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RESEARCH ARTICLE

KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG PRESCRIBERS OF GOVERNMENT MEDICAL COLLEGE AND HOSPITAL, AURANGABAD (MAHARASHTRA)

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ABSTRACT

Gross underreporting of adverse drug reactions (ADR) is a cause for a concern. No medicinal product is entirely or absolutely safe for all people, in all places, at all times.Safety and efficacy are two major concerns about any drug.Though Pharmacovigilance programme was started in India in 1982, the awareness about it is much lower. Multispecialty faculties participated in the study. A questionnaire based evaluation was done. The faculties were explained the detail study procedure, and informed consent was taken. A fixed time was allotted for answering the objective and subjective type of questions. Showed that Overall KAP of Pharmacovigilance scores were low. Findings strongly suggest that there is a great need to create awareness and to promote the reporting of ADR amongst prescribers of GMCH (Government Medical College and Hospital) Aurangabad. One positive finding is healthcare professionals are having a very good positive attitude towards Pharmacovigilance.

Key words: KAP, Multispecialty hospital, Pharmacovigilance

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INTRODUCTION

The World Health Organisation defines an adverse drug reaction as a response to a drug which is noxious, unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.[1]

Pharmacovigilance is a science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problems.[2]

To undergo drug treatment you have to be very healthy because apart from your sickness, you have to withstand the medicine. No medicinal product is entirely or absolutely safe for all people, in all places, at all times. Safety and efficacy are two major concerns about any drug.Though Pharmacovigilance programme was started in India in 1982, the awareness about it is much lower.[3]

ADR (adverse drug reactions) accounts for 0.2 to24 % of hospital admissions, 3.7% of patients have fatal ADRs.[4] ADR leads to number of medical and economic consequences like prolong hospital stay, increase the cost of treatment and risk of death also increases. Hence, early detection and prevention of ADR is necessary.

Monitoring of adverse drug reactions is carried out by various methods, of which voluntary or spontaneous reporting is commonly practised. Because of variation in drug response, individual prescribing habits, drug regulatory systems, and availability of drugs etc., it has been recommended for every country to set up their own Pharmacovigilance programme.[5]

India became a collaborating member of WHO-ADR monitoring programme 30 years after its establishment. The pattern of drug use and ADRs in India is quite different due to socioeconomic, ethnic, nutritional and other factors. The Drug Controller General of India(DCGI) and Indian council of medical research (ICMR) have established ADR monitoring centres in many hospitals in major cities of India. Despite these efforts and presence of large number of tertiary care facilities Pharmacovigilance is still in its infancy. Gross underreporting of ADR is a cause for a concern, the reasons for which may be meagre funds, lack of trained staff and lack of awareness about detection, communication and spontaneous monitoring of ADRs.[4]

Considering the deep concern over the Pharmacovigilance prevailing amongst the prescribing doctors, the present study was done to know the KAP of Pharmacovigilance among prescribers of Government Medical College and Hospital, Aurangabad; a major referral centre for Marathwada, region in Maharashtra. The hospital renders multispecialty and superspeciality services.

Methodology:

- This was a cross sectional, observational, questionnaire based study.
- n=73 faculty doctors including Professors, Associate Professors, Assistant Professors and Resident doctors participated and completed the study.
- Study was approved by the Institutional Ethical Committee of Government Medical College, Aurangabad. Informed consent was obtained from all the study participants after explaining the procedure of the study.
- An inclusion criterion was faculties and resident doctor working in Government Medical College and Hospital, Aurangabad, who are ready to participate in the study.

Procedure:

- For the purpose of study KAP questionnaire was used.

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- Questionnaire was designed by all the faculties from the Department of Pharmacology of Government Medical College, Aurangabad.
- KAP questionnaire about Pharmacovigilance included twenty questions, out of these nine questions were for testing knowledge, five for attitude, six for practice, both open as well as close end questions were designed.
- All the participants were briefed about the nature and purpose of study before subjecting the questionnaire.
- All the questions were compulsory and prescribers were asked not to disclose their identity, 30 minutes time was given to all the participants, five marks were given for each question.
- Assessment was done by the head of the department to keep the marks obtained and results unbiased.

  Data analysis was analysed using MS Excel spread sheet and percentage of observations was noted.

Table: 1

KAP of Pharmacovigilance Questionnaire	
Q1	What is Pharmacovigilance?
Q2	What is the difference between Adverse drug reaction and Adverse drug event?
Q3	What is the difference between side effect and toxic effect?
Q4	Does ADR reporting have any specific format? Yes/No Explain
Q5	Where to report adverse drug reactions?
Q6	Have you reported ADR at any time? If yes then explain
Q7	P drug concept is related to A) Potent drug B) Promoted drug C) Personal drug D) Patented drug
Q8	Pharmacovigilance reporting centre for Maharashtra is. A) B.J. Medical college, Pune B) KEM Hospital, Mumbai C) Director of Medical Education & Research, Mumbai D) MGM, Mumbai
Q9	Do you follow guidelines of rational drug use? If yes explain
Q10	Is ADR reporting a need of today's clinical practice? Yes/No
Q11	Is ADR reporting a professional obligation? Yes/No
Q12	Are you willing to make ADR reporting? Yes/No

Q13	Do you keep records of ADR? Yes/No
Q14	Do you take proper medication history? Yes/No
Q15	Do you provide ADR information of prescribed drug? Yes/No
Q16	Are instructions about ADR reporting given to patient? Yes/No
Q17	Is there a need to include Pharmacovigilance in undergraduate curriculum to create awareness among the budding Doctors? Yes/No
Q18	What are OTC drugs?
Q19	Is there a need of formation of Drugs and Therapeutic Committee for each institute? Yes/No
Q20	What is the source of new drug information to you? A) Medical Representative B) Drug Index C) Colleagues D) Internet

Evaluation Parameters:

- Nine questions were regarding knowledge of pharmacovigilance.
- Five questions were about attitude towards pharmacovigilance
- Six questions were about practice of pharmacovigilance.

RESULTS:

Table: 2

Assessment of Questionnaire

Questions	**Attempted**	**% of candidates who attempted**	**Not Attempted**	**% of candidates who did not attempted**
Q1	30	41.09	43	58.91
Q2	14	19.17	59	80.83
Q3	46	63.01	27	36.99

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Q4	47	64.38	26	35.62
Q5	32	43.83	41	56.17
Q6	11	15.06	62	84.94
Q7	10	13.69	63	86.31
Q8	30	41.09	43	58.91
Q9	40	54.79	33	45.21
Q10	72	98.63	1	1.37
Q11	50	68.49	23	31.51
Q12	65	89.04	8	10.96
Q13	37	50.68	36	49.32
Q14	68	93.15	5	6.85
Q15	51	69.86	22	30.14
Q16	50	68.49	23	31.51
Q17	67	91.78	6	8.22
Q18	29	39.72	44	60.28
Q19	67	91.78	6	8.22
Q20	72	98.63	1	1.37

Question number 1, regarding Pharmacovigilance, showed only 31(41.09%) participants attempted the question, 43(58.91%) participants not attempted the question. Only one participant was able to write the answer correctly (1.37%).The mean score is 0.70.

Question number 2, difference between adverse drug reaction and adverse drug event showed, 14 (19.17%) participants attempted the question and 59(80.83%) not attempted. The mean score is 0.29.

Question number 3, difference between side effect and toxic effect elaborates that 46(63.01%) participants attempted the question and 27(36.99%) participants not attempted. 11(15.07%) participants attempted correctly. The mean score is 1.79.

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Question number 4, format of ADR reporting, 47(64.38%) participants attempted the question 26(35.62%) not attempted. only 2 (2.74%) participants have written correctly about format .The mean score is 1.27.

Question 5, the place where ADR is to be reported. 32 (43.83%) participants attempted correctly, 41(56.17%) not attempted the question. The mean score is 2.19.

Question 6, has any participant reported ADR any time, 11(15.06%) attempted the question, 62(84.94%) not attempted and 1 participant had written it correctly. The mean score is 0.30.

Question 7, P drug concept, 10(13.69%) participants attempted correctly, 63(86.13%) not attempted the question. The mean score is 0.68.

Question 8, Pharmacovigilance centres for Maharashtra state, 30(41.09%) participants attempted the question correctly, 43(58.91%) participants not attempted. The mean score is 2.05.

Question 9, guidelines for rational drug use, 40(54.79%) participants attempted the question, 33(45.21%) participants not attempted the question, 3(4.11%) participants have written correctly. The mean score is 1.11.

Question 10, ADR reporting need of today's clinical practice, 72(98.63%) participants attempted the question correctly, 1(1.37%) not attempted the question. The mean score is 4.93.

Question 11, ADR reporting whether it's a professional obligation, 50(68.49) attempted the question and said it's a professional obligation, 23(31.51%) participants not attempted.The mean score is 3.42.

Question 12, willingness of ADR reporting, 65(89.04%) participants attempted the question and written they are willing, 8(10.96%) participants not attempted the question .The mean score is 4.45.

Question 13, record keeping of ADR, 37(50.68%) participants attempted the question and said that they maintain records. 36(49.32%) participants not attempted the question .The mean score is 2.53.

Question14, medication history, 68 (93.15%) participants attempted the question and said that they take proper medication history. 5(6.85%) participants not attempted the question. The mean score is 4.66.

Question 15, information of ADR of a drug to the patient, 51(69.86%) participants attempted the question correctly and said, they provide information about drug ADR to the patients.22 (30.14%) participants not attempted the question. The mean score is 3.49.

Question 16, instruction about ADR given to patients, 50(68.49%) participants attempted the question correctly and written, they give instructions about ADR to patients, 23(31.51%) participants not attempted the question. The mean score is 3.42.

Question 17, need of inclusion of Pharmacovigilance in MBBS syllabus, 67(91.78%) participants attempted the question correctly and said that it should be included in the syllabus of II MBBS .Only 6(8.22%) participants not attempted the question. The mean score is 4.59.

Question 18, OTC drugs, 29(39.72%) participants attempted the question correctly. 44(60.28%) participants not attempted the question .The mean score is 1.73.

Question 19, need of drugs and therapeutic committee for each institute, 67(91.78%) participants attempted the question correctly and said that there is a need of therapeutic committee for each institute, 6(8.22%) participants not attempted the question. The mean score is 4.59.

Question 20, sources of drug information, 72(98.63%) participants attempted the question and only 6 participants answered correctly .The mean score is 1.59.

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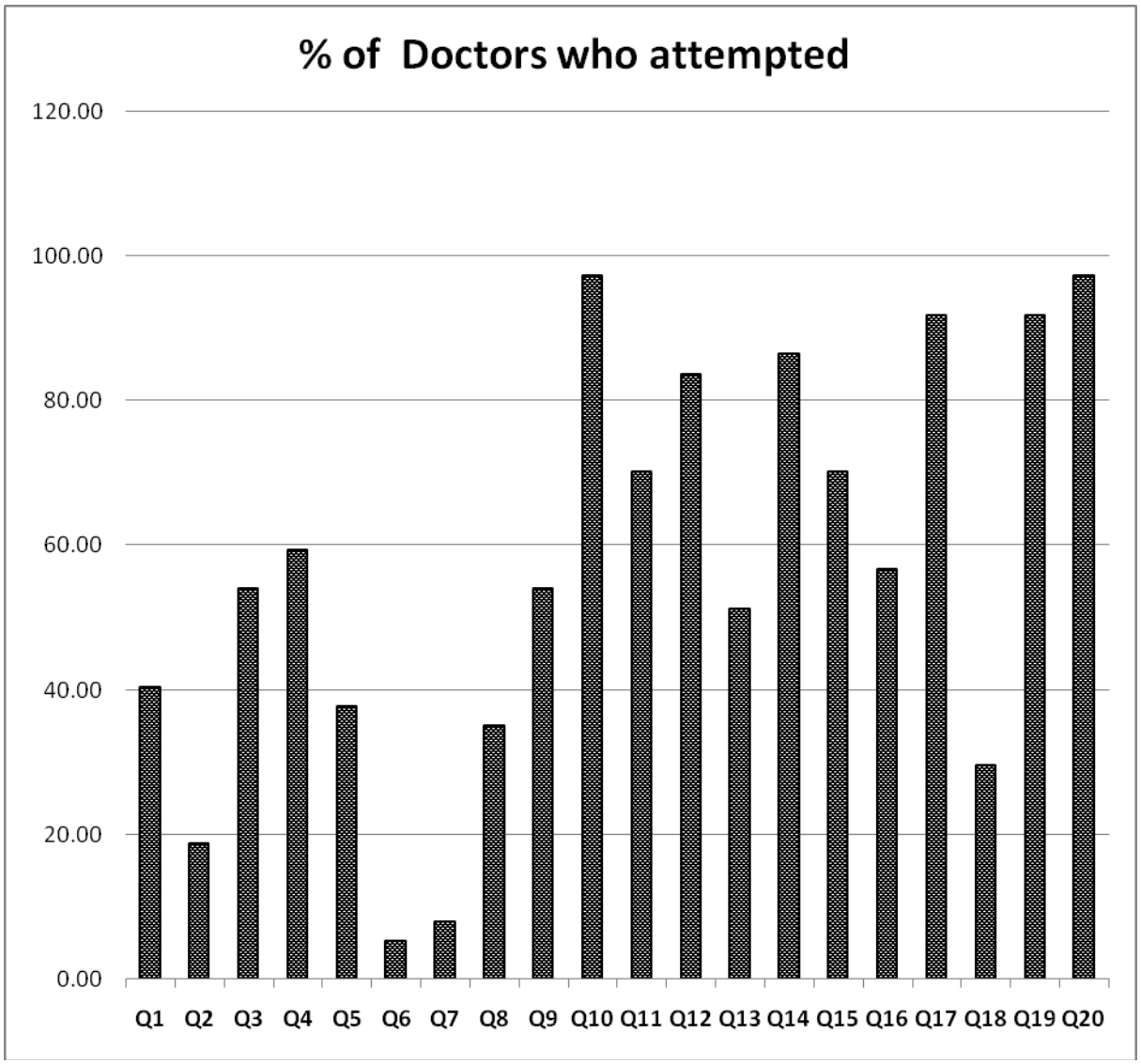
Graph: 1: Percentage of Doctors who attempted



DISCUSSION:

Pharmacovigilance is an integral and essential part of patient care. Healthcare systems rely mainly on the detection and reporting of the suspected ADR, to identify the new reactions, record the frequency with which they are reported, evaluate factors that may increase risk and provide information to prescribers, with a view to prevent future ADRs. With this view National Pharmacovigilance Programme has launched in India.[6]

The most important outcome of the Pharmacovigilance is the prevention of patients being affected unnecessarily by negative consequences of pharmacotherapy.[4] Pharmacovigilance programmes have played a major role in detection of ADRs and banning of several drugs from the market. However underreporting of ADRs is one of the major problems associated with Pharmacovigilance programmes. Even in countries like UK where Pharmacovigilance

programmes are well established, a high level of underreporting is documented.[7]

This is the first study in Marathwada region that evaluated KAP of doctors about Pharmacovigilance and ADRs in a tertiary care multispecialty and super speciality hospital. Overall scoring was low. A mean score for correct answers regarding knowledge of Pharmacovigilancewas 16.89 % that means an alarming situation needs immediate attention of Pharmacovigilance. Similar results were noted by Subish Palaian et al and suggested educational and awareness interventions for professionals.[7]On the contrary Sushma Muraraiah et al, found that the paediatric hospital has good knowledge about ADR reporting, but lack of facilities discourage them from reporting.[8]

Two participants explained about format of ADR reporting form. Thirty participants had knowledge about Pharmacovigilance reporting centres for Maharashtra, attempted correctly .From our study it become evident that all the participants have very less information about Pharmacovigilance and approaches of ADR reporting.Similar observations were noted by Mukeshkumar B Vora et al; they have suggested attention of this issue on priority basis.[10]

Conducting CME on Pharmacovigilance and giving training to prescribers about Pharmacovigilance seems to be an immediate necessity.The training programme should cover the location of Pharmacovigilance centres, reporting procedure and method of filling ADR reporting form. [7,9,10]

Also prevention is better than cure, knowledge of budding doctors in a tertiary care teaching hospital can be increased by including Pharmacovigilance topic in undergraduate curriculum and again adding training programme during internship and residency.

With regards to the practice of Pharmacovigilance, 56.71% participants correctly attempted. More than 50% participants are keeping records of ADR, they are giving instructions to the patients about ADR, they are taking proper medication history, and also they are giving information about ADR of prescribed drug to the patient, only they are not reporting ADRs to the Pharmacovigilance centres. Underreporting of ADRs is a worldwide phenomenon and this has been established from previous studies.[8]

The major reasons for underreporting of ADRs are lack of knowledge about the reporting procedure, unavailability of reporting centre mailing addresses, unavailability of ADR report form, lack of knowledge of the existence of a national ADR reporting system, the belief that ADR in question was already well known, ADR is not serious, uncertainty concerning the causal relationship between the ADR and drug, forgetting to report the ADR and lack of time, ignorance of reporting procedure. One of the better means of overcoming underreporting is to increase the KAP of healthcare professionals regarding ADR monitoring and Pharmacovigilance programmes.[7] The other methods can also be adopted to increase the reporting of ADRs like encouraging patients self-reporting, strengthening of monitoring centres, periodic hands on, training courses to health professionals including nurses and medical officers of PHCS and economic incentives to health professionals can also be considered.[6]

Observations regarding attitude of doctors towards Pharmacovigilance showed a mean score of more than 4, 98.63% participants felt ADR reporting is required in clinical practice, 68.49% doctors think that it's aprofessional obligation, 89.04%doctors are ready to report ADR, 91.78% doctors said that Pharmacovigilance programme should

be included in undergraduate curriculum. 91.78% said that there should be separate drugs and therapeutic committee for each institute as per WHO guidelines.

From our study, it has been noticed that maximum number of doctors are having positive attitude towards Pharmacovigilance programme which is a welcome sign towards National Pharmacovigilance programmes.

CONCLUSION:

Our finding strongly suggests that there is a great need to create awareness regarding Pharmacovigilance and to promote the reporting of ADR amongst prescribers. The educational interventions which can be undertaken are training programmes and CME periodically. The Medical Education department and health care providers for the state should implement various programmes for increasing awareness. Also incentives may be considered for reporting.

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