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ORIGINAL RESEARCH

Impact of educational intervention on sensitisation and ADR reporting among paramedics in a teaching hospital in north India

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ABSTRACT

Aim: Impact of educational intervention on sensitisation and ADR reporting among paramedics in a teaching hospital in north India.

Material and methods: This study was done at a tertiary care teaching hospital using a cross-sectional design and a questionnaire. The survey was carried out after obtaining clearance from the Institutional Ethics Committee. The participants consisted of 100 undergraduate paramedical students. The participants were provided with a comprehensive explanation of the study's nature and aim, and their informed permission was acquired. The students were informed about the voluntary nature of their participation in the research.

Results: A cohort of 100 paramedical students participated in a pre- and post-test questionnaire. The results were statistically significant in terms of the participants' awareness of the location of the PV center, showing an improvement of 83%. The majority of the students had an understanding of the significance of Pharmacovigilance (PV) and the process of Adverse Drug Reaction (ADR) reporting by physicians. Nevertheless, there was a substantial increase in the understanding of ADR reporting among dentists, nurses, and pharmacists ($P < 0.0001$). Prior to the educational intervention, the majority of students were knowledgeable of the need of reporting adverse drug reactions (ADR) with allopathic medications. However, they were unaware of the importance of reporting ADRs related to herbal and traditional medicine, blood products, and biological and paramedical devices. Following the intervention, there was a notable increase in the proportion of individuals who were aware of the need to report adverse drug reactions (ADR) for herbal and traditional medicine, blood products, and biological and paramedical devices. This improvement was statistically significant ($P < 0.001$). There was a substantial increase of 84% in knowledge of the procedure of reporting Adverse Drug Reactions (ADR) after attending a lecture. This improvement was statistically significant with a p-value of less than 0.001. Following the lecture, 72% of individuals said that ADR reporting should be considered a professional duty, in contrast to the 54% who held this view before to the intervention

Conclusion: The research indicates a clear need to enhance knowledge among paramedical students in order to increase the reporting of adverse drug reactions (ADRs). In conclusion, participating in educational initiatives such as ongoing paramedical education and seminars focused on raising awareness of PV would be beneficial in enhancing the state of ADR reporting.

Keywords: PV, ADR, Knowledge, Paramedical students

INTRODUCTION

The welfare and security of patients during drug administration is a significant concern for all healthcare professionals (HCPs). An adverse drug reaction (ADR) is a harmful and unanticipated response to a medicine that occurs at dosages typically used in humans for preventing, diagnosing, or treating diseases, or for altering normal bodily functions [1]. Pharmacovigilance (PV) is a systematic process for monitoring and detecting adverse drug reactions (ADR). It encompasses the scientific and operational tasks involved in discovering, assessing, comprehending, and preventing any negative effects or issues associated to drugs.

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For instance, the assessment of the pharmacovigilance (PV) of antineoplastic medicines is crucial to ensure the safety of individuals and to optimize the use of healthcare resources in a cost-effective manner. ADRs may have a significant impact on both clinical outcomes and cost considerations in clinical practice [3, 4]. ADR sometimes necessitates extra medical interventions during the management of ADRs, resulting in a financial burden that might be reduced by ADR reporting. The failure to accurately report adverse drug reactions (ADRs) limits and disrupts efforts to prevent or mitigate the negative impacts of medications [5]. Moreover, failing to inform and disclose adverse effects of a medication, even after personally encountering them, is morally unacceptable. This action may deliberately expose other patients or customers to the potential dangers associated with the same medications [6]. Rapid reporting of adverse drug reactions (ADRs) is a logical and perhaps the most effective method for monitoring medication safety [7]. The reporting of adverse drug reactions (ADRs) and pharmacovigilance (PV) have important consequences for public health, since they play a role in preventing future occurrences of similar ADRs, potentially saving lives and decreasing the cost impact.

The pharmacovigilance program in India was initiated in 2010 with the objective of protecting the health of the Indian people by ensuring that the advantages of taking medication are greater than the hazards associated with its usage.6 Despite diligent attempts, the documentation of severe adverse drug reactions (ADRs) seldom surpasses 10%. The significant level of underreporting might lead to a delay in identifying severe adverse drug reactions (ADRs) and can greatly harm public health. Therefore, the issue of underreporting continues to be a significant barrier to the full achievement of the pharmacovigilance program[8]. The higher rate of underreporting can be attributed to several factors, including a lack of awareness about adverse drug reaction (ADR) reporting, limited time availability, misconceptions about spontaneous reporting and bureaucratic procedures, inadequate information on reporting methods, a scarcity of report forms, and physicians' attitudes towards ADRs[9]. Regrettably, a significant proportion of doctors in India are unaware of The pharmacovigilance plan of India[10].

MATERIAL AND METHODS

This study was done at a tertiary care teaching hospital using a cross-sectional design and a questionnaire. The survey was carried out after obtaining clearance from the Institutional Ethics Committee. The participants consisted of 100 undergraduate paramedical students. The participants were provided with a comprehensive explanation of the study's nature and aim, and their informed permission was acquired. The students were informed about the voluntary nature of their participation in the research.

The research tool used was a self-created, prevalidated semi-structured questionnaire that included both open-ended and close-ended questions. Clear and concise directions for how to complete the questionnaire were provided. The acquired information includes demographic data and the knowledge, attitudes, and practices (KAP) related to adverse drug reaction (ADR) reporting. The questionnaire had 19 questions pertaining to photovoltaics (PV), with 8 questions assessing knowledge, 5 questions evaluating attitude, 4 questions gauging awareness, and 2 questions examining practice. The binary scale was used. Knowledge-, awareness-, and practice-related questions were awarded one point for accurate replies and zero points for bad ones. The participants were allotted a duration of 2 hours to finish the questionnaire. Following that, a three-hour lecture on photovoltaics (PV) was conducted. This educational intervention comprised a theoretical PowerPoint presentation on the definition and primary goals of pharmacovigilance (PV), the PV program in India, guidelines for reporting adverse drug reactions (ADRs) including the responsible parties and the Vigiflow database. The presentation also covered challenges in reporting ADRs, the classification and incidence of ADRs, different scales for assessing causality, and the role of healthcare professionals in reporting suspected ADRs. Finally, the intervention addressed the subsequent actions taken after an ADR is reported. Participants were instructed to complete an identical questionnaire after an educational intervention in the form of a lecture. The pre- and post-test questionnaires were compared.

Statistical Analysis: The data were presented in the form of numerical counts and corresponding percentages. The Chi-square test was used to statistically compare the data before and after the test, using SPSS version 25.0. A significance level of $P < 0.05$ was regarded to indicate statistical significance.

RESULTS

A cohort of 100 paramedical students participated in a pre- and post-test questionnaire. There were 52 male responses and 48 female respondents. The average age of the participants was 21.01 ± 2.22 years. The response rates between pre- and post-intervention showed significant improvement among the majority of paramedical students, indicating the usefulness of the intervention in enhancing the reporting system. There was a general improvement in all three domains, namely awareness, knowledge, and attitude. The results were statistically significant in terms of the participants' awareness of the location of the PV center, showing an improvement of 83%. The majority of the students had an understanding of the significance of Pharmacovigilance (PV) and the

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process of Adverse Drug Reaction (ADR) reporting by physicians. Nevertheless, there was a substantial increase in the understanding of ADR reporting among dentists, nurses, and pharmacists ($P < 0.0001$). Prior to the educational intervention, the majority of students were knowledgeable of the need of reporting adverse drug reactions (ADR) with allopathic medications. However, they were unaware of the importance of reporting ADRs related to herbal and traditional medicine, blood products, and biological and paramedical devices. Following the intervention, there was a notable increase in the proportion of individuals who were aware of the need to report adverse drug reactions (ADR) for herbal and traditional medicine, blood products, and biological and paramedical devices. This improvement was statistically significant ($P < 0.001$). Table 1. There was a substantial increase of 84% in knowledge of the procedure of reporting Adverse Drug Reactions (ADR) after attending a lecture. This improvement was statistically significant with a p-value of less than 0.001, as shown in Table 2. Following the lecture, 72% of individuals said that ADR reporting should be considered a professional duty, in contrast to the 54% who held this view before to the intervention (Table 3). The majority of students (79%) said that they are familiar with the Central Drug Standard Control Organization (CDSCO) Adverse Drug Reaction (ADR) reporting form and had personally seen an ADR. The respondents' overall attitude towards ADR reporting after the lecture might be summarized as follows: 35% believe that ADR reporting should be voluntary, 3% believe that it should be remunerated, 41% believe that the identity of the reporter should be hidden, 20% believe that the name of the prescriber should be disguised, and 69% believe that ADR reporting should be obligatory. The text refers to Table 4.

Table: 1Respondents knowledge about adverse drug reaction reporting

	Pre-test score		**Post-test score**		**P**
	Number	**Percentage**	**Number**	**Percentage**	
Who can report an ADR?					
Paramedical doctors	94	94	100	100	0.04
Dentist	50	50	100	100	0.001
Nurses	15	15	98	98	0.001
Pharmacist	48	48	97	97	0.001
Physiotherapist	44	44	94	94	0.001
All of the above	3	3	83	83	0.001
ADR with which of the following should be reported?					
Allopathic medicines	92	92	97	97	0.21
Herbal/traditional medicine	23	23	82	82	0.001
Blood products	30	30	81	81	0.001
Biological and paramedical devices	54	54	89	89	0.001
All of the above	8	8	68	68	0.001

Table: 2 Awareness about adverse drug reaction reporting practices

Questions	**Pretest score**		**Post-test score**		**P**
	Number	**Percentage**	**Number**	**Percentage**	
Aware of PV?	96	96	100	100	0.17
Aware of location of PV?	17	17	100	100	0.001
Aware of ADR monitoring and reporting centre in India?	40	40	98	98	0.001
Aware about the process of ADR reporting?	16	16	100	100	0.001
ADRs should be reported for newly marketed agents?	93	93	99	99	0.05
Observed any ADR in a patient?	16	16	77	77	0.001
Seen an ADR form from CDSCO?	3	3	79	79	0.001

ADRs=Adverse drug reactions, PV=Pharmacovigilance, CDSCO=Central drug standard control organization

Table: 3 Respondents' attitude regarding adverse drug reaction reporting

	Pretest score		**Post-test score**	
Factors encouraging reporting of ADR	**Number**	**Percentage**	**Number**	**Percentage**
Training/projects/CME/newspaper/social media	15	15	51	51

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Increase awareness among people and patients	14	14	31	31
Co-operation amongst various stake holders	1	1	11	11
Incentives	19	19	29	29
Easy process of reporting and easy availability of forms	29	29	33	33
Reporting ADR is a professional obligation	54	54	72	72
Paramedical students play a role in ADR reporting	91	91	96	96
ADR reporting benefit both doctor and patient	97	97	100	100

CME=Continuing paramedical education

Table: 4 Respondents' awareness about what should be applicable to adverse drug reaction reporting

What should be applicable to ADR reporting	Pretest score		Post-test score		P
Voluntary	21	21	35	35	0.04
Remunerated	2	2	3	3	0.21
Conceal identity of the prescriber	19	19	20	20	0.23
Conceal identity of the reporter	23	23	41	41	0.004
Compulsory	8	8	69	69	0.001

DISCUSSION

There is no drug that is completely devoid of risks. Ensuring the proper and secure use of medications is a significant obstacle for healthcare practitioners. Global studies have conclusively shown the impact of adverse drug reactions (ADRs). Adverse drug reactions (ADRs) are a significant contributor to death, illness, hospitalizations, and higher costs for the healthcare sector. Therefore, it is important to conduct safety surveillance of medications in order to enhance patient care. Pharmacovigilance has a potential function in this particular scenario. Pharmacovigilance in India has been more prominent after the implementation of the Pharmacovigilance Programme of India (PvPI)."

The majority of students in this research have prior knowledge on the definition of ADR prior to the intervention. Nevertheless, they were unaware of the precise location of the PV facility in India. Meher et al. conducted a research that revealed similar findings regarding the awareness of second-year students about the location of the PV center in India. While it is well recognized that medical professionals such as physicians and dentists have the ability to report adverse drug reactions (ADRs), this research found that there was little knowledge (15% for nurses and 48% for pharmacists) of their ability to do so prior to the training intervention. Following the lecture, there was a substantial increase in the proportion of individuals who were knowledgeable about who may report Adverse Drug Reactions (ADR) ($P < 0.001$). It is crucial to be aware of who may report an Adverse Drug Reaction (ADR), since the participation of paramedical personnel in the spontaneous reporting of ADRs is vital. This engagement will contribute to enhancing the reporting rates, as paramedical workers have more prolonged and frequent contact with patients compared to physicians. Several investigations have observed similar results [12,13]. Prior to the intervention, the majority of the respondents believed that adverse drug reaction (ADR) reporting should only be done for allopathic drugs, which aligns with the results published by Gupta and Udupa[12]. The respondents' perception was altered after the educational intervention. Healthcare professionals must be made aware that adverse drug reactions (ADRs) should be reported for drugs from all healthcare systems. This is crucial because many patients regularly use medicines from various healthcare systems, including Ayurvedic, Homeopathy, and Unani, and all of these medicines carry the risk of ADRs.

The majority of respondents expressed the belief that Adverse Drug Reactions (ADRs) should be notified for newly developed medications. This commonly held misperception must be acknowledged and appropriate actions should be made to correct it. Pharmacovigilance (PV) focuses specifically on adverse drug reactions (ADRs), which are harmful and unanticipated responses to drugs that occur at typical therapeutic levels used for preventing, diagnosing, or treating diseases, or for altering normal bodily functions[14]. Therefore, it is necessary to record adverse drug reactions (ADRs) for all medications. A further research conducted among resident physicians found that 93% of the doctors were more likely to report an adverse drug reaction (ADR) if it occurred with a newly introduced medication[12].

After the intervention, there was a substantial increase in the proportion ($P < 0.001$) of respondents who were aware with the procedure of ADR reporting and monitoring center in India. The majority of respondents expressed the view that enhancing awareness of adverse drug reaction (ADR) reporting can only be achieved via educational initiatives such as seminars and conferences. The level of awareness on this topic rose following the talk. A smaller

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proportion of respondents mentioned other factors, such as mandating ADR reporting, offering incentives for reporting, streamlining the reporting procedure, and enhancing patient knowledge. Following the presentation, 72% of the participants in this research agreed that ADR reporting is a professional obligation. A minority of participants (10%) said that enhancing collaboration among different stakeholders is a viable solution to address this issue. This approach is very commendable since Adverse Drug Reaction (ADR) reporting necessitates collaboration across several disciplines for effective teamwork. After the intervention, 69% of the participants recommended that ADR reporting should be mandatory. This may undoubtedly enhance the rates of reporting. It is noteworthy that the majority of students are cognizant of the fact that paramedical students have a significant role in reporting adverse drug reactions (ADRs), and that ADR reporting is advantageous for both physicians and patients. Upon evaluating the procedure, it was discovered that none of the participants had previously documented an adverse drug reaction (ADR). CDSCO presented the ADR reporting form to the students during the presentation. The aforementioned data indicate that a lack of understanding of the reporting system is one of the factors contributing to under-reporting. This finding is consistent with previous research [15,16]. When questioned about the requirements for ADR reporting, the majority of students expressed the view that it should be mandatory in order to enhance the ADR reporting rate. There was a substantial increase in the percentage after the intervention, with a statistically significant difference ($P<0.001$). A smaller proportion of respondents mentioned other factors, such as implementing incentives for reporting, ensuring anonymity of the reporter and prescriber, and determining the appropriate criteria for ADR reporting, in order to enhance the rate of ADR reporting. Furthermore, an additional research that has been published has proposed the use of monetary rewards as a means to improve the reporting of adverse drug reactions (ADRs)[17]. This strategy is inadequate for addressing the problem, since it raises the risk of over reporting in order to get financial rewards[18]. The feedback from students in our research group about ADR monitoring indicated that educational intervention has enhanced their understanding and proficiency in reporting ADR.

CONCLUSION

The research indicates a clear need to enhance knowledge among paramedical students in order to increase the reporting of adverse drug reactions (ADRs). It is necessary to include the topic of ADRs (adverse drug reactions) in the clinical pharmacology and therapeutics curriculum for undergraduate paramedical education. This will help to raise awareness among paramedical students about this significant problem. In conclusion, participating in educational initiatives such as ongoing paramedical education and seminars focused on raising awareness of PV would be beneficial in enhancing the state of ADR reporting.

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