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A KAP Study on Adverse Drug Reaction Reporting and Pharmacovigilance Programme of India Among General Population in Hyderabad

Are Varshini*[1], Deverakonda Sunidhi[2], Pininti Saahithi Reddy[3], Thavidaboina Sowmya[4], Oinam Jimmy Devi[5] and Tulasi Pasam[6]

[1,2,3,4]: 5th year PharmD, Sarojini Naidu Vanita Pharmacy Maha Vidyalaya
[5]Assistant professor, Department of Pharm. D, Sarojini Naidu Vanita Pharmacy Maha Vidyalaya.
[6]Research scholar, NIPER-Hyderabad.

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*Corresponding Author Email: varshini.aare@gmail.com

Abstract

Aim: The main objective of the study is to assess the knowledge, attitude, and practice (KAP) about pharmacovigilance among general population and to bring awareness on ADR reporting. **Methods:** A KAP cross-sectional survey study was conducted for a period of 6 months from November 2020 to April, 2021among general population in two levels- survey 1 and survey 2 by circulating Google form questionnaire in three languages- English, Hindi and Telugu and an information leaflet on the ADR reporting and Pharmacovigilance Programme of India, was included in survey 2 questionnaire. **Results:** A total of 120 responses in the 1st survey and 65 responses in 2nd survey were received. In survey 1, 34(28.3%) have experienced an adverse drug reaction and 104(86.66%) were willing to report if they have an easy option. 60(92.3%) thinks reporting ADR will benefit or improve the patient care. This study showed that 69.2% respondents who are participated in the first survey and 90.8% respondents who participated in the second survey have knowledge about an ADR and 47.5%of the respondents participated in the 1st survey and 76.9% in 2nd survey had good knowledge about ADR reporting and Pharmacovigilance Programme of India. **Conclusion:** In present study, it was observed that there is a need for increasing the awareness of the adverse drug reaction system among consumers and empowering them to report ADRs by them, which would ultimately improve the drug-safety environment.

Keywords
Adverse drug reaction, Adverse drug event, Pharmacovigilance, Pharmacovigilance program of India.

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INTRODUCTION:

A negative effect following the ingestion of a drug is referred to as an Adverse Drug Event (ADE) and is defined as 'any untoward medical occurrence that may present during treatment with a medicine, but which does not necessarily have a causal relationship

with the treatment [1]. The ADR is one of the major public health problems. The WHO defines the ADR as a response to a medicine which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function [2].

A serious adverse event (SAE) is defined as any untoward medical occurrence that at any dose which:

1. Results in death,
2. Life-threatening
3. Requires inpatient hospitalization or causes prolongation of existing hospitalization
4. Results in persistent or significant disability/incapacity,
5. May have caused a congenital anomaly/birth defect, or
6. Requires intervention to prevent permanent impairment or damage [3].

Detection and monitoring of ADRs plays an important role in patient safety, as more than 50% of approved drugs are associated with some type of adverse effects that are not detected prior to their approval for clinical use. The incidence of ADR in Indian population ranges between 1.8-25.1%, with 8% resulting in hospitalization. The poor and inadequate data is available on ADR though they are implicated as 7th common cause of death and up to 57% of ADRs are unrecognized by attending physicians [1].

Benefits of ADR reporting:

1. Providing an indirect measure of the quality of pharmaceutical care through identification of preventable ADRs and anticipatory surveillance for high-risk drugs or patients.
2. Complementing organizational risk-management activities and efforts to minimize liability.
3. Assessing the safety of drug therapies, especially recently approved drugs.
4. Measuring ADR incidence.
5. Educating HCPs and patients about drug effects and increasing their level of awareness regarding ADRs.
6. Providing quality-assurance screening findings for use in drug-use evaluation programs.
7. Measuring the economic impact of ADR prevention as manifested through reduced hospitalization, optimal and economical drug use, and minimized organizational liability [4].

Causality assessment:

It is a method used to estimate the strength of relationship between drug(s) exposure and occurrence of adverse reaction(s). The causal assessment objectives are based on four basic principles-temporal eligibility, dechallenge and outcome, rechallenge and outcome, and confounding factors [5].

WHO causality assessment and Naranjo algorithm are the most used scales for determining whether an ADR is actually due to the drug or due to the result of other factors [5]. The causality assessment will be performed by ADR Monitoring Centre (AMC) and the reports are reviewed at the National Coordination Centre (NCC).

On July 2010, the Government of India initiated the Pharmacovigilance Programme of India (PvPI) with AIIMS, New Delhi and NCC for monitoring ADRs in the country for safeguarding public health by assuring the safety of medicinal products [6].

Under-reporting of ADRs:

- Lack of knowledge on how, what, and where to report
- Lack of time
- The drug-reaction association is uncertain
- The reaction is already well known
- Guilt or fear of litigation
- Belief that all registered medicines are safe
- Non-availability of reporting forms
- Problems with establishing reporting systems in hospitals
- Insufficient training to recognize ADRs [7].

In addition to HCPs, consumers or patients also plays important role in Pharmacovigilance as they can speed up the process of ADR detection. It promotes better understanding of ADRs as the reports coming from patients are more direct, detailed, and clear than indirect reports from HCPs. It has the potential to add value to Pharmacovigilance by reporting types of drugs and reactions different from those reported by HCPs; generating new potential signals; and describing suspected ADRs in enough detail to provide useful information on likely causality and impact on patients' lives. Furthermore, it provides the patients an opportunity to learn how to manage their medications and communicate better with HCPs [8].

MATERIALS AND METHODS:

The cross-sectional study was conducted for a period of 6 months from November 2020 to April 2021.The study was approved by the ethical committee of Medicover Hospitals, Hitech city, Madhapur. The study was conducted among general population in two levels- survey 1 and survey 2 by circulating Google form questionnaire in three languages- English, Hindi and Telugu.

In survey 1, 27 basic questions were included regarding ADR reporting and Pharmacovigilance Program of India. The questionnaires are both open

ended and closed ended. First survey helped us to know whether the person participated in the survey was aware or not about ADR reporting and pharmacovigilance.

In survey 2, an information leaflet about ADR reporting and pharmacovigilance program of India was provided along with 24 open ended and closed ended questions. The information leaflet provided to the participants in the survey 2 was to bring awareness regarding ADR reporting and Pharmacovigilance Programme of India.

The data collected from the response feedback of the questionnaire survey were analyzed for the knowledge, attitude and practice about ADR and ADR reporting.

RESULTS AND DISCUSSION:

In our study, 120 responses were received in survey 1 and 65 responses in survey 2. Among 120 responses in survey 1, 90 (75%) respondents were female, and 30(25%) respondents were male, and 67.5% respondents were in the age group of 16 – 25 years. In survey 2, 35 (63.63%) responders were females, and 20 (36.36%) responders were males and 89.2% people were in the age group of 16 – 25 years whereas 29.5 year was the average mean age in the study conducted by Akram Ahmed [9].

As shown in Table 1, 69.2% people know the meaning of adverse drug reaction of a medicinal product. 28.3% people responded said that they have experienced an adverse drug reaction (side effect) for a drug whereas in the study conducted by Prerna Upadhyaya et al. out of 50% of the doctors observed an ADR but only 40% of them has been reported [10]. 68.3% people responded that they know that ADRs can be reported. And 10% people said that they have reported ADRs. 47.5% respondents were aware about the National Pharmacovigilance Program of India (PvPI) for reporting ADRs but only 25.84% were aware that they can report ADR directly and 20% knows about the apps for reporting an ADR.

Table No.1: Main closed ended questions asked in the Survey 1 along with responses

S.no.	Question	Responses	No. of responses	Percentage of responses
1.	Do you know what an adverse drug reaction (side effect) or unwanted, noxious effect of a medicinal product is?	Yes	83	69.2%
		No	23	19.2%
		Maybe	14	11.7%
2.	Have you ever experienced an adverse drug reaction (side effects) of a drug?	Yes	34	28.3%
		No	80	66.7%
		Maybe	6	5%
3.	Do you know that adverse drug reaction (ADR) can be reported?	Yes	82	68.3%
		No	29	24.2%
		Maybe	9	7.5%
4.	Have you ever reported any ADR?	Yes	12	10%
		No	106	88.3%
		Maybe	2	7.5%
5.	Do you know that in India there is a National Pharmacovigilance Program for reporting of adverse drug reactions with main goal of patient safety?	Yes	57	47.5%
		No	51	42.5%
		Maybe	12	10%
6.	Do you know that you can directly report ADRs?	Yes	31	25.84%
		No	86	73.30%
7.	Are you aware of apps which are used to report ADRs?	Yes	24	20%
		No	95	79.16%
8.	Are you aware of the term under-reporting?	Yes	67	55.84%
		No	47	39.16%

Figure No. 1: Graphical representation of the knowledge of survey 1 population on ADR reporting

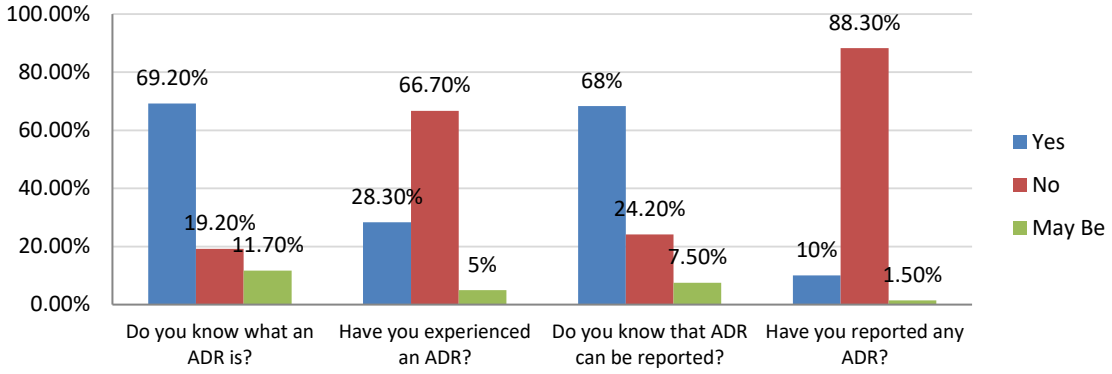

Figure No. 2: Graphical representation of the knowledge of survey population on national Pharmacovigilance Programme of India (PvPI).

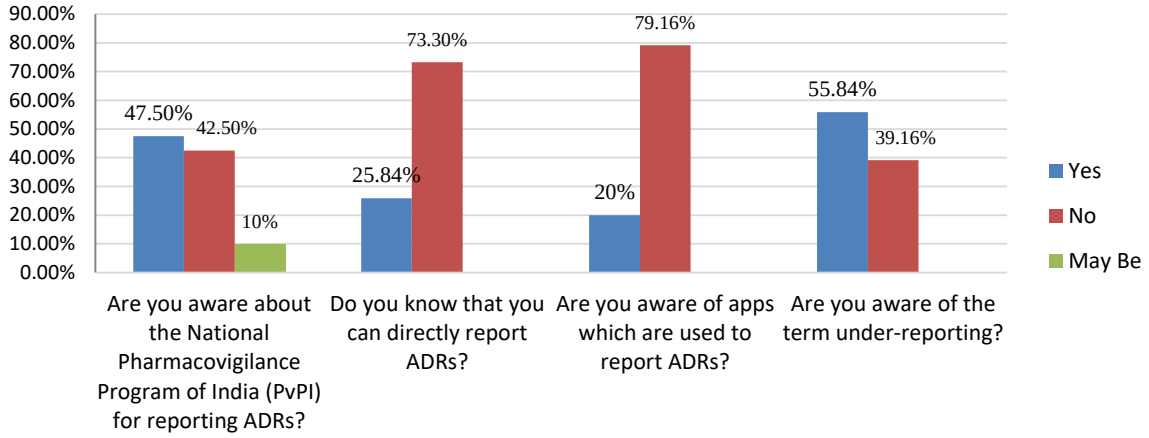

Table No. 2: Study participants of survey 1 responses on cause for under reporting.

S.no	Responses	No. of responses	Percentage of responses
1.	Opinion that only safe drugs are on the market	24	20%
2.	Lack of knowledge	69	57.5%
3.	Lack of time	9	7.5%
4.	Impossible to point out the suspected drug	4	3.34%
5.	Opinion that reporting does not influence treatment Scheme	14	11.7%
6.	Total	120	100%

Figure No. 3: Graphical representation of survey population views on causes of under reporting

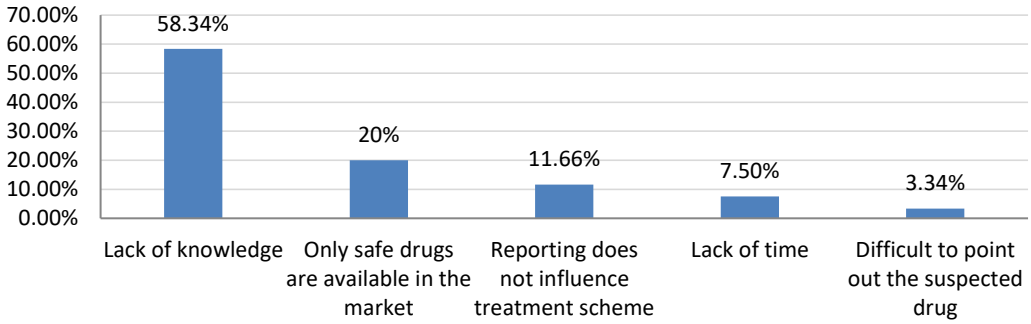

Table No. 3: Main closed ended questions asked in the survey 2 with the responses.

S. No.	Question	Response	No. of responses	Percentage of responses
1.	Do you know what an ADR is?	Yes	59	90.8%
		No	06	9.2%
		Maybe	0	0%
2.	"A serious adverse drug reaction means?"	A reaction that may lead to hospitalization	21	32.3%
		A reaction that is life-threatening	35	53.8%
		A reaction that requires another drug treatment	03	4.6%
		A reaction that resolves on its own	01	1.5%
		I do not know	05	7.7%
3.	Have you heard of Pharmacovigilance?	Yes	54	83.1%
		No	10	15.4%
		Maybe	01	1.5%
4.	Have you ever come across an ADR reporting form?	Yes	18	27.7%
		No	45	69.2%
		Maybe	02	3.1%
5.	If you experience any ADR, will you report it to the ADR monitoring center situated in nearby hospital?	Yes	54(83.1%)	83.1%
		No	03	4.6%
		Maybe	08	12.3%
6.	Do you think reporting ADR will benefit or improve the patient care?	Yes	60	92.3%
		No	02	3.1%
		Maybe	03	4.6%
7.	Do you think ADR reporting should be voluntary?	Yes	55	84.6%
		No	03	4.6%
		Maybe	07	10.8%
8.	Will you encourage pharmacovigilance?	Yes	58	89.2%
		No	01	1.5%
		Maybe	06	9.2%
9.	Will you share your knowledge regarding ADR and its Reporting System with others and make them aware?	Yes	58	89.2%
		No	01	1.5%
		Maybe	06	9.2%

Figure No. 4: Graphical representation of the knowledge of survey 2 population on ADR reporting and PvPI.

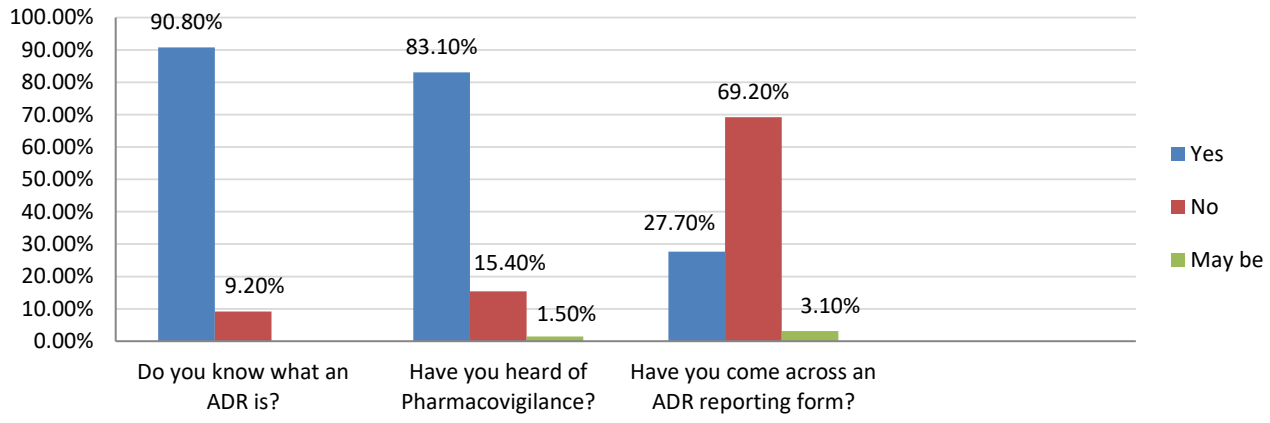

Figure No. 5: Graphical representation of the attitude of survey 2 population on ADR reporting.

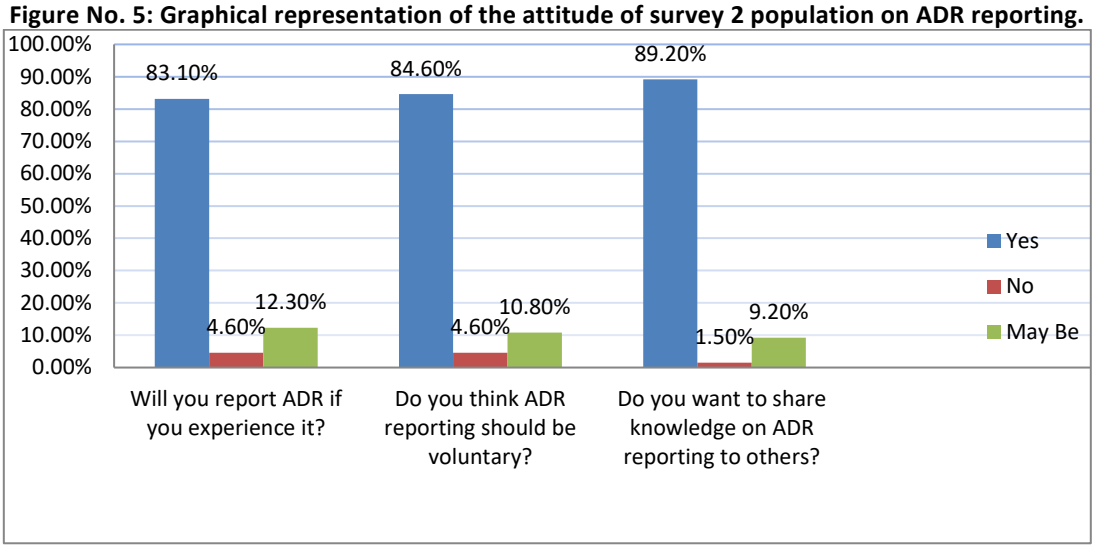

Figure No. 1 shows the knowledge of survey 1 population on ADR reporting, and it was found that more than half of the participants knows about an ADR, and it can be reported but very few of them have reported an ADR. Similarly figure no. 2 shows the knowledge of survey population on national Pharmacovigilance Programme of India (PvPI) and less than half of the participants knows about PvPI and 1/4th of the respondents knows that ADR can report an ADR directly through PvPI.

Table 2 shows the responses of survey 1 participants about their idea which causes under-reporting of ADR. The causes for under reporting according to the participants in the study conducted by Sandeep Kumar Gupta et al. were no remuneration (31.7%), lack of time to report ADR (23.8%), belief that a single unreported case may not affect ADR database (21.8%), and difficulty to decide whether ADR has occurred or not (22.8%) whereas according to our study population, lack of knowledge(57.5%), opinion that only safe drugs in the market (20%), opinion that reporting doesn't change anything (11.7%) are the main causes for under reporting [11].

As seen in the table no.3, 90.8% people participated in survey 2 knew about ADR. 32.3% responders believed that a serious adverse drug reaction may lead to hospitalization, 53.8% believed that serious adverse drug reaction will be life-threatening, 4.6% responders believed that a serious adverse drug reaction might be a reaction that requires another drug treatment and 1.5% responder believed that a serious adverse drug reaction may resolve on its own. 83.1% people in survey 2 have heard of Pharmacovigilance. 83.1% people said that they will report an ADR if experienced and 92.3% people believed that reporting ADR will help improving the patient care and 89.2% choose to encourage pharmacovigilance system. These findings were in similar to the finding of Akram Ahmed et al. where 95% of the population in the study believes that reporting ADR will improve patient safety [9].

In our study, 96.7%of 1st survey participants believe that reporting ADR is necessary and 87.7% people in 2nd survey believe that in each hospital there should be a ADR monitoring centre, which is higher when compared to response of the study conducted by Asmatanzeem Bepari et al. in which only 44.5% study population believes ADR reporting is necessary and 36% believe that every hospital needs a ADR monitoring centre and 87% of study population believes the same, in the study conducted by Upadhyaya et al. [12,13].

Figure no. 4 shows the knowledge of survey 2 population on ADR reporting and PvPI and majority of them knows about an ADR and pharmacovigilance. This can be due to the information leaflet that has been provided along with the questionnaire. Similarly, figure no. 5 shows the attitude of the participants on ADR reporting.

In our study, 69.2% and 90.8% of the responders in 1st and 2nd survey respectively knows the meaning of adverse drug reaction (ADR) whereas in a study conducted by Akram Ahmed et al. among Indian pharmacists, 95% of study population knows the meaning of ADR [9]. The difference can be because of the study conducted by Akram Ahmed was in Indian pharmacist as study population whereas in our study it's in general population irrespective of their occupation.

In our study, 47.5% participants in 1st survey and 76.9% participants in 2nd survey were aware of existing pharmacovigilance system in India when compared with a systemic study conducted by Akshaya Srikanth B et al. where only 55.6% population are aware of PvPI [14].

66.7% of 1st survey participants and 73.8% of 2nd survey participants believed that all types of ADRs should be reported whereas in the study conducted by Sonalia and Pimpalkhute, 83.33% of study population believes that only serious ADRs should be reported and 35.72% of study population believes that reactions to new products must be reported [15].

Providing the information leaflet about ADR reporting and Pharmacovigilance Programme of India in 2nd survey increased the knowledge about ADR reporting and better the attitude and practice of the respondents.

CONCLUSION:

ARDs are one of the most important factors which can causes morbidity as well as mortality. Besides these, even it can increase the length of hospitalization, number of drugs, burden on the patients both emotional as well as financially. Thus detecting, identifying, monitoring and management on time are very necessary steps and reporting of the ADR can help in doing the above steps by improving the knowledge of it and to help in rationalizing the drug use.

But for proper identification, monitoring and reporting of any ADR, the general population besides health care professionals should have knowledge of ADR and its reporting system. Thus, there is a requirement to create awareness and educating the people on ADR and its reporting, so that they can improve the Pharmacovigilance system of India and even to reduce the unnecessary exposure to certain medications.

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