Research Article

Development of a validated questionnaire to assess awareness and attitude of community pharmacists toward pharmacovigilance

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ABSTRACT

Objectives: Spontaneous reporting of adverse events aids in adverse drug reactions (ADR) risk prevention. Community pharmacists (CPs) play a crucial role in the systematic ADR reporting process (Pharmacovigilance) due to their ready accessibility to patients and professional training in pharmacology. Hence, awareness and attitude of CPs need to be assessed to develop strategies to promote their active involvement in pharmacovigilance. **Methodology:** We developed and validated a 20 item, three domains containing a questionnaire to assess the knowledge and attitude of CPs toward pharmacovigilance. The questionnaire was examined for reliability (reproducibility and internal consistency) and convergent and discriminant validity. **Results:** Intraclass correlation coefficient was >0.7 while Cronbach's alpha score was >0.8 and hence the questionnaire was considered to have sufficient reproducibility and internal consistency. Hence, no significant modification was made in the questionnaire. **Conclusion:** This questionnaire could aid in assessing the awareness and attitude of CPs toward pharmacovigilance and thereby develop strategies to promote ADR reporting by CPs.

KEY WORDS: Adverse drug reaction, Awareness, Pharmacovigilance, Questionnaire, Validation

INTRODUCTION

Adverse drug reactions (ADRs) are detrimental. They are one of the major causes of morbidity and mortality across the globe.[1] Despite compromising safety, ADRs tend to levy additional economic burden to the patient by causing an unnecessary hospital admission or increasing the duration of hospital stay.[2] Hence, suspected ADRs need to be crucially monitored, reported, and analyzed to arrive at ADR risk mitigation strategies. As far as the Indian sub-continent is concerned, ADRs account for 3.4% of hospital admissions whereas 3.7% of hospitalized patients experience ADRs.[3,4] On the other hand, ADR reporting is still in infancy in India. The Central Drugs Standard Control Organization through the Pharmacovigilance Program of India (PvPI) has made ADR reporting accessible to all health care providers (HCPs) including physicians, pharmacist, and nurses.[5] The PvPI has also made ADR reporting through mobile-based applications accessible to facilitate the spontaneous reporting process for early detection of signals of new rare and serious adverse events.[6] However, ADRs still remain under-reported in India by HCPs, especially community pharmacists (CPs), due to lack of awareness about the reporting modalities and hectic work schedule.[7] CPs have pivotal roles to play in the signal detection process as they are drug experts who bridge the gap between the patient and the prescriber.[8] The quality of reports being sent to national or global pharmacovigilance systems can be enhanced when they are screened or reported by a pharmacist.[9] Moreover, CPs have high chances of reporting an adverse event since they are readily accessible to patients. In addition to reporting ADRs, CPs can directly educate patients or fellow pharmacists regarding the importance and modalities of reporting adverse events.[10] Several studies have reported that a lack of knowledge about the modalities of reporting an adverse event to be the major cause of underreporting.[11] Under reported adverse events may consequentially impair the signal detection

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process and compromise quality of treatment with a given medication.[12] Hence, the awareness and attitude of CPs toward pharmacovigilance need to be assessed to determine domains that need to be strengthened to promote ADR reporting among CPs. Active involvement of CPs in the pharmacovigilance process can have significant incremental effects on the spontaneous reporting process and can promote the quality of treatment outcomes.[13] Hence, this study is designed to develop and validate a standard questionnaire to assess awareness and attitude of CPs toward pharmacovigilance and ADR reporting.

METHODOLOGY

Study Site and Approval

This study was conducted for 2 months in 22 CP across Chennai. The protocol was reviewed and approved by the Institutional Ethics Committee before study commencement (Ref No.: VISTAS-SPS/IEC/II/2018/09). Consent from the authorities of the CP was obtained before administration of questionnaires to CPs.

Subject Recruitment and Confidentiality

CPs in pre-identified study sites were requested participation. The study protocol was thoroughly explained to the participants by the investigator. CPs were enrolled in the study only on 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

This was a cross-sectional survey.

Sample Size

The sample size was estimated using the following formula for calculation of sample size for the quantitative variable.

$$\text{Sample size} = (Z_{1-\alpha/2})^2 (SD)^2/d^2$$

Where $Z_{1-\alpha/2}$ is standard normal variate as mentioned in the previous section, where SD is the standard deviation of a variable taken from previously done studies, d is the absolute error or precision.[14]

Study Methodology

Validation of questionnaire

Reliability analysis

Internal consistency of individual items in each domain of the questionnaire was examined to assess the overall reliability. The homogeneity of questions in each domain was determined in terms of Cronbach's alpha (α) coefficient, whose value of 0.7 or above was considered for the questionnaire to be internally consistent. Reproducibility of answers was also examined through the administration of the questionnaire to mentally stable patients on day 1 (test arm) and day 15 (re-test arm: Washout period of 14 days) and computation of intraclass correlation coefficient (ICC). An ICC of 0.7 or above was considered significant for test-rest reproducibility.

Construct validity

Corrected-item to total correlation (CITC) scores and average variance extracted were computed to examine convergent and discriminant validity of the construct, respectively.

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 have an active registration with any of the state pharmacy councils and willing to provide written informed consent.

Exclusion Criterion

The following criteria were excluded from the study:

- Unqualified individuals dispensing medications in CP.
- Pharmacists who are not working in a community setup.
- CPs who are unwilling to provide written informed consent.

Statistical Methods

Descriptive summary of demographic and clinical variables is presented either as mean±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 20.0 and GraphPad Prism 6.0.

RESULTS

Qualified CPs working in community setup were requested participation. The printed version of the questionnaire was issued to 22 CPs across Chennai. All the CPs filled independent responses to the questions and returned the questionnaires to the investigator. Hence, the response rate was 100%. Descriptive summary of demographical parameters of the studied population is shown in Table 1.

Reproducibility of responses was examined through computation of ICC. Two sets of answers from the CPs in the test-retest arm were obtained and examined. A coefficient of 0.7 or higher was considered as a

measure of significant reproducibility as shown in Tables 2-4.

Purification of items was not carried out because the CITC of all individual items was >0.5 and the Cronbach's alpha of all the individual constructs was >0.8 suggesting the constructs to be consistent before purification itself as shown in Table 5.

Factor structures were accepted as the composite reliabilities, and average variances extracted for individual constructs were above acceptable limits as shown in Table 6.

Discriminant Validity

The empirical distinction of individual constructs was examined through discriminant validation. The squared correlation of each pair was less than the variances extracted suggesting a significant empirical distinction between the constructs as shown in Table 7.

Majority of the CPs possess adequate knowledge and display a positive attitude toward adverse event reporting and pharmacovigilance. However, they are not currently into the process of ADR reporting. This necessitates the need to assess factors that impair effective participation of CPs in the pharmacovigilance process despite possessing adequate knowledge and positive attitude.

DISCUSSION

The role of CPs in spontaneous reporting of adverse events is globally well recognized.[15] CPs play pivotal roles in the spontaneous reporting and signal detection process as they are professionally trained drug experts who bridge the gap between patients and the prescribers.[16] CPs play diverse roles in the pharmacovigilance process including a collection of adverse event data from patients, storing them in pharmacy information systems, assessing their causality and reporting to national or global pharmacovigilance centers.[17] In addition, to this routine sequence of events, CPs can directly educate patients about the importance and modalities of reporting adverse events to pharmacovigilance centers.[18,19] Quality and consistency of the questionnaire were determined by reliability analysis. The overall consistency of the questionnaire and individual domains was determined through Cronbach's alpha while the magnitude of the contribution of individual question toward Cronbach's alpha was determined through CITC scores. As the CITC score of all individual questions was >0.5 and the Cronbach's alpha of all the domains was >0.8, the questionnaire, on the whole, was found to be consistent. Hence, no question in the construct was dropped, and the questionnaire as such was subjected to further statistical validation. CITC scores were also interpreted to determine the convergent validity as they quantify the relationship between each of the

Table 1: Summary of demographics (*n*=22)

Demographic	Category		Number of CPs (%)
Age (in years)	**Range**	**Summary statistics**	
	18–35	31.6±3.8	7 (31.9)
	36–65	44.7±9.1	15 (68.1)
Gender	Male		16 (72.7)
	Female		6 (27.3)
Educational qualification	Diploma in pharmacy		8 (36.4)
	Bachelor of Pharmacy		7 (31.8)
	Master of Pharmacy		4 (18.2)
	Doctor of Pharmacy		2 (9.1)
	Ph.D. in pharmacy		1 (4.5)
Years of experience	<5 years		11 (50)
	5–10 years		3 (13.6)
	10–20 years		6 (27.3)
	>20 years		2 (9.1)
Type of employment	Self-owned		14 (63.6)
	Employed		8 (36.4)
Location of pharmacy	Urban		12 (54.5)
	Rural		10 (45.5)

Table 2: Reliability analysis: Summary of tests for reproducibility

Domain	Maximum score	Median scores*		*P* value**	ICC
		Day 1	Day15		
Knowledge	6	2 (−1, 5)	2 (−1, 5)	0.9999	0.91
Attitude	8	4 (1, 7)	4 (1, 7)	0.75	0.89
Practice	6	−2 (−4, 2)	−2 (−4, 3)	0.25	0.89

*Data represented as median (minimum, maximum), ***P*-value retrieved through Wilcoxon matched pairs signed-rank test, ICC: Intraclass-correlation

Table 3: Mean score, Cronbach's alpha, and Intraclass correlation coefficient

Constructs	Items	Mean score (*n*=22)	Cronbach's alpha coefficient (*n*=22)	Intraclass correlation coefficient (*n*=22)
	Assessment of knowledge	61.4	0.97	0.91
	Assessment of attitude	69.9	0.93	0.89
	Assessment of practice	30.3	0.9	0.89
	Do you believe all drugs available in the market are safe?	100	0.98	0.94
	Are you aware that community pharmacists can report ADRs?	68.2	0.98	0.96
	Are you aware that ADRs can decrease quality of treatment and compromise patient safety?	81.8	0.97	0.86
	Are you aware that ADRs can levy unnecessary health care costs?	59.1	0.94	0.85
	Are you aware of PvPI for reporting ADRs in India as a concern of safety?	22.7	0.97	0.95
Knowledge	Do you know the significance of ADR reporting?	36.4	0.95	0.92
	I feel that I should be involved in ADR reporting	95.5	0.92	0.88
	I feel it is important for me to attend the training program in pharmacovigilance	45.5	0.92	0.87
	I'm confident enough to report ADRs that I identify	59.1	0.97	0.92
	I prefer to consult a physician before ADR reporting	81.8	0.92	0.86
Attitude	I feel that I could significantly contribute to the signal generation process	68.2	0.95	0.87
	I feel it necessary to report ADRs caused by OTC drugs	72.7	0.88	0.95
	Reporting ADRs are one of the responsibilities of a practicing pharmacist	68.2	0.94	0.9
	I would recommend ADR reporting to my fellow pharmacist	68.2	0.97	0.88
	Have you reported any ADR that you have observed in a patient during your practice?	4.5	0.97	0.82
	Do you counsel patients regarding possible ADRs while dispensing medication at your facility?	9.1	0.92	0.82
	Do you counsel patients on how to handle an ADR or drug-related event?	18.2	0.85	0.95
Practice	Will you be able to spend a few minutes to report ADR through any modality?	45.5	0.88	0.97
	Are you aware that ADR reporting is not cost consuming?	36.4	0.9	0.9
	Do you fear legal issues that may arise due to ADR reporting?	68.2	0.87	0.9

PvPI: Pharmacovigilance Program of India, ADR: Adverse drug reactions

questions and the total score of the individual domains. On the whole, the questionnaire exhibited acceptable internal consistency with overall Cronbach's alpha >0.8 and sufficient reproducibility with ICC >0.75.[20] In addition, we determined the empirical distinction of individual domains through discriminant analysis. The squared correlation of each pair was found to be less than variances extracted suggesting that each domain is empirically distinct from each other. This method of determining the empirical distinction between the domains of the questionnaire was adopted from previous literature.[21] Thus, we have developed and validated a questionnaire to assess the knowledge, attitude, and practice of CPs toward pharmacovigilance and ADR reporting. A cross-sectional survey was carried out with the validated questionnaire among the study population. It was observed that the majority of CPs have adequate knowledge about pharmacovigilance and ADR reporting while the majority of CPs was poorly practicing pharmacovigilance. The results of our study are on par with previous studies which have also reported poor practice of CPs toward pharmacovigilance.[22] However, we observed that majority of CPs has adequate knowledge and display a positive attitude toward ADR reporting and hence factors that impair effective participation of CPs in the pharmacovigilance process need to be determined and critically analyzed.

Table 4: Reliability analysis: Tests for internal consistency

S. No	Questions	Factor loading	Corrected item-to-total correlation	Construct wise Cronbach's Alpha
Domain I – Assessment of knowledge				
1	Do you believe all drugs available in the market are safe?	0.776	0.636	
2	Are you aware that community pharmacists can report ADRs?	0.671	0.752	
3	Are you aware that ADRs can decrease the quality of treatment and compromise patient safety?	0.725	0.674	
4	Are you aware that ADRs can levy unnecessary health care costs?	0.816	0.593	
5	Are you aware of PvPI for reporting ADRs in India as a concern of Safety?	0.814	0.712	
6	Do you know the significance of ADR reporting?	0.692	0.735	0.97
Domain II – Assessment of attitude				
7	I feel that I should be involved in ADR reporting.	0.647	0.728	
8	I feel it is important for me to attend the training program in Pharmacovigilance	0.716	0.653	
9	I'm confident enough to report ADRs that I identify	0.883	0.681	
10	I prefer to consult a physician before ADR reporting	0.658	0.728	
11	I feel that I could significantly contribute to the signal generation process	0.723	0.677	
12	I feel it necessary to report ADRs caused by OTC drugs	0.598	0.812	
13	Reporting ADRs are one of the responsibilities of a practicing pharmacist	0.782	0.649	0.93
14	I would recommend ADR reporting to my fellow pharmacist	0.751	0.699	
Domain III – Assessment of practice				
15	Have you reported any ADR that you have observed in a patient during your practice?	0.684	0.816	
16	Do you counsel patients regarding possible ADRs while dispensing medication at your facility?	0.82	0.742	
17	Do you counsel patients on how to handle an ADR or drug-related event?	0.727	0.651	
18	Will you be able to spend few minutes to report ADR through any modality?	0.792	0.784	
19	Are you aware that ADR reporting is not cost consuming?	0.676	0.877	
20	Do you fear legal issues that may arise due to ADR reporting?	0.648	0.728	0.9

PvPI: Pharmacovigilance Program of India, ADR: Adverse drug reactions

Table 5: Factor structure analysis of individual constructs and convergent validity

Kaiser-Mayer-Olkin sampling adequacy measure=0.881				
Item	**Assessment of knowledge**	**Assessment of attitude**	**Assessment of practice**	**Construct wise Cronbach's alpha**
K_1	0.744			
K_2	0.852			
K_3	0.783			0.97
K_4	0.821			
K_5	0.765			
K_6	0.712			
A_1		0.783		
A_2		0.754		
A_3		0.846		0.93
A_4		0.758		
A_5		0.772		
A_6		0.846		
A_7		0.816		
A_8		0.768		

(Contd...)

Table 5: ***(Continued)***

Kaiser-Mayer-Olkin sampling adequacy measure=0.881				
Item	**Assessment of knowledge**	**Assessment of attitude**	**Assessment of practice**	**Construct wise Cronbach's alpha**
P_1			0.776	
P_2			0.861	
P_3			0.748	0.9
P_4			0.742	
P_5			0.865	
P_6			0.837	
Eigen value	2.193	2.53	2.242	
% of variance	5.98	4.47	6.38	16.83 (Total)

Table 6: Acknowledgment of factor structure for individual constructs

S. No	Construct	Number of items in construct	Composite reliability	Convergent validity (AVE)
1	Assessment of knowledge	6	0.922	0.641
2	Assessment of attitude	8	0.914	0.627
3	Assessment of practice	6	0.892	0.645

AVE: Average variance extracted

Table 7: Discriminant validity and squared correlation between the constructs

	Assessment of knowledge	Assessment of attitude	Assessment of practice
Assessment of knowledge	0.59[a]		
Assessment of attitude	0.40*	0.42[a]	
Assessment of practice	0.25*	0.38*	0.60[a]

*Denotes significant empirical distinction at 99% confidence interval (P<0.01); [a]Denotes the average variance extracted of the constructs

CONCLUSION

A 20-item containing, three domain questionnaires were developed and validated to assess the knowledge, attitude, and practice of CPs toward pharmacovigilance. This questionnaire has been developed to quantify the awareness and attitude of CPs toward ADR reporting and thereby arrive at outcomes to develop systematic strategies for promotion of ADR reporting by CPs. This questionnaire can be used in an interventional study setup to quantify the effect of educational programs to promote the role of CPs in pharmacovigilance. CPs play a crucial and irreplaceable role in the ADR reporting process as they are drug experts who bridge the gap between patients and a busy prescriber. Hence, this questionnaire could have significant roles in the assessment of awareness of CPs toward pharmacovigilance and promotion of their involvement in ADR reporting thereby accelerate the signal detection process. In addition, we also observed that despite adequate knowledge and a positive attitude toward pharmacovigilance CPs lag in practicing pharmacovigilance. Hence, factors that impair effective participation of CPs in the pharmacovigilance process need to be determined and critically analyzed.

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