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Knowledge, attitude and practice on adverse drug reactions among healthcare professionals - A comparative study

*Nasr Khallafallah Nasr Elhidrbi[1], Mouaid Mohamed Eltayeb[1], Asavadi Divya[2], Uppara Veerendra[2], Mohanraj Rathinavelu[3]

[1]II Year Student, Masters of Pharmacy, [2]Pharm. D Intern, Doctor of Pharmacy and [3]Assistant Professor and In-Charge, Department of Pharmacy Practice, Raghavendra Institute of Pharmaceutical Education & Research, RIPER, Anantapuramu, Andhra Pradesh, India – 515721

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ABSTRACT

The world health organization (WHO) defines an ADR as any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological functions. It is a prospective comparative study between rural and urban practitioners with an aim to assess KAP about adverse drug reactions among health care professionals practicing in Anantapur and Bengaluru. KAP questionnaire regarding ADR reporting and adverse drug reactions was prepared and validated by experts. Despite of invitation around 113 community pharmacists were attended the educational programme and among that 58 community pharmacists. The comparison of mean score (1.89, 2.74) of pre and post intervention results shows that there was a significant difference on knowledge with a p value of <0.001. As a whole there was a significant difference between pre and post educational intervention mean score (9.82, 12.89) on KAP about Adverse drug reactions and their reporting system in India. Based on the results of this study, it is necessary to offer continuous ADR educational program until we reach the point that voluntary reporting of adverse drug reactions becomes conventional and habitual among the healthcare professionals.

Keywords: ADR reporting, India, Healthcare proessionals, Pharmacovigilance

INTRODUCTION

The safety of patients and the safe use of medicines are high requisitions in the modern world. Medication safety is a more significant issue, because of immense competition among pharmaceutical manufacturers; medicinal products may be registered and marketed in many countries simultaneously. As a result, adverse reactions may not always be readily identified and so are not monitored systematically. Pharmacovigilance is a systematic and structured process for the monitoring and detection of adverse drug reactions (ADRs) in a given context [1].Pharmacovigilance has constantly grown its importance in last 15 years, relating to the absolute amount of adverse drug reactions (ADRs) and to the fact of several hospital admissions are due to ADRs [2][3].

The world health organization (WHO) defines an ADR as "any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function" [4].Thus this definition excludes overdose (either accidental or intentional), drug abuse, and treatment failure and drug administration errors.

Pharmacovigilance is an arm of patient care and surveillance. It aims at getting the best outcome from treatment with medicine. Adverse drug reactions (ADRs) are common causes of morbidity and mortality in both hospital and community settings. Adverse drug reactions (ADRs) are global problems of major concern. They affect both children and adults with varying magnitudes; causing morbidity and mortality [5-6, 7-8]. ADRs are responsible for about 5% to 20% of hospital admissions [5, 6].

Studies from different settings indicate inadequate knowledge about pharmacovigilance among healthcare professionals as well as attitude that are

***Corresponding Author Address:** Mr. Nasr Khallafallah Nasr Elhidrbi, II Year Student, Masters of Pharmacy, Department of Pharmacy Practice, Raghavendra Institute of Pharmaceutical Education & Research, Anantapuramu, Andhra Pradesh., India – 515721, E-mail: moley4u@gmail.com*

associated with high degree of underreporting [9-14].Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this discipline. The Pharmacovigilance Programme of India (PvPI) like most others around the world suffers from underreporting of ADRs by the healthcare professionals; this can delay the detection of important ADRs. However, the Indian national Pharmacovigilance programme lacks continuity due to lack of awareness and inadequate training about drug safety monitoring among healthcare professionals in India [15]. The success of a pharmacovigilance program depends upon the involvement of the healthcare professionals and reporting the ADRs. Providing information on suspected ADRs is as much a moral duty for the doctor as other aspects of patient care [16].

Therefore, the aim and objective of this study was to evaluate the perceptions of and knowledge about Pharmacovigilance and ADR reporting among healthcare professionals practising in rural and urbanized settings of India.

MATERIAL & METHODS

Study design: Prospective – comparative study.

Study site: The study was conducted among various healthcare professionals, between Anantapuramu (healthcare resource limited) rural part of Andhra Pradesh state and Bengaluru an urban part of Karnataka state in south India.

Study duration 6 months.

Sample size: 130 Healthcare professionals.

Study criteria

Inclusion criteria: All the willing and practicing healthcare professionals at the core area (surrounding distance not more than 10 Kilometres) of Anantapuramu and Bengaluru were selected randomly and invited to participate in survey.

Exclusion criteria: Healthcare professionals those who are unwilling were excluded from the study. Health care professionals those who are not using drugs as part of their practice (eg. Physiotherapists, Occupational therapist) were also excluded.

Sources of data: The data's were collected by direct structured interview to the healthcare professionals.

Study protocol: KAP questionnaire regarding Adverse Drug Reactions and its Reporting system was prepared and validated by experts. The survey was done at Bathalapalli (Anantapuramu district), Chikkasandra (Bengaluru district) by visiting the professionals on their official place. The informed consent was obtained from all the study subjects recruited into the present study.

Overall 58 completed survey questionnaires were collected from Anantapuramu and 72 completed questionnaires were collected from Bengaluru and then they are evaluated. Furthermore the data was compared between rural (Anantapuramu) and urban (Bengaluru) part of south India.

Statistical analysis: Student't' test was used to analyse the significance between the two groups of rural and urban. Further Descriptive statistics were also used to explore the result

RESULTS

In our study, the total respondents were 130 healthcare professionals, 72 (55.38%) from urbanized settings of Bengaluru, Karnataka and 58 (44.62%) from rural settings of Anantapuramu, Andhra Pradesh. There were three different kinds of healthcare professionals participated in the present study which included physicians, nurses and pharmacists. In urbanized settings there were more number of nurses and female population was found to be high. Based on experience nurses (10) were more and least were pharmacists (4). Overall, the respondents in urbanized setting were found to consult minimum of 20 patients per day. The demographic detail of healthcare professional respondents in urbanized settings is shown in Table. 1 (Baseline data of healthcare professionals in Bengaluru).

In our rural study settings the respondents with more experience was found to be physicians (10) and were pharmacists (4). Overall, the respondents in rural setting were found to consult minimum of 10 patients per day. The demographic detail of healthcare professional respondents in rural settings is shown in Table. 2 (Baseline data of healthcare professionals in Anantapuramu).

There was a statistically significant association between years of experience and knowledge of pharmacovigilance. Here, the main reasons for poor reporting according to respondents were lack of knowledge about reporting format for ADRs and lack of incentives for ADR reporting. Meanwhile, 90% of the pharmacists believed that the role of the pharmacist in ADR reporting was essential.

Knowledge: Table 3 (Knowledge of healthcare professionals towards adverse drug reaction and its reporting system) shows the clear view about

knowledge of healthcare professionals about ADRs and their Reporting system in India. The questionnaire comprises of 4 questions which evaluate the knowledge, between the rural and urban areas of our study participants, aware that there is a national pharmacovigilance programme available in India for ADR monitoring, but still plenty of healthcare professionals believes that medicines are safe if the patients takes at right dose, right route and at right time.

Attitude: The results of attitude were depicted in Table 4 (Attitude of health care professionals towards adverse drug reaction and its reporting system), questionnaire comprises of 8 questions which evaluate the attitude, Most of the participants of Anantapuramu about 72.41% and 76.38% of urban areas though that adverse drug reaction reporting process is time consuming, but about 72.38% of rural area and 84.72% of urban areas think that ADR reporting and monitoring system would benefit the patient. In addition to that almost more than 86.20% of the rural area and 94.44% of urban areas believe that there is lack of time to actively look or an ADR while at work.

Practice: In this study the practice based questions were 6, among the study participants 17.24 % participants of rural and 30.55% of urban areas knowing how to report an ADR, The healthcare professionals who reported any suspected adverse drug reaction to any of the reporting and monitoring centres in urban areas was found to be 30.50% and in rural area was found to be 13.79 %. Among the healthcare professionals of rural area 8.62% and from urban areas 25.00 % who report any ADR to Company, and the data about practice were shown in Table 5 (Practice of health care professionals towards adverse drug reaction and its reporting system).

From the Table 6 (Over all comparison of mean score of KAP), we found significant difference on KAP between rural and urban practitioners with regards to ADRs and ADR reporting system. Therefore the total KAP in Anantapuramu area was recorded as 9.82(0.359) and Bengaluru area was taken as 12.89(0.325) and the net the p value was <0.0001is considered to be significant.

DISCUSSION

Our literature survey shows that ignorance (not feeling the need to report well recognized reaction), diffidence (concern that the ADR report may be wrong) and indifference (lack of time to fill in a report and a single unreported case may not affect ADR database) would significantly influence ADR-reporting among the doctors working in a Nigerian teaching hospital. However, not only the physicians from our study also the pharmacists and nurses believed that they have a key role in identifying and reporting of ADR[17]. From these findings, it can be ascertained that underreporting of ADRs is due to insufficient promotion of the Pharmacovigilance program by the competent authorities rather than the negative attitudes of the pharmacists themselves. The present study findings also revealed the same kind of concept that lack of publicity for pharmacovigilance program. A study reported that even an experienced professional could not be able to report an ADR due to lack of awareness our results are also in the same way [18].

The present study aimed to understand the awareness among health care professionals towards ADR reporting and to compare the differences between rural and urban practitioners regarding this context. The present study participants have poor knowledge on ADRs. However when compared to rural practitioners, urban practitioners was found to have high level of knowledge. Not only knowledge it also included good attitude and practice on ADRs. There was the similar study carried out among community pharmacies in Malaysia, where majority of the pharmacists were not aware of the pharmacovigilance system was already in place in Malaysia. The majority of the CPs had a positive attitude and behaviour towards their role in ADR reporting and the main reason given for this was that reporting of ADRs was seen as one of their core duties. The major barrier to ADR reporting was a lack of knowledge about ADR reporting processes [19].

From our study findings, it can be ascertained that underreporting of ADRs is due to insufficient publicity of the pharmacovigilance program by the competent authorities rather than the negative attitudes of the pharmacists themselves. The findings of the study showed the positive attitude of healthcare professionals towards the Pharmacovigilance system which is in agreement with previous studies carried out elsewhere [20].

Majority of the respondents in our study were unaware of the existence of adverse drug reactions (ADRs) reporting and monitoring system (National Pharmacovigilance programme) in India, which implies the need of rigorous interventional programs.

Limitations of the study: The main limitation of our study was the relatively small number of respondents. The general applicability of this study to whole country is somewhat limited because it was conducted in areas with a restriction to

surrounding 10 kilometres. However, this survey can serve as a preliminary study and is valuable in providing insights into perceptions of health care professionals on issues regarding adverse drug reactions.

CONCLUSION

In conclusion, the study indicates that the need for designing educational programs for health care professionals practicing in rural areas, in order to improve the level of knowledge towards the ADRs and its reporting system in India. Further it does not mean that the urban health care practitioners can be left out, they also needs to be offered. It is necessary to offer continuous ADR educational program all the health care professionals until we reach the point that voluntary reporting of adverse drug reactions becomes conventional and habitual.

Table 1: Baseline data of healthcare professionals in Bengaluru.

Healthcare professionals	Total number	Gender (n)	Age in years (n)	Experience (n)
Physicians	24	Males (15) Females (9)	25-34(7) 35-44(15) 45-54(2)	≥4years(8) ≥10years(10) ≥20years(6)
Nurses	28	Males (8) Females (20)	25-34 (15) 35-44(10) 45-54(3)	≥4years(8) ≥10years(16) ≥20years(4)
Pharmacists	20	Males (12) Females (8)	25-34 (8) 35-44(10) 45-54(2)	≥4years(5) ≥10years(13) ≥20years(2)

Table 2: Baseline data of healthcare professionals in Anantapuramu.

Healthcare professionals	Total number	Gender (n)	Age (n)	Experience (n)
Physicians	20	Males(14) Females(6)	5-34(6) 5-44(12) 5-54(2)	≥4years(5) ≥10years(12) ≥20years(3)
Nurses	25	Males(5) Females(20)	5-34 (14) 5-44(8) 5-54(3)	≥4years(10) ≥10years(12) ≥20years(3)
Pharmacists	13	Males(9) Females(4)	5-34 (7) 5-44(5) 5-54(1)	≥4years(7) ≥10years(4) ≥20years(2)

Table 3: Knowledge of healthcare professionals towards adverse drug reaction and its reporting system.

S.No	Questions	Frequency of correct answer (Anantapuramu) N (%)	Frequency of correct answer (Bengaluru) N (%)
1	Do you know what adverse drug reaction is?	38(65.51)	60(83.33)
2	Do you know the difference between adverse event and adverse effect?	27(46.55)	55(76.38)
3	Do you think all the medicines are safe when you dispense them even if the patients takes at right dose, right route and at right time?	40(68.96)	68(94.44)
4	Did you know the existence of adverse drug reactions (ADRs) reporting and monitoring system (National Pharmacovigilance programme) in India?	18(31.03)	33(45.83)

Table 4: Attitude of health care professionals towards adverse drug reaction and its reporting system.

S.No	Questions	Frequency of correct answer (Anantapuramu) N (%)	Frequency of correct answer (Bengaluru) N (%)
1	Do you think adverse drug reaction reporting process is time consuming?	42(72.41)	55(76.38)
2	Do you think community pharmacists have an essential role to play in ADR reporting	36(62.06)	50(69.44)
3	Do you think ADR reporting and monitoring system in your practice settings, is useful for your practice?	27(46.55)	48(66.66)
4	Do you think that ADR reporting and monitoring system would benefit the patient?	42(72.41)	61(84.72))
5	Community pharmacists are usually unwilling to report adverse drug reactions because of fear of crime	38(65.51)	57(79.16)
6	Do you think that there is lack of time to actively look or an ADR while at work?	50(86.20)	68(94.44)
7	Is pharmacist's assistance in detection, reporting and management of adverse drug reaction useful?	32(55.17)	58(80.55)
8	Will you able to report an ADR if the reporting forms will be distributed into the pharmacy?	28(48.27)	42(58.33)

Table 5: Practice of health care professionals towards adverse drug reaction and its reporting system.

S.No	Questions	Frequency of correct answer (Anantapuramu) N (%)	Frequency of correct answer (Bengaluru) N (%)
1	Do you know how to report ADR?	10(17.24)	22(30.55)
2	Do you know where to obtain the ADR forms	12(20.69)	28(38.88)
3	Have you ever observed a suspected adverse drug reaction?	25(43.10)	42(58.33)
4	Have you reported any suspected adverse drug reaction to any of the reporting and monitoring centres?	08(13.79)	22(30.50)
5	Do you think that your level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred?	22(37.73)	43(59.72)
6	Did you report any ADR to Company?	05(8.62)	18(25.00)

Table 6: Over all comparison of mean score of KAP

S. NO	Domain	Anantapuramu Mean (SEM)	Bengaluru Mean (SEM)
1	Knowledge *	1.89(0.122)	2.74(0.108)
2	Attitude *	4.74(0.223)	5.55(0.161)
3	Practice *	2.57(0.172)	3.43(0.157)
4	Total *	9.82(0.359)	12.89(0.325)

* Considered significant, p value <0.05 (Student t test).

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