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KNOWLEDGE, ATTITUDE & PRACTICES OF ADR REPORTING AMONG PRACTITIONERS OF INDIAN SYSTEM OF MEDICINE (AYURVEDA): A SURVEY IN ODISHA, INDIA.

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ABSTRACT

Objective: To assess the knowledge, attitude and practices (KAP) about Adverse drug reporting of ASU drug and pharmacovigilance among Ayurveda healthcare professionals working in state of Odisha, India. **Material and Methods**: A survey questionnaire for assessing the Knowledge, Attitude and the Practice (KAP) of Pharmacovigilance was designed and distributed among 110 Ayurvedic physicians working in different districts of state of Odisha. **Results:** Among the 110 doctors, 63 responded. Analysis of the data revealed that 53.96% of the subjects knew about the concept of 'pharmacovigilance', 46.03% were aware of the existence of the National Pharmacovigilance Program. 17.46 % have encountered any of the adverse events with ASU drugs but none has ever reported any ADR and none are familiar with standardized form for Reporting adverse drug reactions of ASU drugs. **Conclusion:** There is a need for a regular training and the re-enforcement for the ADR reporting among the health care personnel. The inappropriate perception regarding the reporting process, lack of time, a poor knowledge on the reporting mechanism and inadequate expertise seemed to be the main reasons for not reporting the ADRs. A majority of the respondents suggested regular training sessions on a priority basis

for the success of the pharmacovigilance program and for the better clinical management of the patients in general.

KEYWORDS: *Adverse Drug Reaction, Pharmacovigilance, Ayurveda.*

INTRODUCTION

Measures for enhancing patient safety are gaining more importance and priorities in current health care scenario. Objectivity of Pharmacovigilance (PV) is to reduce the risk of drug related adversities for the patient. In India the challenges & oppurtunities in this regard are many and worthy to study at this point of time.[1] Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects and all other problems related to medicines[2] Moreover it has a vital role in therapeutic decision-making, either for an individual or national or in global perspective.[3] The practices of PV also needs to be directed in right way to ensure the authenticity & of procedure & serving the purpose in rightly. National Pharmacovigilance Programme (NPP) was launched in India keeping in view of the increasing global concern regarding safety of Ayurvedic drugs.[4]

In this study we have an objective to assess the awareness about ADR, pharmacovigilance in Ayurveda, discuss various ways to make it operationally better among physicians and promote a culture for reporting regularly to the respective peripheral or higher centers.

METHODOLOGY

This cross-sectional survey was conducted during month of February-June 2012 and continued for one month. A list of 110 Ayurveda physicians working in state of Odisha was prepared by random sampling, all of them were contacted telephonically and Subject Information sheet & Informed Consent Form was sent them by post, out of which 91 participated. Each of them was asked to fill a structured questionnaire delivered by mail. A response rate of 69.23% was recorded during survey. The questionnaire consisted of doctor's demographic data, and a total of 13 questions that focused on assessment of knowledge regarding ADRs reporting and pharmacovigilance, physician's attitude and practice toward ADRs reporting process and their Recommendations and suggestion to improve the drawback in the system. Data obtained was analyzed using Excel 2007.

RESULTS & DISCUSSION

Table no. 01 Showing Age, gender, and level of professional education & of clinical posting wise distribution of survey participants (N=63)

Age group (in years)	Total number of Respondents (n)	Percentage
25-35 yrs	38	60.31
35-45 yrs	14	22.22
45 & above	11	17.46
Gender		
Male	42	66.66
Female	21	33.33
Level of Professional education		
Under-graduation	53	84.12
Post-graduation	07	11.11
PhD	03	04.76
Type of clinical posting		
Posted at AYUSH wing of PHC (N), PHC, CHC	54	85.71
Posted in Mobile health Units	05	07.93
Others (Pvt. Practitioners/Working in NGOs)	04	06.34

The observations from the demographic data of survey participants in the study are shown inTable No 01. It was observed that the majority of physicians were in age group (25-35yrs). Out of 63 doctors participating in the survey, 42 were males and 21 were females. In this study 85.71% of doctors were having clinical Postings at AYUSH wing PHC (N), CHC.Analysis of education level shows that most of the participation doctors were having qualification as under graduation.

Table No. 02 Assessing Knowledge Attitude &practices regarding ADR reporting (N=63)

Sl no	Question	Response	n	N (%)
1	Do you know about the concept of pharmacovigilance?	Yes	35	55.55
2	What is the definition of pharmacovigilance?	Correct answer	23	36.50
3	What do you mean by Adverse drug reaction?	Correct answer	26	41.26
4	Do you think reporting adverse drug reaction is necessary?	Yes	48	76.19
5	What is the importance of reporting an adverse drug reaction?			
	Necessary for the safety of patients	Yes	45	93.75[@]
	Identification of previously unrecognized ADRs	Yes	30	47.61[@]
	Identification of factors that might predispose to an ADR	Yes	28	58.33[@]

6	Are you aware of existence of National Pharmacovigilanceprogramme for ASU drugs in India?	Yes	29	46.03
7	Are you aware of existence of pharmacovigilancecentre for ASU drugs in Odisha?	Yes	17	26.98
8	Have you attended any CME or training programme about Pharmacovigilance of ASU drugs	No	60	95.23
9	Where is National Pharmacovigilance center for ASU drugs is situated in India	Correct response	12	19.04

[@] N= 48

It was observed that out of the 63 responding Doctors, only 36.5% defined 'pharmacovigilance' correctly while 41.26% defined ADR correctly. Only 4.77% had attended a CME or training programme or workshop about ADR reporting and Pharmacovigilance. Further it was noted that most of them did not know that national pharmacovigilance center for ASU drugs is situated at Gujrat Ayurveda University Jamnagar.

Table No. 03 Showing ADR experience & familiarity with the reporting process (N=63)

Sl no	Question	Response	n	N (%)
	Have you ever encountered any adverse event with ASU drugs	Yes	11	17.46
	Have you ever reported any ADR	No	63	100
	Are you familiar with standardized form for Reporting adverse drug reactions of ASU drugs?	No	63	100

Table No. 04 Recommendation and suggestion supported by participants for improving ADR reporting

Sl no	Question	Response (n)	%
1	What are your view/suggestions for improving ADR reporting of ASU drugs?		
	Training of AYUSH doctors through CME programmes/Workshops should be conducted at regular interval	55	87.30
	ADR reporting and Pharmacovigilance should be part of undergraduate and postgraduate teaching curriculum	42	66.66
	Details of reported ADR of ASU drugs should be regularly communicated to Practicing doctors through Regional pharmacovigilance center website or other suitable means	57	90.47
	Online educational module should be prepared by NPC for awareness of AYUSH doctors	31	49.20

It was observed that most of the participants were of the view that for improving ADR reporting IEC modules must be adopted on regular basis.

Ayurveda as a system of medicine has been practicing since thousands of years. Since then many changes & subsequent challenges in processing, manufacturing, distributing & practicing Ayurveda has been encountered. Prior to the industrialization era Ayurvedic medicines were prepared by the physician for their patients but in current times Ayurvedic drugs available in the market are either based on the classical references from the Samhita(classical text) or proprietary drugs consisting of different of herbal or herbomineral combination. The Drugs and Cosmetics Act, 1940 covers manufacture and marketing of these ayurvedic drugs.[5] Ayurvedic drugs mostly being herbal compositions are popularly believed to be safe, devoid of any adverse drug reaction but this can't be universalized now a days. Moreover the all the proprietary drugs (combining drugs without classical references & principles) has complicated the situation.

Possible causes of ADR may have cause in the defective manufacturing or if guidelines for administration of the drug was not followed properly either by physician or the patient. Classical texts of Ayurveda has described the concept of synergistic & antagonistic combinations *(virodhitwa)* of different substances. Thus combination of drugs, or processing & dosing etc have greater role to play for the desired therapeutic effect of a composition.[6] Thus the Physician has a vital role to play while prescribing a drug from wider range regarding the possible occurrence of ADR. As per the toxic profile of a drug it may have broad range of chances to affect many organs of different systems. Therefore the underestimation of ADR reporting needs to be taken more seriously & in a well coordinated way.[7]

ADRs are not only causing morbidity and mortality but also imposes considerable economic burden on the family, and nation as a whole. Although most commonly used drugs cause adverse effects, some of them with potentially serious consequences, relatively little is known about their economic impact. The cost of treatment of drug-induced adverse effects is an additional cost of pharmaceutical treatment.[8] Voluntary spontaneous reporting of ADRs by the health care professionals is the most important pillar of PV. Most of the data is expected to be generated at the peripheral level of health care system. But statistics all over world shows there is under reporting of ADR.[9-12]

The study carried out by Desai *et al* showed that while the right attitude for ADR reporting existed among most prescribers, the actual practice of ADR reporting was lacking. Indian studies at Mumbai, Mysore, and Muzzafarnagar have shown high knowledge, but poor

practice for ADR, among prescribers.[13] Pimpalkhute *et al* found in their study that although 64.28% of respondents were aware of pharmacovigilance, only 35.72% were aware about the process of ADR reporting and only 25% had ever reported an ADR to any of the ADR monitoring center. These results are quite similar to those reported from many other studies in India.[14]

In our survey it was revealed that 17.4 % of the (n=11) participants had encountered the adverse event with ASU drugs. But none has ever reported this due to the non-familiarity with the entire procedure & the standardized form (for Reporting adverse drug reactions of ASU drugs) being out of their reach.

Insignificant emphasis of PV in the undergraduate curricula also could also be a possible reason for underreporting. Other factors include-poor knowledge of the procedure for reporting and lack of awareness of the existence of forms for reportingADRs.[15] Repeated educational interventions like CME, regular information (digital, print) sharing had been shown to be useful to enhance level of awareness & rate of reporting ADR among the physicians.[16] Findings of *Figueiras et al* also supports the training programme for improving ADR reporting.[17]

Therefore regular training & communication is the need of hour to encourage the health care professionals for improvement of ADR reporting and achieve affordable health for all in global scenario.

CONCLUSION

Pharmacovigilance is a demanding science offering great opportunities for reducing harm to patients and costs to healthcare systems. From small beginnings, with the right knowledge and skills, pharmacovigilance can make an important contribution to the health of the nation. ADR reporting is an important aspect of post marketing surveillance. Most of the previous published studies shows ADR is often underreported which also is corroborated in current survey. It was observed that with the physicians were aware about importance of ADR reporting but they are less informed about the procedures of reporting. Majorities of the respondents were of opinion that CME training programmes will improve their knowledge & attitude regarding ADR reporting & Pharmacovigilance. Thus, Authors recommends for more sensitizing programs, public materials about ADR reporting should be made available to ISM doctors working at grass root health care system. This step will not only promote ADR

reporting but also will be helpful in reducing overall economic burden of health care cost, morbidity & mortality.

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