



A non-randomized interventional study to promote the knowledge, attitude and practices of community pharmacists towards pharmacovigilance

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ABSTRACT

Pharmacovigilance promotes the safe and effective use of medicines and thereby optimizes the treatment quality. However, lack of awareness among community pharmacists towards pharmacovigilance decreases the proportion of adverse drug reactions reported and impairs the signal detection process. Hence this study was designed to assess and promote the awareness and attitude of community pharmacists towards pharmacovigilance. This educational interventional study was carried out with 102 community pharmacists across Chennai. A pre-validated three domain-containing questionnaire, 20 items was used to assess the knowledge, attitude and practice before and after the educational intervention. Knowledge, attitude and practices of community pharmacists towards pharmacovigilance was significantly increased after the educational intervention ($P < 0.05$, 95%CI). Median difference in an overall score of knowledge and practice was observed to be 4 and 4.5, respectively. Though the frequency of ADR reporting was not found to be greatly increased in our study, mass educational programs with adequate sampling intervals are needed to strengthen the signal generation process.

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INTRODUCTION

Pharmacovigilance involves the sequential activities of detecting, assessing, understanding, managing, and preventing of adverse drug reactions (ADRs) (Campbell *et al.*, 2015). Pharmacovigilance aims to promote the safe and effective use of

medicines, thereby increasing the quality of treatment each patient receives (Sahu *et al.*, 2014). Minimizing the risk of adverse events through pharmacovigilance also tend to decrease the direct and indirect costs spent towards pharmacotherapy (Qing-Ping *et al.*, 2014). Treatment decisions are always made taking risk-benefit ratio into consideration. Therefore, pharmacovigilance paves path for developing systemic strategies for ADR risk stratification (Al-Worafi *et al.*, 2017). The unequivocal role of pharmacists in ADR reporting is a crucial element for effective pharmacovigilance (Toklu and Mensah, 2016). Community pharmacists usually spent adequate time with patients and possessed relevant clinical expertise to understand the onset of ADRs (Tsuyuki *et al.*, 2018). Moreover, the quality of ADR reports sent to global pharmacovigilance process can be enhanced upon screening by community pharmacists (Baniyadi *et al.*, 2014).

However, ADRs are often under-reported by health

Table 1: Summary of Demographics (N=102)

S. No	Demographic	Category	Number of CPs (%)	
1.	Age (in years)	Range	Summary Statistics a	Frequency
		18-35	28.2 ± 3.2	43 (42.2)
		36-65	42.2 ± 5.0	59 (57.8)
2.	Gender	Male	72 (70.6)	
		Female	30 (29.4)	
3.	Educational Qualification	Diploma in Pharmacy	28 (27.5)	
		Bachelor of Pharmacy	44 (43.1)	
		Master of Pharmacy	18 (17.6)	
		Doctor of Pharmacy	06 (5.9)	
		Ph.D. in Pharmacy	06 (5.9)	
4.	Years of experience	Less than 5 years	32 (31.4)	
		5 – 10 years	07 (6.9)	
		10 – 20 years	44 (43.1)	
		Greater than 20 years	19 (18.6)	
5.	Type of Employment	Self – owned	94 (92.2)	
		Employed	08 (7.8)	

Data represented as Mean ± SD. SD: Standard Deviation

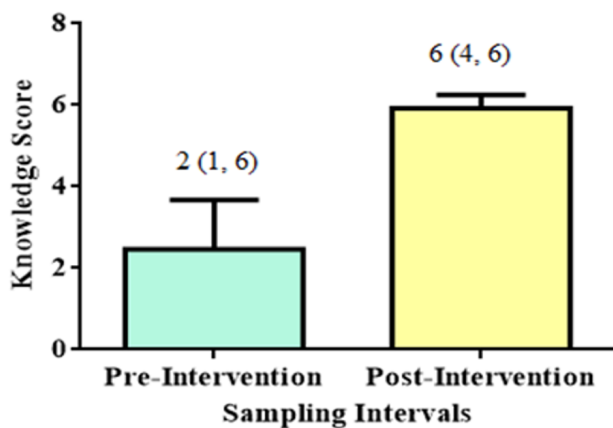


Figure 1: Effect of Educational Intervention on Knowledge. P Value = 0.000, 99% CI, Median of differences = 4

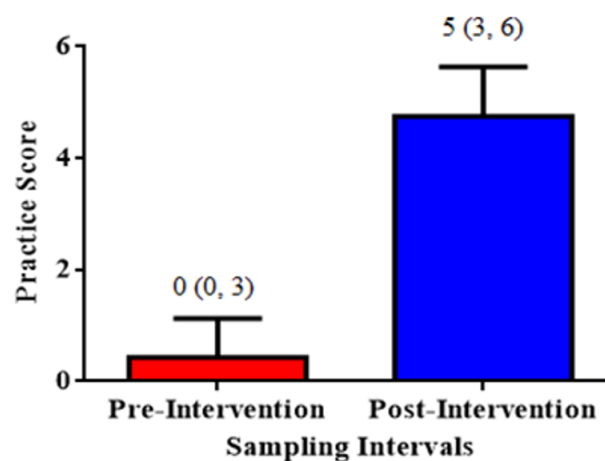


Figure 2: Effect of Educational Intervention on Practice. P-Value= 0.000, 99% CI, Median of differences = 4.5

care professionals, including community pharmacists, due to the lack of awareness about significance, reporting modalities and regular work schedule (Almandil, 2016). Unreported ADRs have detrimental effects on the signal generation process and compromise the quality of pharmacotherapy. In order to ease and facilitate the spontaneous reporting the Pharmacovigilance Program of India (PvPI), has put forth several initiatives such as the launch of mobile applications for ADR reporting (Kalaiselvan et al., 2016). Health care professionals, especially community pharmacists, need to be educated regarding the significance of pharmacovigilance and reporting modalities to strengthen the signal gen-

eration process (Yu and Lee, 2017). Pharmacists trained in pharmacovigilance would educate fellow pharmacist and colleagues on the significance of ADR reporting and reporting strategies and thereby promote pharmacovigilance (Olsson, 2008). Hence, it is crucial to assess the awareness and attitude of community pharmacists towards pharmacovigilance and provide adequate training to promote their active involvement in ADR reporting as they are health care professionals readily accessible to patients.

Table 2: Effect of Educational Intervention on Response Towards Knowledge Questions (N=102)

S. No.	Item	Proportion of correct response (%)		P-value a	McNemar's Chi-Square
		Pre-intervention	Post-intervention		
K1	Are you aware that all drugs in the market are not safe?	96.1	98.0	0.687	-
K2	Are you aware that community pharmacists can report ADRs?	13.7	100.0	0.000**	86.01
K3	Are you aware that ADRs can decrease the quality of treatment and compromise patient safety?	84.3	99.0	0.000**	60.308
K4	Are you aware that ADRs can levy unnecessary health care costs?	27.5	97.1	0.000**	65.333
K5	Are you aware of the Pharmacovigilance Programme of India (PvPI) for reporting ADRs in India as a concern of Safety?	14.7	100.0	0.000**	85.011
K6	Do you know the significance of ADR reporting?	9.8	98.0	0.000**	88.011

^aStatistical significance of the difference in response proportions were determined through McNemar's Chi-square test (2 x 2 matrix).

**represent a statistically significant difference in proportion at 99% confidence interval. McNemar's Chi-square value was not computed for item K₁ due to statistical insignificance between paired proportions

METHODOLOGY

Study Site and Approval

This study was conducted for a period of 5 months in 95 community pharmacies across Chennai. The protocol was reviewed and approved by the Institutional Ethics Committee of VELS Institute of Science, Technology and Advanced Studies before study commencement. Consent from the authorities of the community pharmacies was obtained prior to administration of questionnaires to CPs. (Ref No.: VISTAS-SPS/IEC/II/2018/09).

Subject Recruitment and Confidentiality

Community pharmacists in pre-identified study sites were requested participation. The study protocol was thoroughly explained to the participants by the investigator. Community pharmacists were

enrolled into the study only on the provision of written informed consent. All data were documented in specially designed case report forms, and access was restricted to the investigator to ensure non-violation of subject rights and confidentiality.

Study Design

Non-Randomized Experimental.

Sample Size

A sample size of 102 community pharmacists was calculated using the nMaster software.

Inclusion Criterion

CPs in identified study sites with the minimum qualification for the practice of pharmacy profession as prescribed by the Pharmacy Council of India (PCI) have an active registration with any of the state pharmacy councils and willing to provide written

Table 3: Effect of Educational Intervention on Attitude Towards Pharmacovigilance (N=102)

S. No	Item	Proportion of correct response (%)						Likeli hood Ratio	Pearson's Chi-Square	McNemar Bowker	P Value a
		Pre-intervention			Post- intervention						
		-1	0	+1	-1	0	+1				
A1	I feel that I should be involved in ADR reporting.	21.6	65.7	12.7	3.9	5.9	90.2	1.241	0.735	78.1	0.000**
A2	I feel it is important for me to attend the training programme in Pharmacovigilance.	87.3	2.0	10.8	4.9	5.9	89.2	3.187	1.801	86.0	0.000**
A3	I'm confident enough to report ADRs that I identify.	83.3	12.7	3.9	2.0	2.0	96.0	1.491	0.833	96.0	0.000**
A4	I prefer to consult a physician before ADR reporting.	6.9	84.3	8.8	0.0	3.9	96.1	1.980	2.406	-	-
A5	I feel that I could significantly contribute to the signal generation process.	3.9	83.3	12.7	2.0	3.9	94.1	1.464	1.081	83.0	0.000**
A6	I feel it necessary to report ADRs caused by OTC drugs.	5.9	66.7	27.5	0.0	0.0	100.0	-	-	-	-
A7	Reporting ADRs are one of the responsibilities of a practicing pharmacist.	54.9	27.5	17.6	4.9	2.9	92.2	9.905	10.278	77.8	0.000**
A8	I would recommend ADR reporting to my fellow pharmacist.	-	92.2	7.8	4.9	3.9	91.2	1.542	0.840	-	-

^aStatistical significance of the difference in response proportions were determined through McNemar's Bowker test(3 X 3 matrix) at 95% confidence interval.

*represent a statistically significant difference in proportion at 99% confidence interval. McNemar's Bowker test was not performed for items A₄ and A₈ due to absence of negative responses post-intervention and absence of negative responses pre-intervention respectively. Likelihood ratio, Pearson's Chi-Square and McNemar's Bower values were not computed for item A₆ due to absence of negative and neutral responses post-intervention

Table 4: Effect of Educational Intervention on Response Towards Practice Questions (N=102)

S. No.	Item	Proportion of correct response (%)		P-value	McNemar's Chi-Square
		Pre-intervention	Post-intervention		
P1	Have you reported any ADR that you have observed in a patient during your practice?	1.96	22.54	0.000	55.221
P2	Do you counsel patients regarding possible ADRs while dispensing medication at your facility?	5.9	84.3	0.000	74.298
P3	Do you counsel patients on how to handle an ADR or drug-related event?	0.0	81.4	-	-
P4	Will you be able to spend a few minutes to report ADR through any modality?	5.9	94.1	0.000	88.011
P5	Are you aware that ADR reporting is not cost consuming?	9.8	96.1	0.000	86.011
P6	Are you aware that ADR reporting does not cause any legal issue?	18.6	95.1	0.000	76.013

^AStatistical significance of the difference in response proportions were determined through McNemar's Chi-square test (2 x 2 matrix) at 95% confidence interval. McNemar's Chi-square value was not computed for item P₃ due to the absence of correct response pre-intervention

informed consent.

Exclusion Criterion

1. Unqualified individuals dispensing medications in community pharmacies.
2. Pharmacists who are not working in a community setup.
3. CPs who are unwilling to provide a written informed consent.

Statistical Methods

Descriptive summary of demographic and clinical variables is presented either as mean \pm SD or as median (minimum and maximum). Choice of the descriptive and inferential statistical method was based on distribution normality as determined

through normal probability plot and Shapiro-Wilk test. Statistical analyses were performed using International Business Machines – Statistical Package for the Social Sciences (IBM – SPSS) 20.0 and R statistical package.

RESULTS AND DISCUSSION

Age, gender, educational qualification, years of experience and type of employment wise distribution of Community Pharmacists are shown in Table 1. Pre and post-intervention knowledge of Community Pharmacists towards Adverse Drug Reactions and Pharmacovigilance are shown in Table 2. Effect of educational intervention on Knowledge of Community Pharmacists is illustrated in Figure 1. Pre and post-intervention attitude of Community Pharmacists towards Adverse Drug Reactions and its reporting are shown in Table 3.

Pre and post-intervention Practice of Community Pharmacists towards Adverse Drug Reactions and its reporting are shown in Table 4. Effect of educational intervention on the Practice of Community Pharmacists is illustrated in Figure 2. Training and education of community pharmacists on the aspects of pharmacovigilance would promote ADR reporting and enhance the quality of ADR reports sent to global monitoring centers (Li *et al.*, 2018). Hence, in this interventional study, we assessed the knowledge, attitude and practice of community pharmacists and provided them adequate education on the importance of ADR reporting, the role of the PvPI and different modalities of reporting adverse drug reactions using a pre-validated questionnaire (Anbalagan and Shanmugasundaram, 2019). It was observed that the overall knowledge of community pharmacists enhanced after the educational intervention. Though 96.1% community pharmacists were aware of the fact that no drug molecule is free of adverse effects, they were unaware about their significant role in pharmacovigilance process. Lack of awareness of community pharmacists towards pharmacovigilance is of significant concern as it leads to under-reporting of ADRs (Said and Hussain, 2017). The attitude of community pharmacists towards ADR reporting was relatively less before the educational intervention. Twenty-two per cent of community pharmacists expressed a negative opinion regarding their participation in pharmacovigilance while 65.7% of pharmacists expressed neutral attitude and only 12.7% felt that they should be involved in ADR reporting. The initial negative and neutral attitude of community pharmacists towards ADR reporting could be due to hesitation to take up the additional workload, fear of legal issues and/or monetary loss. This was evident in item A₂ regarding their interest in attending pharmacovigilance, where 87.3% of pharmacists expressed a negative opinion. Pharmacists stated indirect monetary loss due to refraining from work by attending the training program as a reason. Similar results have been reported in previous studies where pharmacists have initially expressed a negative opinion to attend pharmacovigilance training programs (Syed *et al.*, 2018). However, there was a significant improvement in pharmacist attitude towards pharmacovigilance with 90.2% feeling that they should be involved in pharmacovigilance. The initial response of pharmacist towards practice was also found to be low. Initially, 1.96% of pharmacists stated that they have reported previously reported adverse events which increased only to 22.54% after an educational intervention. This relatively low increase in ADR reporting is because

of the less time interval between the sampling points (1 Month). Almost 60% of pharmacists reported that they haven't observed any adverse event in the last month. Hence future studies with longer time intervals between sampling points are crucial to determine the effect of educational interventions on the attitude towards pharmacovigilance. However, the other practices of the community pharmacist in the prevention of ADR, such as counselling care has significantly improved after the intervention. The results of our studies are on par with previous studies that have previously attempted to promote the knowledge, attitude and practice of community pharmacists towards pharmacovigilance (Ahmad *et al.*, 2013; Alsaleh *et al.*, 2017).

CONCLUSION

We have assessed the awareness and attitude of community pharmacists toward pharmacovigilance using a pre-validated questionnaire. Knowledge, attitude and practice of community pharmacists towards ADR reporting was also increased through educational intervention. Promotion of awareness and attitude of community pharmacist toward pharmacovigilance would strengthen the signal generation process and aid in enhancing the quality of treatment. Nationwide mass educational programs to promote the awareness and attitude of community pharmacists towards pharmacovigilance are required to train community pharmacist across the country on aspects of pharmacovigilance.

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