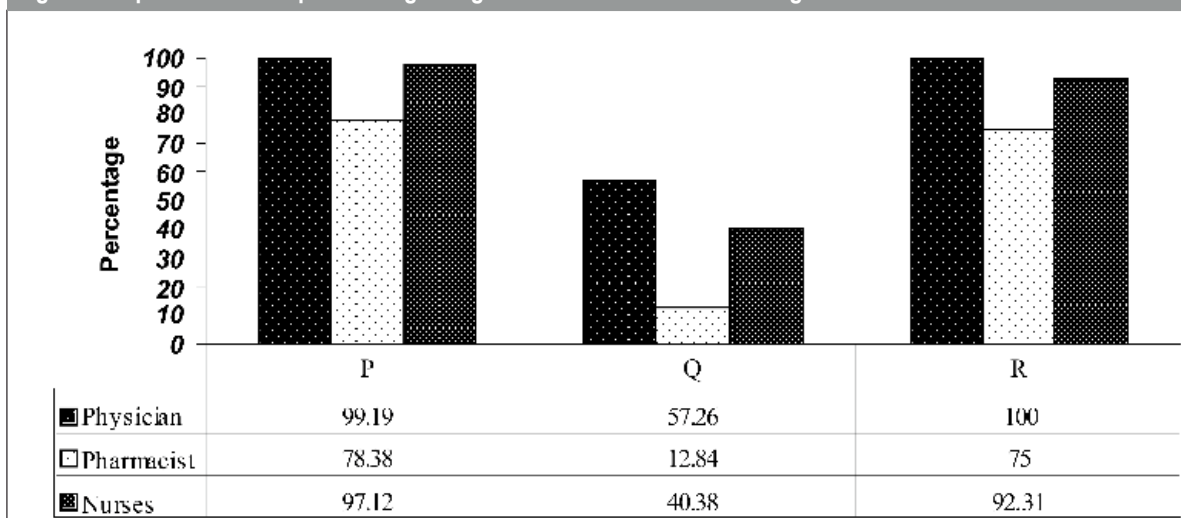
H- Inform patients about therapeutic effects, I- Inform patients about side effects, J- Do patient inform you about side effects, K- Do you report ADR, L- Have set procedure of reporting ADR in their organization, M- Have ADR reporting form, N- Underreporting due to uncertainty of drug causing it, O- Underwent continuing education program.

reporting centres of Delhi was found quiet low among HCPs (22, 5.85%). Furthermore, 98.14% of healthcare professionals did not know the ADR reporting procedures to the ADRs monitoring system, which is much higher than that was found in China (71.4%) by Li Quing et al. As per study conducted by Li Quing et al. in 2004, 44.1% HCPs believed that ADRs are already well known & thus need not be reported, while in our study 35.11% HCPs were of similar opinion. These may be the direct reasons for the

underreporting of ADRs. From these results we can assume that the weightage given by HCPs to ADR monitoring and reporting is abysmal.

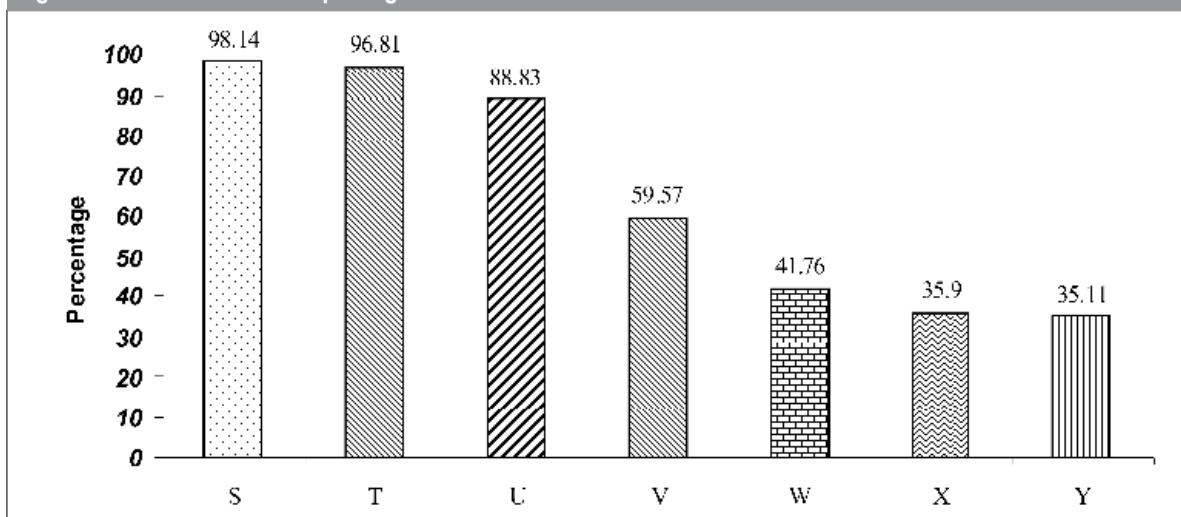
It is recognised, however that the attitude of the HCPs towards the reporting of adverse drug reaction (ADRs) is of great importance in determining whether they actually generate reports.^{24,25} Majority of the HCPs in our study i.e. 90.43% felt that ADR monitoring is essential which is in alliance with 94% reported by of LI Quing. Though HCPs (90.43%) felt

Fig.5: Intra-profession comparison regarding attitude towards Pharmacovigilance



P- Essentiality of ADR monitoring, Q- Underreporting due to feeling that ADR is well known, R- Essentiality of education and training for increasing ADR reporting.

Fig.6: Main reasons for not reporting ADRs.



S- Did not have phone no. and address of pharmacovigilance centres, T- Did not know the correct reporting centres of ADRs monitoring system, U- Did not have ADR reporting form, V- Did not have set procedure of reporting ADR in their organization, W- Lack of knowledge regarding pharmacovigilance and ADR, X- Uncertainty about causal drug causing ADR, Y- Feeling that ADR is well known.

ADR monitoring is essential only 45.48% reported them, indicating that the attitude of HCP's is not analogous with their skills. 299 (79.52%) HCPs agreed that they did not report ADR because they did not know where to report. This indirectly indicates that remaining 77 (20.48%) HCPs knew where to report ADR but this is in contradiction to the fact that only 42(11.17%) HCPs had ADR reporting forms and merely 7 (1.86 %) had phone number and address of reporting centres of Delhi. This indicates that reporting revolves in the interior

of their organisation or they report the ADR verbally to chief pharmacist, physician, purchasing department of hospital manufacturing industry, department in-charge, product management team etc and not to the NMC, RMC or peripheral monitoring centre. This kind of reporting is not of much help in ensuring patient safety on the national & global level.

Thus we can say that majority of the HCPs were ignorant about the existence of ADR monitoring centres, 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 centres. A regulation is required to implement the "system of reporting adverse events" associated with the drugs.¹⁸ ADR reporting should be mandatory on doctors was the opinion of 87.90% physicians. This shows their willingness to contribute in the pharmacovigilance program. HCPs strongly felt the need to undergo training to increase their participation in the ADR reporting.

When intra-professional comparison was undertaken, it was found that the pharmacists were limping behind the nurses & physicians in their knowledge, skills & attitude towards Pharmacovigilance & ADR reporting.

CONCLUSION

The overall awareness of HCPs 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 HCPs to monitoring centers designated by pharmacovigilance program of India was very low. Sensitization and orientation of HCPs towards reporting of ADRs to monitoring centers is essential to improve reporting rate. Implementing the following suggestions would significantly improve ADR reporting.

1. Hospitals should build local 'Pharmacovigilance Unit' for disbursement and collection of ADR reporting forms.
2. The NPP should periodically collect ADR forms from hospitals.
3. Periodical meetings of experts from NPP with HCPs to boost reporting.
4. ADR drop boxes should be introduced at strategic sites in hospitals.
5. Pharmacovigilance workshops for HCPs should be initiated.
6. Facilitate ADR reporting by e-mail, fax and phone.
7. Incorporation of pharmacovigilance in the syllabus of study courses.
8. Associating ADR reporting with rewards.
9. Felicitating HCPs for maximum ADR reporting per year.
10. Assurance of non-involvement in legal matters, if they arise.
11. Positively changing the mindset to make ADR reporting, an accepted routine.
12. The Government of India may pass a law for making to make ADR reporting mandatory.

This study has thrown light on the bare facts of ADR reporting

in Delhi and would force the Government of India, to think in the direction of implementing the suggestions to improve the ADR reporting.

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