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"EVALUATION OF EFFECTIVENESS OF CME PROGRAMME ON KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AND ADR REPORTING AMONG THE NURSING PROFESSIONALS IN A TERTIARY CARE TEACHING HOSPITAL IN EASTERN INDIA"

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ABSTRACT

Background: Due to paucity of evidence on awareness of Pharmacovigilance and adverse drug reaction (ADR) reporting among nurses from India, we decided to undertake this research to fill this vacuum. **Objectives:** Our primary objective was to assess their knowledge, attitude and practice about Pharmacovigilance & ADR and secondary aim was to uplift their potential for providing safe patient care through a continuing medical education (CME) programme (held on 26.2.2015). **Methodology:** We conducted a cross sectional questionnaire based study involving the nursing professionals working in MGMMC & LSK Hospital, Kishanganj. The numbers of correct responses before and after CME were compared by proportional z-test ($P< 0.05$). **Results:** From 65 nurses 16.92% have heard the term Pharmacovigilance, 1.54% nurses had little knowledge about Pharmacovigilance but none were aware about National

Pharmacovigilance programme of India. 30.77% knew full form of ADR, 64.62% reported that they get information on ADRs from internet. Not a single participant had seen or filled up ADR form. In attitude we saw that lectures on Pharmacovigilance and ADR were not included in their curriculum. In practice 30.77% participants have ever experienced an ADR but no one reported formally. They have no free access to ADR form. While evaluating CME effectiveness, we noticed that there were significant improvements in all three areas. **Conclusion:** Though time was a constraint to this study, yet it was one of our genuine initiatives towards implementation of Pharmacovigilance activities for the first time in this population.

KEYWORDS: CME, Pharmacovigilance awareness, ADR reporting Training.

INTRODUCTION

In recent years Pharmacovigilance (PV) has gained much importance in India and worldwide to bring about a pause on erratic prescribing behaviour of physicians, polypharmacy, extensive and sometimes wrong drug promotions by drug manufacturing companies.[1] To update the knowledge on PV & Adverse Drug Reaction (ADR)-reporting several programmes like seminars, conferences and continuing medical education programmes (CMEs) are being arranged in different corners of our country, medical institutions, corporate hospitals and in pharmaceutical industries.

We know that Pharmacovigilance, as defined by the WHO, is "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems, particularly long-term and short-term side-effects of medicines, biomedical products (e.g. Vaccines), herbal drugs, traditional medicines".[2]

Whereas ADR, as defined by the WHO, is "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or modification of physiological function".[2][3] Approximately (0.2-24)% of hospital admissions are due to adverse drug reactions [4] and the documented cases accounts to nearly 6-10%.[5] It is only the tip of the iceberg. The actual number of cases with adverse drug reaction is practically huge than what we observe in healthcare documentation because of underreporting.

So, it is evident that the knowledge of Pharmacovigilance and the system of ADR reporting are very limited till date among the doctors, nursing personnel and pharmacists in our country. To carry out the Pharmacovigilance programme (PVP) in full fledged form in any institution the co-ordination between pharmacologists, clinical doctors, nursing personnel is essential.

Education is, 'the weapon' to fight against unawareness and consequent wrong practices provided, it is being dispersed in a methodical and interesting way to the population in need for the betterment of the society at large. The present CME was organised in an attempt to spread knowledge about PV and ADR-reporting at the grass root level in our institution. Our intention was to acquaint and motivate the nursing professionals to be involved proactively in PVP.

As there are few evidences of such type of educational programme on nursing professionals and practically nil from the state of Bihar and also quite a little data are available on awareness on knowledge, attitude and practice of PV and ADR reporting among nurses from our country; we decided to take an initiative to fill this vacuum through this research.

MATERIALS AND METHODS

This cross sectional questionnaire based study was conducted in a tertiary care teaching hospital with a bed strength of 666. In February 26th 2015 a CME was organised successfully by the department of pharmacology involving the nursing professionals (study population = 200) working in MGM Medical College & LSK Hospital, Kishanganj (Bihar); to assess their knowledge about PV & ADR and to aware them about Pharmacovigilance program and its importance.

Of the 200 nursing staffs only 65 nursing personnel attended and completed the CME till the end. Our study was designed to address especially the nursing professionals who are believed to be the first and foremost healthcare providers coming in contact to the patients directly on a day to day basis.

Our primary objective was to assess their existing knowledge, attitude and practice about PV & ADR and the secondary objective was to increase their potential for providing better patient care and safety through this educational intervention programme.

The questionnaire

A single set of pretested predesigned self responding questionnaire, containing Section-A(Table 1) & Section-B (Table 2), were given to all the participants who attended. They were asked to fill up both the section-A and the pre-CME part of section-B prior to the CME sessions and the post-CME part of section-B was to be answered once the CME was over. Participants were requested to submit the dully filled set of questionnaire after the sessions prior leaving our seminar hall.

Both the sections were designed in knowledge, attitude and practice (KAP) format using previous literatures as reference and modulated to match the requirements of our study population. The questions were designed in such a way that (section-A) the numbers 1 to 7, 8 to 9, and 10 to 12 represented the existing knowledge, attitude and practice respectively of the study population. In the same set the section-B was specifically designed to assess the impact and effectiveness of the CME on the same population. Again in section-B the numbers 13 to 21, 22 to 25, and 26 to 29 represented the knowledge, attitude and practice respectively in two halves (pre and post CME).

Content of the CME

This was a one day program of 4 hours duration. We obtained approval from institution authority and the ethics committee for conducting the CME as well as to perform the questionnaire based survey. Total 65 nursing personnel attended the CME. The whole programme was conducted through a three power-point presentation format. It was conducted by the personnel representing the PV committee of the institute, professor and senior residents of the department of Pharmacology. The contents of the three presentations were an overview of PV, ADR, and how to fill up the ADR reporting form respectively.

In the first two presentations the theoretical aspects of PV & ADR were explained both in authentic and easy understandable ways. The last talk was all about how to fill up the ADR forms taking the (Central Drugs Standard Control Organization) CDSCO-ADR format as reference with special emphasis giving to the areas where utmost responsibility lies on the nursing professionals. Throughout the entire session we were open to suggestions and criticism. As a motivational tool we kept the provision for ‘participation certificates’ authorised by the academic section of the institution for those who attended till the end of the programme and returned the questionnaire provided to them.

Statistical Analysis

A statistical analysis was required to understand the effectiveness of the CME session. To compare the knowledge, attitude and practice (KAP) format before and after the CME we performed proportional z-test. We preferred to perform proportional z-test so that we can get the exact proportion of nursing personnel who were exposed to KAP of Pharmacovigilance. Here we have employed two sample (large sample) proportional z-test for all the questions in the section-B (question no.13 to 29). We considered left tailed test in all the correct feedback options (option which goes in favour of good change due to CME) except few((Q 17,18,19 &25), where we have performed two tailed z-test. Here, P1 and P2 be the proportions of the sample before and after the CME respectively. We were interested to test whether the P2 in the after CME sessions had been improved from the P1 or not.

H0 : P1 = P2

Vs, H1 : P1 < P2

The test statistic $z = \dfrac{(P1- P2)}{S.E\ (P1-P2)} \sim N(0,1)$

As the alternative hypothesis is less than type, the critical region at 5% level of significance is $z \leq -1.645$. To take a conclusion based on z value we have considered probability value of z, i.e P values have been verified with 95% confidence level.

RESULTS

Section–A, (Table:1) knowledge part showed that only 11(16.92%) have heard the term Pharmacovigilance, 3(4.62%) did not reply and rest have never even heard the term at all. Out of all only one nursing personnel (1.54%) had a bit of knowledge about PV like incidence of drug reaction in hospitals are monitored through Pharmacovigilance process, there is a specific form for reporting ADR, etc. None of them were aware about National PVP of India whereas only 20(30.77%) knew that ADR stands for adverse drug reaction. Though they had an idea that drug reactions do happen but they did not have any formal education on the topic previously. Majority 42(64.62%) reported that generally they get information regarding the ADR's of new drugs from internet. No one had ever seen or filled up an ADR form.

In the attitude part we observed that lectures on PV and ADR were not included in their curriculum. In practice 20(30.77%) nursing personnel out of 65 participants have ever experienced an ADR but none of them have reported any ADR formally nor do they have free access to ADR form.

(Table: 1) Section- A: Response on knowledge, attitude and practice of PV and ADR

Question numbers	Questions	Positive Response in Number (%)	Negative Response in Number (%)	No Response Number (%)
Knowledge of nursing professionals				
1	Have you ever heard the term PV?	11(16.92)	51(78.46)	3(4.62)
2	Do you have any basic knowledge about PV?	01(1.54)	64(98.46)	0
3	Are you aware about National PVP of India?	0	65(100)	0
4	Do you know the term ADR?	20(30.77)	45(69.23)	0
5	Source from which you generally get information regarding the ADR's of new drugs Textbooks Journals Seminar / Conferences Internet	 0 0 14(21.54) 42(64.62)	Not Applicable	Not Applicable
6	Do you have any idea that ADR reporting has a specific format?	01(1.54)	64(98.46)	0
7	Do you know how to fill up the form?	0	64(98.46)	01(1.54)
Total		65(100)		
Attitude of nursing professionals				
8	Have you ever been taught about PV during your training period?	0	51(78.46)	14(21.54)
9	Have you ever been taught about ADR reporting previously?	0	47(72.31)	18(27.69)
Total		65(100)		
Practice of nursing professionals				
10	Have you ever seen any case of ADR?	20(30.77)	45(69.23)	0
11	Have you ever reported any ADR?	0	61(93.85)	4(6.15)
12	Do you have free access to ADR Forms?	0	65(100)	0
Total		65(100)		

In the section-B, (Table-2) we tried to evaluate the effectiveness of CME on their current knowledge, attitude and practice of PV and ADR. In the knowledge part we noticed that 23(35.38%) could state the full form of ADR and the number increased to 64(98.46%) after the CME. Interestingly we discovered that in section-A 20(30.77%) persons said that they have heard the term. This diversity in result could be due to plagiarism. In questions number 13 to 21 the results revealed that nursing professional got a significant (p-value < 0.5) improvement in their knowledge in comparison to their pre-CME status. Similarly following the CME, attitude based questions (Q 22 to Q 25) depicted a picture like most of the participants responded in favour of inclusion of PV training in their curriculum (67.69% Vs 93.85%,p <0.5), 98.46% said that knowledge of ADR reporting are necessary (Vs 53.85%, p <0.05) and 90.77% (Vs 32.31%, p <0.05) felt that incorporation of ADR reporting in teaching curriculum will improve reporting in practice. On the contrary only 29.23% supported compulsory ADR reporting on job though it was again a significant value as the pre CME value was zero.

While evaluating impact on practice of PV we saw that 96.92% found the process of filling of ADR reporting form was easy in comparison to 1.54% before the CME(p <0.05), all of them came to know what should they do if they practically come across a case of ADR (Vs only 36.92% before CME, p <0.05), 90.77% chose ADR reporting form as the mode of reporting if they face any ADR (Vs 16.92% before CME, p <0.05), and 87.69% nursing personnel expressed that this program carried an importance in their day-to-day practice (Vs 4.61, p <0.5).

(Table-2) Section- B: Assessment of impact of CME on knowledge, attitude and practice of PV and ADR (level of significance at P <0.05)

Q N	Questions	Response in Number (%) before CME	Response in Number (%) after CME	Nature of Hypothesis	Z-score	P-value	Significance
KNOWLEDGE							
Q 13.	Full form of ADR is i. Acute drug reaction ii. Advanced drug reporting iii. Adverse drug reaction iv. None of the above	 41(63.08) 01(1.54) 23(35.38) 0	 01(1.54) 0 64(98.46) 0	Ho : P1 = P2 H1 : P1 < P2	-6.72238	< 0.00001	significant
Q 14.	ADR reporting should be done when a drug is given in i.Less than therapeutic dose ii.Therapeutic dose iii.Over dose iv.Any dose	 0 09(13.85) 0 56(86.15	 0 65(100) 0 0	Ho : P1 = P2 H1 : P1 < P2	-8.83487	< 0.00001	significant
Q 15.	Which ADR's should be reported i. All serious ADR's ii. ADR's to new drugs iii. New ADR to old drug iv. Vaccine related ADRs v. ADR's from herbal products vi. All ADR's	 63(96.92) 0 0 0 0 02(3.08)	 0 0 0 0 0 65 (100)	Ho : P1 = P2 H1 : P1 < P2	-8.29461	< 0.00001	significant
Q 16.	Commonest case of ADR reported is i.Hepatotoxicity ii.Nephrotoxicity iii.Skin manifestation iv.Fever	 02(3.08) 01(1.54) 43(66.15) 19(29.23)	 0 0 65(100) 0	Ho : P1 = P2 H1 : P1 < P2	-5.8278	< 0.00001	significant

Q 17.	Which drug is banned due to ADR's i. Nimesulide ii.Thalidomide iii.Pioglitazone iv.Rofecoxib	59(90.77) 06(9.23) 0 0	01(1.54) 14(21.54) 03(4.61) 47(72.30)	Ho : P = 0.5 H1 : P ≠ 0.5	4.019198902	0.0000584	significant
Q 18.	ADRs are predictable OR non-predictable? i.predictable ii.non-predictable iii.both iv.not known	0 54(83.08) 0 11(16.92)	0 04(6.15) 61(93.85) 0	Ho : P = 0.5 H1 : P ≠ 0.5	14.71	<0.00001	significant
Q 19.	Serious adverse Event should be reported to the Regulatory body within- i.01 day ii.07 calender days iii.14 calender days iv.15 calender days	0 54(83.08) 0 11(16.92)	03(4.61) 01(1.54) 61(93.85) 0	Ho : P = 0.5 H1 : P ≠ 0.5	14.71	<0.00001	significant
Q 20.	Which healthcare professionals are responsible for reporting ADR's in a Hospital i.Doctors ii.Pharmacists iii.Nurses iv.Dentists v.All	42(64.62) 0 16(24.62) 05(7.69) 02(3.08)	0 0 0 0 65 (100)	Ho : P1 = P2 H1 : P1 < P2	-4.7519.	0	significant
Q 21.	While filling up an ADR form which of the points is not mandatory to be filled up i.Points 1,5,7,8,11,15,16,18 ii.Points ,3,4,6,9,10,12,13,14,17 iii.Points 2,3,4,7,8,9,10,11,12,13 iv.Points 1,5,6,9,10,12,13,14,17	17(26.15) 13(20) 22(33.85) 13(20)	0 63(96.92) 01(1.54) 01(1.54)	Ho : P1 = P2 H1 : P1 < P2	-6.8476.	0	significant

ATTITUDE							
Q 22.	Do you think that teaching about PV should be included in nursing course curriculum? i.Yes ii.No iii.Not responded	44(67.69) 0 21(32.30)	61(93.85) 0 04(6.15)	Ho : P1 = P2 H1 : P1 < P2	-3.5109.	0.00022	significant
Q 23.	Whether knowledge about ADR reporting is necessary or not? i.Yes ii.No iii.Not responded	35(53.85) 19(29.23) 11(16.92)	64(98.46) 0 01(1.54)	Ho : P1 = P2 H1 : P1 < P2	-5.6092	0	significant
Q 24.	Do you feel that incorporation of ADR reporting in teaching curriculum will improve reporting in practice? i.Yes ii.No iii.Not responded	21(32.31) 39(60) 05(7.69)	59(90.77) 02(3.08) 04(6.15)	Ho : P1 = P2 H1 : P1 < P2	-5.3437.	0	significant
Q 25.	Should ADR reporting be made Compulsory in regular patient care? i. Yes ii. No iii.Not responded	0 60(92.31) 05(7.69)	19(29.23) 21(32.31) 25(38.46)		-3.6818	0.000116	significant
PRACTICE							
Q 26.	Filling up of ADR reporting form is difficult? i. Yes ii. No iii. Not responded	48(73.85) 01(1.54) 16(24.61	0 63(96.92) 02(3.08)	Ho : P1 = P2 H1 : P1 < P2	-4.5329	0	significant

Q 27.	If you come across any ADR what will you do? i. Counsel the patient about the drug and treat ii. Report the PV cell in the institution but no counselling of patient iii. Stop the suspected offending drug(s) immediately and change to another option as per doctor's advice, Counsel the patient about the ADR and report the PV cell in the institution iv. Continue with the same treatment as ADRs can happen during clinical practice	23(35.38) 18(27.69) 24(36.92) 0	0 0 65(100) 0	Ho : P1 = P2 H1 : P1 < P2	-7.0287	0	significant
Q 28.	If you encounter an ADR on duty which method would be best for you to report? i. Reporting form ii. Telephone iii. Email iv. Post v. Direct conversation	11(16.92) 47(72.30) 0 0 07(10.77)	59(90.77) 05(7.69) 0 0 01(1.54)	Ho : P1 = P2 H1 : P1 < P2	-5.5365	0	significant
Q 29.	Does this program has any importance in your day-to-day practice? i. Yes ii.No iii.No idea	03(4.61) 57(87.69) 05(7.69)	57(87.69) 01(1.54) 07(10.77)	Ho : P1 = P2 H1 : P1 < P2	-3.782	7.8E-05	significant

DISCUSSION

Considering the changing scenario in the healthcare system around the country, the healthcare providers are facing increasing demand from consumers' to provide an improved, cost effective and most importantly safe patients' service. Pharmacovigilance activity is one such effort which ensures the above demands of the patients.

In our study we first recorded the baseline knowledge-attitude-practice scenario of PV and ADR of nursing professionals and later on we tried to make them aware of the fact that how important their role is on this platform through an educational program and finally we evaluated and documented the actual impact of our effort.

Surprisingly, we have found a hundred percent response rate that means we received dully filled questionnaire from all 65 participants. A high response rate (93.3%) was also seen in a study done by Pimpalkhute SA et al.[5] whereas the rate was 64.04% in afroz abidi et al's [1] research and 61% in studies conducted by Hardeep et al.[2], Desai et al,[6] and Agarwal R et al.[7]

Our study revealed that the nursing professionals were poorly aware of PV activities and ADR reporting and similar finding was observed in a study done by Sencan N et al. in a 300 bedded American hospital.[8]

After successfully completion of the programme the level of answers to the same set of questions was significantly improved as compared to their previous status with respect to knowledge-attitude-practice. Studies have already established increased awareness about PV following educational intervention.[7][9] There was a significant (with p value<0.05) increase in the knowledge of both PV and ADR among the nursing staffs who successfully attended the entire CME and this observation is in alignment with the experience of Sencan N et al.[8] in their study. Attitude and practice both are modifiable factors and fortunately we were able to make them aware of the right attitude and correct and ethical way of practice on Pharmacovigilance and the ADR reporting which was evident by the significantly positive response given by the nurses after the program. Sencan N et al. also commented in favour of the above stated fact in their research.[8]

In various areas it was found that the nursing personnel did not comment at all. Probable reasons could be their inattentiveness, reluctant attitude or may be fear. The same scenario was observed in Sencan N et al's study as well.[8]

Time was a big constraint to our study so also the professional obligation because of which many interested nursing staffs could not attend the programme but attended their routine duties. In spite of having all those limiting factors we were able to conduct this pilot study from the state of Bihar and were lucky enough to successfully organise such sort of CME for the first time in eastern zone of India.

CONCLUSION

Survival and success of Pharmacovigilance programme and subsequently delivery of safe patient care service require amalgamation of initiatives taken by all healthcare professionals specially those who are directly attached to patients' care. Conducting seminars, CME, or workshops on regular basis always help in knowledge uplifting and in knowing the current and advanced practice in healthcare scenario. This CME was one of our genuine initiatives to improve patient care service in our hospital through timely detection of ADR and its reporting by implementation of Pharmacovigilance activities.

We also reserve a plan to conduct serial CMEs involving different healthcare professional groups at different times to expand knowledge about PV and ADR reporting and to create a positive as well as enthusiastic attitude to indulge healthy and safe patient care practice as an instinct. We sincerely hope to make the ADR reporting forms available in all the wards and OPDs and to implement regular reporting with the help of the PV committee and college authority.

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Conflict of interest

The author declared no conflict of interest.

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