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A Study of Knowledge, Attitude and Practice of Adverse Drug Reaction Reporting among Healthcare Professionals in North India and Identification of Causes of Under-Reporting

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Abstract: ***Adverse Drug Reactions (ADR) are encountered commonly in daily practice and are an emergent cause of morbidity and mortality worldwide. They are an imperative public health crisis causing a substantial fiscal burden on the health care systems. Awareness about the ADR among the health care professionals can decrease the irrational pharmacy and raise an alarm for adverse drug reaction reporting. Good pharmacovigilance practice will identify the risk and risk factors in the shortest possible time so that harm can be avoided or reduced to minimum. This study was conducted in a teaching hospital in Northern India to evaluate the knowledge, attitudes and practice of pharmacovigilance among the healthcare professionals. It also aimed at understanding the causes of under-reporting and to focus on possible ways by which ADR reporting can be improved. The study was an observational, non-interventional, questionnaire-based study. The study revealed positive results where96.3% of Healthcare Professionals included in studywere aware and of Pharmacovigilance. Also, majority of them considered it as a professional obligation. Lack of remuneration, time and trained professionals were the major causes of under-reporting. This study demonstrated that there is improvement in the knowledge and attitude towards pharmacovigilance among health care professionals but the actual reporting practice is still lacking and needs improvement.***

Keywords: Adverse Drug Reactions, Pharmacovigilance, Clinical Research, Health Care Professionals, Patient Safety

1. Introduction

According to WHO (1996) definition a "Drug is any substance or product that is used or is intended to be used to modify or explore physiological systems or pathological states for the benefit of recipient" [11] There are three actions of the drug: the one you want, the one you don't want and the one you don't know about (DJP Barker). Thus, it makes it more crucial to monitor both the known and unknown adverse effects of medicine. [2] No drug can be absolutely devoid of adverse effects but this can be associated with a risk-benefit ratio. It is very important for the professionals who prescribe the drug that they are aware of the quantum and the frequency of the untoward risk. [12]

According to the World Health Organisation (WHO) definition, an "ADR is any noxious, unintended and undesirable effect of drug, which occurs in doses in humans for prophylaxis, diagnosis or therapy". [4]Adverse drug reactions are imperative public health crisis. With the growing demand and supply of the drugs in market the rate of adverse drug reactions is on a rise and they pose great fiscal burden to the economy, society and especially health care systems. [6] The Pharmaceutical industry in India is growing at a rate of 12%-14% per annum with a value of Rs.90, 000 Crores, more drugs are being introduced known as the New Chemical Entities (NCE), vaccines, new routes of administration and new dosage forms even for the existing drugs. These give a reason for monitoring of the adverse drug reactions. [7]

Pharmacovigilance according to WHO is defined as "The science and activities relating to detection, assessment, understanding and prevention of adverse effects of drugs or any other drug related problems." [8] There has been a constant growth of Pharmacovigilance in past 15 years owing to the numerous adverse drug reactions being faced by the world. If these reactions are communicated efficiently, it will lead to intelligent use of medicines and potential adverse drug reactions can be evaded. [1]

1.1 History of Pharmacovigilance

It was in 1968 when the first practical drug monitoring system was established after the infamous thalidomide tragedy. Around 30 years ago the 20th World's assembly adopted a resolution for the conception of a project on an international system for drug monitoring after the thalidomide disaster. This created the basis of World Health Organization's program on International System for Drug Monitoring (IDM). After the pilot test in USA an international data base was set up at the WHO center in Geneva in 1971 and moved to Uppsala, Sweden in 1978. [3] India is also a part of ADR reporting though the reporting rate in India is 1% compared to the 5% reporting rate worldwide. India had two unsuccessful attempts in 1986 and 1987 but thereafter the National Pharmacovigilance Program in India got a kick start after funding from WHO and World Bank. It was inaugurated on November 23, 2004 and on January 1, 2004 it was operational under Central Drugs Standard Control Organisation (CDSCO), New Delhi. CDSCO launched Pharmacovigilance Program of India (Pv.P.I) in July 2010 under Ministry of Health and Family Welfare, Government of India. The All India Institute of Medical Sciences (AIIMS), New Delhi was made the National Coordinating center (NCC) to monitor ADR. In April 2011 under Uppsala Monitoring Centre-World Health Organisation (UMC-WHO), the NCC shifted to Indian

Pharmacopeia Commission, Ghaziabad (U.P.) with approximately 150 ADR monitoring centers (AMC) working in our country.[7]

1.2 ADR Reporting among the Healthcare Professionals

A majority of Indian population prefers government hospitals when they are in need of medical care facilities and thus these could be a good source of generation of ADR database. The involvement of the healthcare professionals and their reporting the ADRs bears the load of the success of Pharmacovigilance programs. The doctors, nurses and pharmacists have immense responsibility in strengthening the Pharmacovigilance mechanism in their vicinity. It should be observed as a moral duty as much as the patients care. [9]

It is a commonly observed that after so many years of the Pv.P.I the reporting percentage in India remains low. Under-reporting is the most commonly known problem of the Pharmacovigilance program. The reasons for under reporting could be lack of time, lack of awareness of the importance of reporting or less knowledge about the ADR. Other reasons could be inadequate funding and lack of trained staff. There is also absence of adequate monitoring, detection, communication and spontaneous reporting of ADRs. [5]

In Nigeria, a study on the perceptions of doctors on Pharmacovigilance showed that only 40.4% of the respondents knew that a Pharmacovigilance center existed in their country. Another study in Turkey showed that only 7% of HCPs reported the ADRs to the Pharmacovigilance center in their country. A study on 82 professionals in Ethiopia concluded that only 57.3% of respondents agreed on reporting as a part of their duty although 56.1% of respondents believed that one report of ADR made no difference. [3] In France a survey was conducted among medical residents which showed their lack of knowledge on Pharmacovigilance. Also, a Nepalese study showed the need for improvement in the Pharmacovigilance teaching practices in their country. [2]

Another major cause that adds up to the under-reporting is the lack of patient interest and motivation and patients' attitude towards the drug reactions. The patients tend to blame the doctor for misdiagnosing and ill-treatment when they are told about ADR which also leads to a fear of legal issues and hence the reactions are left un-reported. Despite of various studies conducted amongst the health care professionals in different countries the answer remains the same, there is a fault in ADR reporting and Pharmacovigilance practices and there is an immediate need for improvement in the knowledge about spontaneous reporting and ADR monitoring among the HCPs.

The rates of reporting can be improved by promoting the awareness of importance of ADR reporting and the procedures by which it is done. The best manner to inculcate this practice is to start it from the basics, at the undergraduate and post graduate levels through didactic lectures which are more teacher-centered with emphasis on learning the facts about drugs and adverse reactions. [10]

Therefore, it is the need of the hour to generate awareness on the importance and relevance of ADR monitoring for a sustainable future and growth of the human society. [7] And in order to improve ADR reporting it is imperative to evaluate the knowledge, attitude and practices of Pharmacovigilance amongst the health care professionals and their awareness and perceptions on ADR monitoring. Thus, the current study was performed to evaluate these factors and to understand the causes of underreporting and to focus on possible ways by which spontaneous reporting can be improved so that the professionals develop a habit of reporting which can lead to development of a health community.

1.3 Objectives

The study was designed to assess the awareness of Pharmacovigilance and Adverse Drug Reaction reporting among the health care professionals in a selected health care teaching facility in north India.

The **primary objective** was to assess the knowledge about Pharmacovigilance and A.D.R. reporting and attitude, practices and perceptions of health care professionals towards Pharmacovigilance.

The **secondary objective** was to evaluate and understand the causes of under-reporting and to focus on possible ways by which ADR reporting can be improved.

2. Material and Methods

- **Study Setting:** This study was conducted at Dr. HSJ Institute of Dental Sciences and Hospital, Chandigarh
- **Study Population:** Health care professionals including BDS, MDS, MBBS, MD and nursing professionals only.
- **Study Design**: This was an observational questionnaire-based study. KAP questionnaire was designed to assess the demographic details of the health care professionals, their knowledge of pharmacovigilance and their attitude towards pharmacovigilance, and their practice on ADR reporting.
- **Study Instrument:** The study instrument was a predesigned questionnaire which was generated from the literature and adapted from previous similar studies. It was validated and designed to assess the awareness, knowledge and practice of Pharmacovigilance among the study population. The questionnaire consists of questions related to the knowledge and information on pharmacovigilance, attitude of the professionals and perception regarding the ADR reporting.
- **Sample Size:** 82
- **Study Period:** 6 months
- **Study Criteria:**

Inclusion Criteria

- Healthcare Professionals including MBBS, MD, BDS and MDS doctors
- The post graduate students pursuing their M.D.S.
- The interns and the Final year students pursuing B.D.S.
- The nursing staff.

Exclusion Criteria

- The professionals on leave were not a part of study.
- The professionals who did not agree to fill the questionnaire.

Sources of Data

The study was conducted in a teaching hospital in North India. The study participants were given a questionnaire which was filled on site. The questionnaire comprised of 35 questions testing the knowledge, attitude and practice about the Adverse Drug Reporting and Pharmacovigilance. A total number of 82 subjects agreed to be a part of study and handed back the answer filled questionnaire.

Study Procedure

The data collection for the study was done between the months of December 2015 to January 2016.Questionnaires were distributed amongst the individuals who agreed be a part of the study. Informed consent was taken from all the participants of the study before taking the information. Twenty minutes were given to mark the answers. The questionnaire was filled in front of the investigator. The data collection was done on site and after 20 minutes the filled in forms were collected from the subjects.

The questionnaire comprised of three sections:

1) Knowledge among the health care professionals on ADR and Pharmacovigilance.
2) Attitude among the health care professionals on Pharmacovigilance.
3) Practice among the health care professionals on Pharmacovigilance.

Knowledge among the health care professionals on ADR and Pharmacovigilance

The questionnaire consisted of 35 questions out of which 21 were based on evaluating the knowledge of the healthcare professionals on the adverse drug reactions and Pharmacovigilance. These included the following questions: 1, 3, 5, 12, 13, 15, 16, 17, 19, 20, 24, 26, 27, 28, 29, 30, 31, 32, 33, 34, and 35. Overall, this section evaluated the basic knowledge about pharmacovigilance and ADR reporting of the HCPs included in the study in the study.

Attitude among the health care professionals on Pharmacovigilance

Attitude and the perspective of the HCPs is equally important as the knowledge about ADR and Pharmacovigilance. To determine what attitude and mind set is present amongst the HCPs, 9 out of 35 questions of the survey evaluated their attitudes and perspectives towards ADR reporting. Questions 2, 4, 6, 7, 14, 21, 22, 23 and 25 formed this section of the questionnaire which included information on the opinions of the HCP on teaching of ADR reporting, establishing ADR reporting centers, need for reporting, and discouragement from reporting and legal and confidential issues.

Practice among the health care professionals on Pharmacovigilance

This section included the information on the practice of ADR reporting and pharmacovigilance amongst the HCP. There were 5 out of 35 questions focusing on this arena, question number 8, 9, 10, 11 and 18. They took account of the training and reporting practices and also the experience of ADR form and ADR in clinical setup and practice.

Questionnaire

1) Are you aware of the term Pharmacovigilance?
2) Do you think ADR reporting is professional obligation to you?
3) The healthcare professional responsible for reporting ADRs in a hospital is/are?
4) Do you think reporting of adverse drug reaction is necessary?
5) Where is the International Centre for Adverse Drug Reaction Monitoring located?
6) Do you think Pharmacovigilance should be taught in detail to healthcare professionals?
7) What is your opinion about establishing ADR monitoring centre in every hospital?
8) Have you ever experienced adverse drug reactions in your patients during your professional practice?
9) Have you ever reported ADR to the Pharmacovigilance centre?
10) Have you ever seen ADR reporting form?
11) Have you ever been trained on how to report Adverse Drug Reaction (ADR)?
12) A serious adverse event in India should be reported to the regulatory body within?
13) Is there any pharmacovigilance committee in your institute?
14) Which factors discourage you from reporting the ADRs?
15) Which of the following defines serious adverse event?
16) Elements which are mandatory to record?
17) Is ADR synonymous to adverse event?
18) Is ADR reporting form available when you are at the job of prescribing medicines to the patients?
19) ADR should be reported only when they are: serious and life threatening, severe and cause disability, mild and causes less inconvenience, all of the above, none.
20) Non-medical people can report ADR to a nearby medical person Yes/No, if yes, by what means of communication?
21) Do you think the ADR reporting and monitoring system would benefit the patient?
22) Do you think confidentiality should be maintained while ADR reporting?
23) Do you worry about legal problems while you think of ADR reporting?
24) Is there any nearby ADR Reporting and Monitoring Centre in your knowledge?
25) Do you envisage role of information technology in facilitating ADR reporting in the country?
26) Pharmacovigilance is the study that relates to: safe, effective and economic use of medicine, detection, assessment, understanding and prevention of adverse effects, all.
27) What are the functions of pharmacovigilance?
28) What does pharmacovigilance include?
29) AIIMS New Delhi is a: peripheral, zonal or regional pharmacovigilance centre.
30) ADRs which are dose-independent can be treated: by withdrawing the drug, by reducing the dose, by replacing the drug, none of the above.
31) What is an augmented drug reaction?

32) What is the name of the "WHO online database" for reporting ADRs?
33) One of the following factors is a major risk factor for the occurrences of ADRs: arthiritis, renal failure, vacuities, none.
34) Who is the chairman of pharmacovigilance programme in India?
35) Match the following: a. thalidomide, b. paracetamol, c. streptomycin, d. phenytoin with 1. Hearing Loss 2. Phocomelia 3. Gum Hypertrophy 4. Liver Toxicity.

Data Analysis

Once the filled in questionnaires were gathered from all 82 participants, the information was checked for completeness and consistency. The data analysis of the KAP questionnaires was carried out using SPSS software.

Ethical consideration

Informed consent was taken and confidentiality was maintained throughout so as to get honest information form the doctors.

3. Results& Discussion

There is a rise in the morbidity and mortality of patients and one major cause accounting for this is the Adverse Drug Reactions. They have resulted in rise in unnecessary expenditures in health care system and hospital admissions. Therefore, the reporting of ADR is accounted as a major part of the patient care. [6] The innumerable social and economic burdens of the adverse drug reactions cultivate a need for the active involvement of the health care professionals in pharmacovigilance program. The aims of this program are the early detection and identification of adverse drug reactions followed by monitoring their frequencies and identification of risk factors and dissemination of important information relating to the improvement in the drugs and their prescription. [2]

Thus, the most important goal remains the reporting of the ADR. Various studies have been carried out in different countries reporting the involvement of the medical and dental professionals as well as pharmacists and nurses in the reporting of adverse drug reactions [13-16] and have established under reporting as a common faulty phenomenon. The other contributing factors which have been highlighted are lack of time, lack of remuneration, unawareness, lack of trained staff, inability to identify the adverse reactions and lack of awareness about communication, detection and monitoring of ADRs. [17-19]

Information regarding the ADR changes on a constant rate and updating the knowledge of the healthcare professionals in this arena is needed. ADR reporting should be understood as a part of patient care [15].

To the best of our knowledge this was the first study conducted in the UT to evaluate the knowledge, attitude, perception and practice of Pharmacovigilance among the health care professionals in a teaching hospital. The response rate was within the accepted range for the survey research. To ensure that there was a maximal response and minimum bias the questionnaire was administered personally to the participants and were also collected personally by hand from the respondents. The below mentioned results were deduced from the study.

Knowledge among the Healthcare Professionals on ADR and Pharmacovigilance

In this study 96.3% of HCP were aware of the term pharmacovigilance. While in a study conducted in Ethiopia only 19.5% were aware of the term pharmacovigilance [3]

Amongst the respondents of this study 80.4% of them believed that the ADR reporting is a responsibility of all including the doctors, nurses and the pharmacists. As low as 15 HCPs believed that it was to be reported by doctors only in comparison to 1 person who thought it to be the responsibility of the Pharmacist.

While in a study by Gupta P. et al., 61% thought that only medically qualified doctors were responsible for ADR reporting [28].

The varied opinion amongst the health care professionals about the international center for ADR monitoring was also collected, reflecting their inadequate knowledge in this arena. In a study conducted amongst pharmacist in India, 81% knew that Sweden was the international center [13] while only 39% of the HCPs in this study knew that Sweden was the International center for adverse drug reaction monitoring. While in another study in South India by Gupta S.K., Nayak R.P., et al., only 41.6% knew the location of the international center [16].

When asked about the reporting timeline of a serious adverse event in India to the regulatory body, only 8.54% respondents answered it correctly. This reflected the poor knowledge on the reporting timelines of ADR. In a study conducted in a tertiary care screening hospital by Datta S. and Sengupta S., 5% knew the correct timelines [12] 75.6% of HCPs in our study knew the incidences included in a serious adverse event. Only 9 respondents did not consider Death as a serious adverse event. In study conducted in Nigeria by Fadare J.O., Enwere O.O. et al., 42% of the practitioners knew about serious adverse event [4].

When asked about the awareness of a Pharmacovigilance committee in their institute 86.5% were aware of its existence while 5 of the respondents did not know about it. Forty-seven (69.1%) participants were aware of the existence of Pv.P.I, while 55 (80.9%) doctors were aware of the AMC in the institute as per a study conducted in India by Khan S.A. et al. [26] In our study 85.3% of the respondents identified all the 4 essential elements to be recorded in ADR form correctly.

In a study conducted among the pharmacists off Saudi Arabia, 88 % of them saw ADR reporting as essential and took complains by the patients seriously [29] There was a mixed data obtained when asked about the synonymy of the term ADR to AE. Where 28% believed that they were not synonymous there was a 30% of participants which considered both the terms similar. 79.27% of the respondents replied that ADR should be reported in all situations even if they are serious and life threatening, severe and cause disability or Mild and cause less convenience.

Only 1.2% of respondents replied that ADR should not be reported in any of the asked situations. All of them agreed that a non-medical person can report an ADR, where 17.0%, 3.6% and 8.4% respondents replied that it can be reported orally, via telephone or E-mail respectively, while 70.3% of them believed that it can be reported via all the 3 means. In a study conducted in Rajasthan by Saurabh M.K. and Karnani R.K., 50% respondents added that ADR can be reported via a telephone [7].

69.5% of the HCPs were aware of an existing ADR Centre near them.In a study conducted by Kharkar M. and Bowalekar S. only 47.5 % professionals knew about the ADR monitoring centers [24]. In our study it was found that only 23.17% of the population had the knowledge of the term pharmacovigilance and what it related to while there were 4.8% people who related it to therapeutic drug monitoring and 10.98% related it to safe, effective, appropriate and economic use of the medicines. 50 respondents considered all the 3 options correct. In a study by Rajesh R. et al. 66% of respondents knew the definition of pharmacovigilance and 61% considered its main function was to deal with safety of drugs [6].

69 of the 82 respondents considered detection and study of adverse drug reactions (ADRs), measurement of risk and effectiveness of drug use and dissemination of ADR information and education as the functions of Pharmacovigilance. 51.2% of people knew that pharmacovigilance includes all the drug related problems, herbal products, medical devices and vaccines while 45.1% believed that it deals only with drug related problems. Also vaccines and antibiotics were considered as reportable by 67% and 54% participants, respectively. Ten (6.5%) participants correctly identified all the listed reportable therapeutic options in a study conducted by Gupta P. et al. [28].

48.7% of professionals that knew AIIMS was a Zonal pharmacovigilance center. In a study conducted in Gujarat, 49.50% professionals had knowledge about the zonal centers and Pharmacovigilance centers [25].

Only 45.1% of the professionals were aware of the term augmented drug reactions while the rest of 45 professionals answered the question wrongly. Similarly, only 12.2% of the professionals were aware about the treatment of dose independent reactions. 6.1% answered that it can be treated by reducing the dose which reflects their poor knowledge on the basic pharmacology of adverse events. In a study among the pharmacy students of South India by Reddy V.L., Pasha S.K.J., et al., 64.8% knew that independent ADR can be treated by drug withdrawal and 57% knew about augmented drug reactions [13].

In another study in Pakistan, 58.5% of the HCPs knew about the types of ADRs [6]. When asked about the major risk factor for adverse drug reaction 67.07% of health care professionals in this study answered renal failure as the major cause, 10.9% as arthritis, 15.8% as vasculitis, 6.1% as visual impairment. In another question which judges the ADR knowledge of these professionals, a majority 81.7% were able to match the drug to correct ADR while only 15 of the 82 professionals could not provide the right answer for this question. These questions reflected the basic knowledge amongst the professionals of the adverse reactions that is taught at the undergraduate level. 32.9% of the HCPs knew that Vigibase is the WHO online database. 53.6% knew that DCGI was the chairman of Pv.P.I.

In a study conducted by Reddy V.L. et al. 24% knew that DCGI was the chairman of Pv.P.I [13] while in another study conducted in Central India, 78.2% professionals knew about the regulatory body responsible for ADR monitoring [8].

Attitude among the Healthcare Professionals on Pharmacovigilance

When asked if reporting was an obligation to them or was necessary, 69.5% believed that it was an obligation to them as a part of their profession and 96.3% responded that adverse drug reaction reporting was necessary. In a study conducted by Upadhyaya H.B. et al, 94% HCPs agreed that it was necessary to report the ADRs and 88 % considered ADR monitoring as mandatory [25]

92.68% of the respondents in this study agreed that Pharmacovigilance should be taught to them and added to their teaching modules. In a study by Saurabh M.K. et al. 48% thought that it should be taught in classes [7].

When asked about their opinion on establishing an ADR monitoring center in very hospital, 78.05% respondents in this study believed that it should be there in every hospital. 51.1 % believed it should be in every hospital as described in a study Reddy et al. [13].

The reasons for discouragement for lack of reporting of ADR varied. 18.29% responded that no remuneration was a cause for lack of reporting while 17.07% believed that it was the lack of time. A single unreported case may not affect the ADR database was the ideology of 6.1% respondents while the rest 25.61% considered it difficult to what qualified as an ADR and what not. 32.93% people thought that all the factors were responsible for lack of reporting.

The reasons for under-reporting of ADRs have been summarized by Inman et al. [23] as the “seven deadly sins” including financial incentives, legal aspects, complacency, diffidence which is belief that reporting should be done when there is certainty that the reaction is caused by the use of a particular drug, indifference that accounts the belief that a single report would make no difference, ignorance that only serious ADRs are to be reported and lethargy. In another study by Iffat W. et al. [6] 33% responded that they had sufficient time to fill the ADR form while 48% considered it as an added burden.

90.24% HCPs agree that ADR reporting and monitoring would benefit the health care system while only 1.22% said that it won’t. 93% professionals in a study in Gujarat believed that it would affect the patient safety [25].

When asked about confidentiality, 78.05% believed that patient confidentiality should be maintained. A major problem seen as a factor adding for lack of reporting is legal

issues and 36.59% respondents worried about the legal problems during ADR reporting. There was also an equal no of HCPs, 37.8% who did not believe it to be a major issue. 21 of the 82 responders were not sure if it was a big problem or not. The study also collects the opinion of the professionals on the role of information technology in ADR reporting and 75.61% acknowledged this role. Only 8.54% of people did not envisage the role of information technology on ADR reporting.

Practice among the Healthcare Professionals on Pharmacovigilance

41.46% had experienced an ADR during their practice and also the same percent of professionals have reported the ADR to the pharmacovigilance center. 56.1% has never experienced an ADR in their patients during practice and 54.8% had never reported an ADR to a pharmacovigilance center. 3.66% of the respondents did not know how to fill the ADR form in this study.

87.9 % of professionals had reported an ADR to an ADR monitoring center as per the data collected by a study in medical practitioners in India [24]. Ninety-eight percent of surgical and medical specialists had ever diagnosed an ADR in one of their patients and 71.9% of surgical specialists and 81.1% of medical specialists had ever diagnosed an ADR, which they had not reported to the national reporting centers or pharmaceutical industry as reported in a study by Elan I. A., et al. [27].

When asked about seeing an ADR reporting form, 86.9% participants in this study had seen it, 1.2% were not informed about the form, 6.1% did not know about seeing an ADR reporting form and rest 6.1% had never seen the ADR reporting form. In a study by Fadare J.O., et al., 85% of the professionals had seen an ADR [4].

In this study52.4% were trained for ADR reporting while 46.3%were not trained. Also 56.1% said that ADR reporting form was available at their job site in comparison to 25.6% of HCPs who responded that the ADR reporting form was available at their work place in a study by Angamo N.T., et al. [3]

ADR reporting is the fundamental responsibility of the healthcare worker and should be opted for as such. Based on the above findings it is imperative that immediate action is required to improve the ADR reporting. The following corrective measures should be taken for this [14, 19-22, 24]

- Increase awareness about pharmacovigilance by adding it to the curriculum at undergraduate level.
- Informing the doctors about the risks of the newly marketed drugs.
- Informing the doctors and patients that drugs are responsible for ADR and the prescribers and the reporter cannot be held responsible for this.
- Holding discussion forums of doctors and promoting ADR so that ADR reporting is considered as a duty towards the society.

4. Strengths and Limitations

Strengths

The major strength of the study was the involvement of Healthcare professionals from various specializations of medicine and dental sciences. The participants were experienced and well informed and exposed to variety of patients. This type of study was first to be conducted in that institute. The questionnaire was well designed and contained all relevant questions on knowledge, attitude and practice of ADR reporting. Confidentiality was maintained to ensure unbiased answers from the participants.

Limitations

The study participants were less i.e. 82. The study findings cannot be generalized as it was conducted in only one teaching hospital.

5. Conclusion

Pharmacovigilance contributes to safety and serves as an indicator of the standards of clinical practice in a country. The healthcare professionals of a country can make efficient use of the positive and negative impacts of treatments and involve in improved understanding of diseases and of medicines. From our study it may be concluded that there was a fair knowledge about Pharmacovigilance amongst the healthcare professionals of a teaching hospital in North India. Though there is a great scope of improvement. It included the uncertainty about the drug causing the ADR and difficulty in assessing the ADR forms. Also lack of remuneration, busy schedules, legal issues, lethargy, fear factors, inadequate training, indifferent attitude and lack of understanding of the importance of reporting ADRs were major factors of low reporting rate. There are gaps between knowledge and ADR reporting among HCPs.

It is very important to bring attitudinal changes in the professionals and integrate ADR reporting as a part of their patient care to bring forth the success of the Pv.P.I. With more knowledge comes immense responsibility to dissipate the knowledge in a fruitful manner. Active participation of the healthcare professionals in ADR reporting with situational awareness will lead to effective detection of adverse reactions in a large population which will definitely decrease the irrational use of drugs.

It is thus recommended that several such studies should be conducted among other institutes to develop strategies to improve the knowledge, attitude and practices amongst the healthcare professionals of adverse drug reaction reporting.

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