

The Impact of the Educational Intervention on Knowledge, Attitude, and Practice of Pharmacovigilance toward Adverse Drug Reactions Reporting among Health-care Professionals in a Tertiary Care Hospital in South India

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Abstract

Background: Knowledge, attitude, practice (KAP)-based educational intervention is an important tool to reduce underreporting of adverse drug reactions (ADRs). Hence, this study aimed to assess the KAP of doctors and nurses working in medicine and allied departments of Jawaharlal Institute of Postgraduate Medical Education and Research on spontaneous reporting of ADRs, following an educational intervention. The study also compared the quantity of ADRs reported before and after 1 year of introducing the educational intervention. **Methodology:** The study was a cross-sectional questionnaire-based study involving doctors and nurses working in a tertiary care hospital in South India. A predesigned structured questionnaire was prepared to suit our ADR monitoring center, validated and then distributed to doctors and nurses working in medicine and allied departments of the institute. The study participants were asked to fill KAP pretest questionnaire followed by interactive educational intervention and post-test questionnaire related to KAP after 1 year. The impact of educational intervention among doctors and nurses was evaluated by their response to the post-test questionnaire and the number of ADR reported after intervention. The appropriate statistical analysis was used through Graph Pad InStat version 3.0. **Results:** A total of 235 health-care professionals were involved in the pre-KAP questionnaire, an educational intervention, and post-KAP questionnaire. Among them, doctors were 39%, and nurses were 61%. The overall response rate among doctors and nurses following educational intervention was statistically significant ($P < 0.0001$). Following the educational intervention, the quantity of ADR reported became double compared to pre-intervention. **Conclusion:** The KAP of health-care professionals improved following educational interventional program on pharmacovigilance. Continued educational intervention may inculcate ADR reporting culture among health-care professionals.

Keywords: Adverse drug reaction, educational intervention, knowledge, attitude, practice, pharmacovigilance, questionnaire

INTRODUCTION

Adverse drug reactions (ADRs), one of the significant causes of morbidity and mortality in all age group of patients, are shown to increase the health-care cost globally.^[1] ADR defined as per the World Health Organization (WHO) is "A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological functions."^[2] India is one of the largest producers of pharmaceuticals in the world with too many new drugs introduced in the country. However, the Pharmacovigilance Programme of India (PvPI)

was started in July 2010 with the primary objective of safeguarding the people's health in India.^[3] So far, the PvPI has established nearly 202 ADR monitoring centers all over India, with the toll-free number and paper-based ADR forms available

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to encourage ADR reporting by health-care professionals as well as public. However, India with a 1.3 billion population with a large number of hospitals, health-care professionals, and wider usage of drugs even though less number of ADRs reported.^[4,5]

Spontaneous reporting system is an important method for monitoring of ADRs owing to cost-effectiveness and the ease of detection of suspected and serious ADR, especially during postmarketing surveillance.^[6] ADRs reported from clinical trials, postmarketing surveillance, and health-care professionals play the vital role in spontaneous reporting of ADRs. However, this method has the limitation of underreporting, inability to calculate the incidence of ADRs, and poor quality of reports in many countries. Of these hindering factors, underreporting of ADRs is the biggest problem experienced globally.^[7] Addressing the issue of underreporting is difficult as its extent is unknown and variable. A better understanding of the predisposing factors for underreporting can be of use to practitioners in establishing ways to improve the reporting culture. One of the reasons for underreporting is the lack of knowledge, attitude, and practice (KAP) on the importance of reporting of ADRs. These problems need to be addressed by ADR monitoring centers through various strategies including imparting of continuous awareness on ADR reporting, highlighting on different aspects of reporting ADRs, and emphasis on the role of health-care providers in drug safety issues.^[8] Many studies conducted in India about pharmacovigilance related to KAP of medical practitioners toward ADRs reporting these studies suggested that there is a greater need to create more awareness and educational intervention to promote the reporting of ADRs among the health-care professionals.^[9-11] Few studies have focused on the effect of the intervention to improve the ADR reporting in India. However, these studies have a discrepancy in the quantity of ADR reports received from health-care professionals after introducing educational intervention.^[12,13] Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), a tertiary care hospital having 2150 beds, has been actively involving in pharmacovigilance program since 2005. Through various activities, we have sensitized our health-care professionals to foster ADR reporting culture. In spite of this, underreporting of ADRs is commonly seen in our hospital.^[14] Based on the context, the objectives of the present study was to assess the KAP of doctors and nurses pre- and post-educational intervention on spontaneous reporting of ADRs in medicine and allied departments of JIPMER. The study also compares the number of ADRs reported directly by doctors and nurses before and after 1 year of introducing the educational intervention.

METHODOLOGY

Study setting

This was a cross-sectional, questionnaire-based study conducted in various departments of JIPMER, Puducherry, a tertiary care teaching hospital in South India. Before the conduction of the study, the Institutional Ethics Committee

approval was obtained and conducted according to the Declaration of Helsinki guidelines.^[15] The study carried out by the Department of Clinical Pharmacology, JIPMER, which has been running the ADR Monitoring Centre (AMC) under the PvPI. The study conducted from November 2014 to October 2015, involving doctors and nurses working in the Departments of General Medicine, Pulmonary Medicine, Pediatrics, Psychiatry, Cardiology, Neurology, Dermatology and Sexually Transmitted Disease, Endocrinology, Medical Oncology, Clinical Immunology, and Nephrology. Study flowchart is shown in Figure 1.

Study instrument

A predesigned structured questionnaire adapted from the previous studies was used to assess the KAP of the included professionals.^[12,16,17] The questionnaire was slightly modified to suit our hospital setup. The modified questionnaire content was tested by two expertises of doctors and two expertises of nurses, and suitable modification did according to the expert opinion, and then, the pilot study was carried out five doctors and five nurses (who were not included in the final participants of the study) and validated internal consistency reliability of Cronbach's alpha coefficient was found to be 0.83. The questionnaire contained five parts, including the demographic characteristic of participants, knowledge (question no: 1–9), attitude (question no: 10–14), practice (question no: 15–19), and suggestions (question no: 20) to improve the ADR reporting. After explaining the purpose of the study to the study participants, i.e., doctors and nurses, written informed consent was obtained followed by pre-test questionnaire to identify their initial KAP on pharmacovigilance. After completion of pre-test questionnaire, the interactive educational intervention was provided with the help of clinical pharmacologists and technical associate of the PvPI. The interactive educational intervention differs from regular awareness program of pharmacovigilance because it is consisted of the presentation on our ADR monitoring center's function, the role of the technical associate in ADR collection, the importance of ADR reporting, practical training of ADR form filling and various

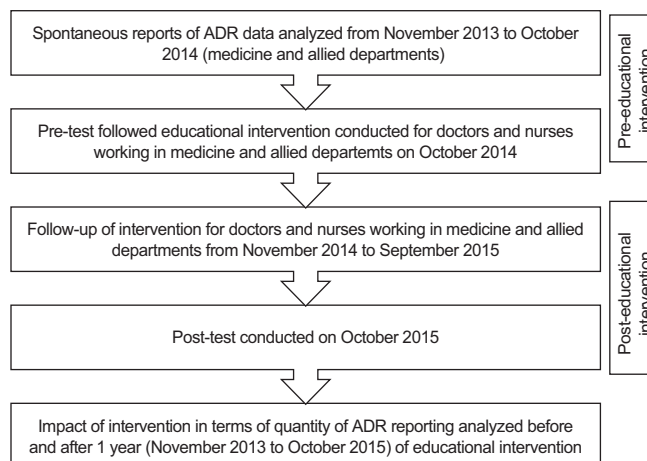


Figure 1: Study flowchart. ADR: Adverse drug reaction

methods of ADR reporting, attitudes and practice of health-care professionals toward ADR reporting. The study participants were followed up for 1 year by the technical associate (PvPI) during regular ward rounds, face-to-face interaction, and short message services (SMS). The impact of the educational intervention was evaluated after 1 year (October 2015) by post-test, with the same questionnaire being distributed to all the participants. Those not willing to participate in post-KAP questionnaire assessment were excluded from the study.

Statistical analysis

Statistical analysis was performed using Graph Pad InStat version 3.0. The normality of the data was tested using Kolmogorov–Smirnov test. The comparison of KAP on pharmacovigilance among health-care professionals before and after the intervention was compared using Fisher exact test. The overall effect of the intervention on KAP of health-care professionals was compared using Wilcoxon matched pair test. The effectiveness of educational intervention between doctors and nurses was compared using Mann–Whitney U-test. $P < 0.05$ was considered statistically significant. The quantity of ADR reporting was calculated based on the total number of ADR reports received from doctors and nurses pre- and post (after 1 year) educational intervention.

RESULTS

Demographic characters of participants

A total of 235 health-care professionals of various departments of JIPMER had participated in pre-test followed by educational intervention and post-test. Among 235 health-care professionals, doctors were 91 (39%) and nurses were 144 (61%). Among 91 doctors, males were 80 (88%), females were 11 (12%). Among nurses, males were 38 (26%), females were 106 (74%). In the study, nurses participated in large numbers compared to doctors, while looking at doctors' category, junior doctors were more involved than senior doctors. Among nurses group, junior nurses participated more compared to senior nurses. The details of doctors and nurses designations are given in Table 1.

Evaluation of knowledge toward pharmacovigilance pre- and post-educational intervention of doctors and nurses

Doctors and nurses knowledge toward ADR reporting was evaluated using nine pharmacovigilance knowledge-related questions. After the educational intervention, there was a significant improvement in knowledge related to pharmacovigilance among doctors and nurses such as the location of AMC, National Coordinating Center, the purpose of monitoring ADRs, who and what are the ADR reported, and the drug withdrawn from Indian market due to ADRs, Table 2.

Evaluation of attitude toward adverse drug reaction reporting doctors and nurses pre- and post-educational intervention

A total of four questions sought information about the attitude toward ADR reporting. The question no. 11 asking information

Table 1: Demographic characteristics of participants

Characteristics	n=235 (%)
Male/female	117/118
Designation	Doctors (n=91) Senior level practitioner: 27 (12) Junior level practitioner: 64 (27) Nurses (n=144) Senior level nurses: 21 (9) Junior level nurse: 123 (52)
Specialties of doctors, n=91 (%)	Cardiology 6 (7) Clinical immunology 4 (4) Dermatology and STD 12 (13) Endocrinology 6 (7) General medicine 25 (27) Medical oncology 6 (7) Nephrology 6 (7) Neurology 5 (5.5) Pediatrics 5 (5.5) Pediatric neonatology 2 (2) Psychiatry 11 (12) Pulmonary medicine 3 (3)

Senior level practitioner: After postgraduation >3 years' experience, Junior level practitioner: Students of postgraduation or after postgraduation <3 years' experience, Senior level nurse: After completion of graduation >5 years working in the institute, Junior level nurses: After completion of graduation <5 years working in the institute. STD: Sexually transmitted disease

about the possibility of ADR causing significant illness or death to the patient and the question no. 12 asking information about the necessity to report all the ADRs did not show any significant difference following the intervention [Table 3]. The question no. 10, 13, and 14 probing the ease of reporting in our institute and professional obligation for reporting ADR and drawbacks in the current system of ADR reporting, showed statistically significant improvement during post education intervention in both groups ($P < 0.05$), as shown in Table 3.

Evaluation of practice toward adverse drug reaction reporting doctors and nurses pre- and post-educational intervention

A total of five questions sought information toward the practice of ADR reporting. The question no. 14, 16, 17, and 18, asked the information regarding, reported ADRs to AMC, seen any patient experiencing ADRs, attended any training program on ADR reporting, and easy access to ADR reporting forms showed statistically significant difference in both doctors and nurses groups. However, for the question no. 15 asking about the habit of reading ADR article, the percentage of correct response was statistically significant only among doctors as shown in Table 4.

Evaluation of overall effectiveness of intervention on knowledge, attitude, and practice among doctors and nurses

The doctors median score of pre-intervention was 12 (range 4–17) and post-intervention was 17 (range 11–19), and nurses median

Table 2: Evaluation of knowledge toward pharmacovigilance pre- and post-educational intervention of doctors and nurses

Serial number	Pharmacovigilance knowledge-related question	Knowledge of doctors, n=91 (%)			Knowledge of nurses, n=144 (%)		
		Pretest correct response, n (%)	Posttest correct response, n (%)	P	Pretest correct response, n (%)	Posttest correct response, n (%)	P
1	Location of AMC in the institute	69 (76)	86 (95)	0.0002*	99 (69)	123 (85)	0.0112*
2	Purpose of monitoring ADRs	71 (78)	83 (91)	0.0180*	110 (76)	127 (88)	0.0419*
3	Drug withdrawn from the Indian market due to ADRs	36 (40)	57 (63)	0.0018*	15 (10)	86 (60)	0.0018*
4	Form is used to notify ADRs to AMC	64 (70)	91 (100)	<0.0001*	99 (69)	143 (99)	<0.0001*
5	Intercom telephone number for reporting ADRs to AMC in the Institute	10 (11)	54 (59)	<0.0001*	40 (28)	105 (73)	<0.0001*
6	Location of National Coordinating Center in India	38 (42)	77 (85)	<0.0001*	51 (35)	117 (81)	<0.0001*
7	Who can report ADRs	73 (80)	88 (97)	<0.0002*	116 (81)	143 (99)	<0.0001*
8	Which ADR should be reported	83 (91)	91 (100)	0.0032*	120 (83)	138 (96)	0.0046*
9	Location of AMC-OPD in the institute	49 (54)	90 (99)	<0.0001*	80 (56)	123 (85)	<0.0001*

*P<0.05, calculated by Fisher exact test. AMC: Adverse drug reaction monitoring center, OPD: Outpatient department, ADRs: Adverse drug reactions

Table 3: Evaluation of attitude toward adverse drug reaction reporting doctors and nurses pre- and post-educational intervention

Serial number	Pharmacovigilance attitude-related question	Attitude of doctors, n=91 (%)			Attitude of nurses, n=144 (%)		
		Pretest correct response, n (%)	Posttest correct response, n (%)	P	Pretest correct response, n (%)	Posttest correct response, n (%)	P
10	User friendly nature of ADR reporting system	50 (55)	79 (87)	<0.0001*	79 (55)	136 (94)	<0.0001*
11	Faith on ADR can cause significant illness or death to patients in sometimes	56 (62)	61 (67)	0.5546	62 (43)	73 (51)	0.3213
12	Need for reporting all ADRs	81 (89)	86 (95)	0.1913	126 (88)	137 (95)	0.1262
13	Reporting ADR as a professional obligation	66 (73)	78 (86)	0.0347*	89 (62)	121 (84)	0.0007*
14	Drawbacks in the current system of AMC in the Institute	49 (54)	74 (81)	<0.0001*	93 (65)	128 (89)	<0.0001*

*P<0.05, calculated by Fisher exact test. AMC: Adverse drug reaction monitoring center, ADRs: Adverse drug reactions

Table 4: Evaluation of practice toward adverse drug reaction reporting pre- and post-educational intervention of doctors and nurses

Serial number	Pharmacovigilance practice-related question	Practice of doctors, n=91 (%)			Practice of nurses, n=144 (%)		
		Pretest correct response, n (%)	Posttest correct response, n (%)	P	Pretest correct response, n (%)	Posttest correct response, n (%)	P
15	Previously reported ADRs to AMC	53 (58)	77 (85)	<0.0001*	36 (25)	56 (39)	0.0483*
16	Habit of reading ADR articles	46 (51)	64 (70)	0.0090*	43 (30)	64 (44)	0.0566
17	Patients experiencing ADRs seen by health-care professionals	80 (88)	88 (97)	0.0287*	110 (77)	130 (90)	0.0212*
18	Attended training program on ADRs reporting	22 (24)	80 (88)	<0.0001*	10 (7)	131 (91)	<0.0001*
19	Easy access to ADRs reporting forms	51 (56)	80 (88)	<0.0001*	75 (54)	131 (91)	<0.0001*

*P<0.05, calculated by Fisher exact test. AMC: Adverse drug reaction monitoring center, ADRs: Adverse drug reactions

score of pre-intervention was 10 (range 2–17) and post-intervention was 15 (range 10–19); it showed improvement in both groups ($P < 0.0001$). Comparison of educational intervention between doctors and nurses demonstrated more improvement in doctors compared to nurses ($P < 0.0001$).

Suggestions to improve the adverse drug reaction reporting

Around 116 (49%) doctors and nurses had given their suggestions for improving ADR reporting. Among the suggestions given, 33% was toward conducting routine pharmacovigilance awareness, continuous medical education (CME), and workshop. The other suggestions to improve ADR reporting are given in Table 5.

Table 5: To improve adverse drug reaction reporting suggestions given by doctors and nurses

Serial number	Suggestions to improve ADR reporting	Doctors and nurses, n=116 (%)
1	Frequent pharmacovigilance awareness via CME/workshop	38 (33)
2	Frequent interactions with health-care professionals	18 (15.5)
3	Frequent SMS/e-mail about ADR reporting	16 (14)
4	Advertise the poster in all areas of hospital	11 (9.4)
5	Make online reporting through HIS	9 (8)
6	Keep ADR register in all the wards and OPD	6 (5.2)
7	Include ADR forms along with case sheet	5 (4)
8	Include ADR column in case sheet	3 (2.5)
9	Include ADR reporting column in resident log book	3 (2.5)
10	Develop the mobile apps for ADR reporting	2 (1.7)
11	Discuss ADR cases every month during meeting	2 (1.7)
12	Make standardized protocol for reporting ADR	2 (1.7)
13	Paste ADR alert sticker to ADR developed patient case sheet	1 (0.8)

OPD: Outpatient department, ADR: Adverse drug reaction, HIS: Hospital information system, CME: Continuous medical education, SMS: Short message service

Comparison of adverse drug reaction reporting before and after 1 year of educational intervention

One year before the study period, a total of 296 ADRs were received by the ADR monitoring center with a mean of 25 ADRs per month (range 7–39). After 1 year of educational intervention, ADRs received increased to 625 ADRs with an average of 52 per month (range 29–81). Figure 2 depicts the trends of ADR reports received by the ADR monitoring center. ADRs reported by doctors and nurses pre- and post-intervention are shown in Figure 3.

DISCUSSION

The present KAP study on pharmacovigilance included doctors and nurses of medicine and allied departments of a tertiary care hospital in South India. KAP is the foremost consider when it comes to ADR reporting. Several studies have reported that health-care professionals have meager knowledge about pharmacovigilance before the educational intervention.^[18-21] To the best of our knowledge, this is the first Indian study after introducing the education intervention about pharmacovigilance, followed the 1 year practice of quantity of ADR reporting among doctors and nurses. In our study, after the educational intervention, more than 85% of the participants were able to respond correctly, such as location of AMC and OPD in the Institute, ADR form used to notify ADRs to the AMC, who can report ADRs to AMC, which type of ADR reported to AMC. These answers show that doctors and nurses have better knowledge on the local hospital-based ADR monitoring center. For the question on the purpose of monitoring ADRs during pre-intervention, 78% of doctors and 76% of nurses were able to give the correct response. This result is in contrast to another Indian study in which response among doctors and nurses for the similar query is 28.3% and 21.1%, respectively.^[12] This difference could be because our ADR monitoring centers is one of the regional centers for the previous National Pharmacovigilance Programme (NPvP 2004). Through NPvP 2004, the health-care professionals might have been given awareness about the purpose of monitoring ADRs.

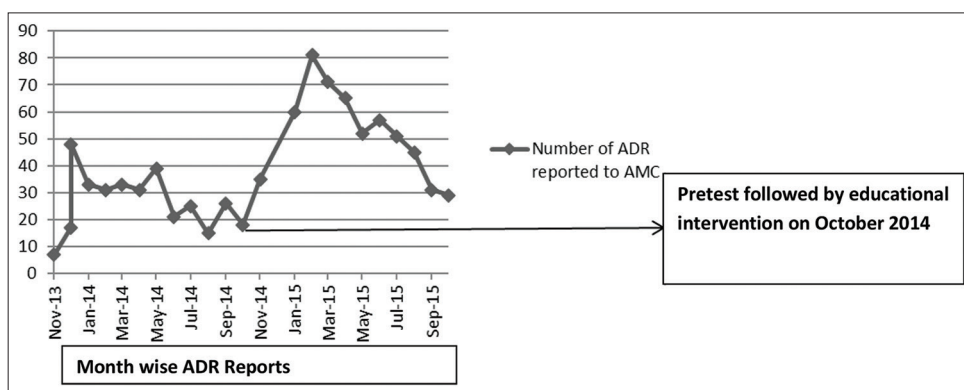


Figure 2: Before and after 1 year of educational intervention ADR report received by AMC. ADR: Adverse drug reaction, AMC: ADR monitoring center

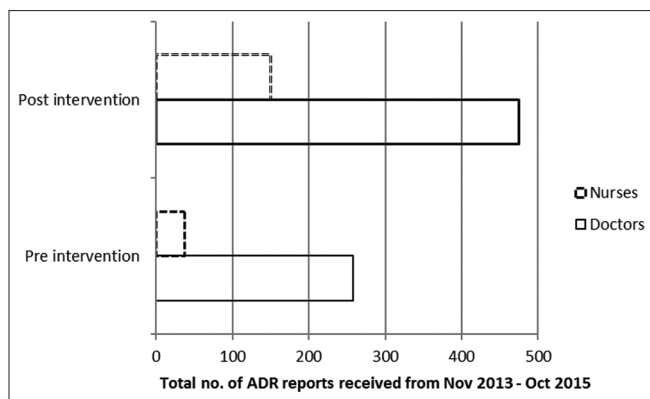


Figure 3: Comparison of ADR reporting before and after 1 year of educational intervention. ADR: Adverse drug reaction, AMC: ADR monitoring center

In the present study, after introducing the educational intervention, 4% of nurses were still unaware regarding the type of ADRs to be reported to AMC. This issue has to overcome by enhancing the knowledge regarding pharmacovigilance, by conducting more workshops, conferences, and CME related to pharmacovigilance.^[22] More than 84% of doctors and nurses felt that ADR reporting is friendly in our institute, it is important, and also a professional obligation. These findings are almost similar to other study conducted by Rajesh *et al.*^[12] This evidence clearly showed that after the introduction of intervention, the attitude of doctors and nurses has improved. This study found that doctors and nurses are unaware about reporting of all ADRs and that ADRs can cause significant illness or death to patients. This shows the uncertainty among health-care professionals that ADRs can lead to illness or death to patients.^[23,24] In the study, pre-intervention 88% of doctors and 77% of nurses have seen patients experiencing ADRs, but of them, only 58% doctors and 25% of nurses have reported ADRs to AMC. This finding is almost similar to other studies done in Nepal and Nigeria.^[25,26]

In our study, most encouraging factor was more than 80% of doctors and nurses after educational intervention agreed of having easy access to ADR reporting forms and no drawbacks in the current system of ADR reporting. These results clearly show smooth functioning and user-friendly approach of ADR monitoring center in the Institute. In the study, education intervention resulted in improvement in ADR reporting in this setup; this was similar to the previous study conducted in Nigeria.^[27] However, even after the educational intervention, 30% of doctors and 56% of nurses were not having the habit of reading ADR-related articles. This issue has to be addressed through frequent sensitization program.^[22] The present study used educational tool to improve the ADR reporting in line with the previous studies.^[12,13,22,24] To improve the spontaneous reporting of ADRs, the health-care professionals suggested regular pharmacovigilance awareness program and repeated SMS, an online reporting facility, frequent interaction with them, to include ADR forms along with case sheet, etc. These suggestions were almost similar to other studies conducted in

Nigeria and the United Arab Emirates.^[28,29] In the present study, after introducing educational intervention, the quantity of ADR reporting has increased twice compared to pre-intervention period. The present study demonstrated that the effect of educational interventions will help improve ADR reporting. However, educational interventions are time bound and hence continuous educational programs on pharmacovigilance are essential.

CONCLUSION

This study showed the majority of doctors and nurses are aware of ADR monitoring center and the importance of ADR monitoring at the local-based hospital, national and global levels. Following educational interventions, the knowledge and attitude toward the ADR reporting seem to have improved. The actual reporting of ADRs has increased by more than two times following educational intervention. Hence, to improve ADR reporting among health-care professionals, there is a need to conduct periodic workshops and continued medical education frequently to sensitize them.

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Conflicts of interest

There are no conflicts of interest.

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