



Development and Validation of Questionnaire to assess the Knowledge, Attitude and Practice towards Adverse Drug Reactions reporting among Healthcare Professionals

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Abstract:

Adverse drug reactions (ADR) are an important public health problem in terms of mortality, morbidity, socio-economic consequences and also its management. The aim of the study was to develop a validated questionnaire on knowledge, attitude and practice pattern (KAP) of healthcare professionals towards ADR reporting as per Central Drugs Standard Control Organization suspected adverse drug reaction reporting form. The development of the questionnaire was conducted in a standardized manner, using an accepted measure development methodology which included item development, content and face validation, pilot testing, and test-retest validation with appropriate statistical tests using SPSS software. The statistical analysis used were Descriptive statistics, Cronbach's α , Cohen's Kappa, T test, paired T test. A final set of 25 questions were framed of which 14, 7 and 4 are to assess KAP respectively. The knowledge questions evaluated knowledge on burden of ADR, reporting ADRs and pharmacovigilance. The attitude questions included opinions about reporting an ADR and includes the agreement towards preformed scale consisting agree, disagree and don't know. The practice questions collect the information regarding the approach to ADR or adverse event in their clinical experience. For categorization of knowledge, composite score was derived and divided into three groups. Score more than 66% is considered as adequate knowledge, 34 to 66% and less than 34% is considered as moderate and poor knowledge respectively. Availability of validated questionnaire which can give a consistent result is a hallmark of this study and this is a step towards providing reproducible results which can be used to assess KAP and to plan for necessary interventions.

Key words: ADR, adverse drug reaction, questionnaire, validation

Introduction:

Adverse drug reaction (ADR) is defined as "one which is noxious and unintended, and which occurs in doses normally used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological functions."¹ ADRs are an important public health problem in terms of mortality, morbidity, socio-economic consequences and also its management.²⁻⁴

The science and activities related to detection, assessment, understanding and prevention of adverse effects is known as pharmacovigilance.⁵ Constant effort has been made by the concerned authorities at different levels of healthcare system in

reinforcing reporting practices. In India, the entire process of monitoring ADRs and to create awareness amongst healthcare professionals about the importance of ADR reporting is taken by Pharmacovigilance Programme of India (PvPI). Spontaneous reporting of ADR by healthcare professionals (HCP) plays a major role in the detection, prevention of further ADR and monitoring such drugs.⁶ However, studies worldwide have shown gross under-reporting of ADR.⁷ Lack of sufficient knowledge and awareness among HCP on ADR reporting system is an important factor.⁸ A systematic review conducted across the globe has found 95% of under-reporting were due to ignorance.⁹

A good knowledge and attitude of HCP about ADR can greatly influence the extent of reporting and can be achieved through educational interventions like CME, conferences, workshops and lectures on pharmacovigilance for undergraduate and post graduate students.¹⁰ Thus, identifying the factors affecting reporting is vital so as to enable the ADR monitoring centers (AMC) / pharmacovigilance teams to implement educational interventions to enhance the rate and quality of reporting of ADR. Although several studies have been done to obtain the information, there is no valid questionnaire available and the consistency of results between each study varied due to difference in questionnaire.¹¹⁻¹⁵ So, there is a need for a standard questionnaire. Hence, this study was initiated to frame and validate a questionnaire to assess the knowledge, attitude and practice (KAP) towards the reporting of ADR among HCPs.

Objective: To develop and validate a questionnaire on knowledge, attitude and practice pattern of health care professionals towards ADR reporting.

Materials and Methods:

The development of the questionnaire on KAP on ADR reporting was conducted in a standardized manner, using an accepted measure development methodology which included item development, content and face validation, pilot testing, and test-retest validation. The study was conducted between December 2014 and June 2015 after obtaining ethical approval and informed consent from all participants. Personally identifiable information was not collected to protect the privacy. The questionnaire was targeted to collect the information on voluntary reporting of ADR by HCP as per Central Drugs Standard Control Organization (CDSCO), Government of India - suspected adverse drug reaction reporting form.

The process involved 2 important steps.

- A. The development of the questionnaire
- B. Scoring to determine the knowledge on burden of ADR, ADR reporting and pharmacovigilance.

A. The development of questionnaire

This was done in a standardized manner, which includes the following.

1. Item development:

- i. The questionnaire regarding KAP towards ADR reporting was developed by a multi-step process by the pharmacologist involved in ADR monitoring center after reviewing reporting system and related publications in Medline using Pubmed. The knowledge and practice questions are mainly composed of open ended questions and for attitude preformed scale which includes agree, disagree and don't know as the options were framed.

2. Content and face validation of items:

- i. Face and content validation of the item were done by the experts (coordinators/members) in the field of pharmacovigilance of different medical colleges and hospitals across the state.
- ii. Questionnaire was circulated among experts. The significance and relevance of each question in assessing the KAP were reviewed.
- iii. The relevant corrections and suggestions from each expert were considered with modifications of ambiguous and unfamiliar terms.

3. Pretesting:

- i. The questionnaire was pretested among 10 randomly selected health care professionals.
- ii. The feedback regarding the clarity, wordings and difficulty in filling the questionnaire were collected.
- iii. The corresponding amendments were made to keep the questions simple and specific.

4. Testing and retesting of the questionnaire:

For testing and retesting the questionnaire, the healthcare professionals in a tertiary care hospital were involved. A total of 70 HCPs were involved.

- i. The questionnaire was tested among 10 members each from different healthcare profession, viz. medical and dental doctors, interns, nurses and final year students of M.B.B.S., B.D.S. and nursing.
- ii. The participants were requested to complete the questionnaire without accessing to any external knowledge sources and the total time taken to complete the questionnaire was measured. Any difficulties in answering the questions were collected.
- iii. Retest was conducted to assess test-retest reliability after one day with the same members.

5. Analysis of the responses to questionnaire:

- i. Item properties were described using following criteria:
 - a) Proportion of missing answers: If the response to the questionnaire is less than 90%, then such responses are not considered for analysis.
 - b) Relevance of items written as not applicable: If the questions are written as not applicable by a particular group of HCP, then such questions are removed from analysis for that specific group.
- ii. For the reliability among knowledge and attitude questionnaire, internal consistency and reproducibility were examined.
 - a) For internal consistency, homogeneity was evaluated using Cronbach's α coefficient and values of 0.7 or more was considered significant.^{16,17}
 - b) For reproducibility, 2 sets of answers were examined.

For knowledge questions, Cohen's Kappa co-efficients were obtained and considering the classification presented by Landis & Koch, Kappa values of > 0.6 were considered as good reproducibility. This indicates at least, fair to substantial reproducibility, which represents the level of agreement between answers.¹⁸

For reproducibility of attitude questions, paired T test was used and 'p' value of less than 0.05 was considered as significant

difference between test and re-test responses.

Final Questionnaire:

- i. The final questionnaire was developed based on the analysis results and experts consensus with four main sections: General information, knowledge, attitudes and practices related to ADR reporting and its significances.

B. Scoring:

The 14 knowledge questions were divided into 2 parts of which 10 questions are for knowledge on ADR reporting and pharmacovigilance and 4 questions are for knowledge on burden of ADR. The maximum score for ADR reporting and pharmacovigilance was 21 and for burden, it was 7. The total knowledge score of a subject is the sum of scores obtained for each question. Missing answers were considered the lowest possible score (0) because we considered that the subject doesn't have knowledge for that domain.

For the question on knowledge about pharmacovigilance, a score of 1 was given to each component i.e. detection, assessment, understanding and prevention and hence maximum 4 was given. For the question on what constitutes serious adverse events, one right answer was scored as 2 with maximum score of 4 and for the type of ADR necessary to report, 0.5 score was given to each right option with maximum score of 2. For the open ended questions which need one word answer, each correct answer was scored as 2 and wrong or unanswered were scored as 0. A score of 1 was given for answers which made sense or close to the correct answers. For closed questions with yes or no options, the correct answers were graded as 1 and incorrect as 0.

Finally, for categorization of knowledge, composite score (CS) was used. A composite score in percentage was derived by dividing individual's score by the maximum possible score. The CS is divided into three groups. CS more than 66% is considered as adequate knowledge, 34 to 66% is considered as moderate

knowledge and less than 34% is considered as poor knowledge.

Results:

Initially, 28 item questions were framed. For knowledge on ADR reporting and pharmacovigilance, 8 questions and for burden of ADR, 5 questions were framed with a total of 13 questions. For attitude and practice, 7 and 8 questions were framed respectively. During content and face validity, the lacunae in the questions on knowledge were attended with 2 additional questions. The general opinion from the experts was that the questionnaire was well structured and included all important issues regarding KAP on ADR reporting for HCP. The evaluation of the face validity by the panel of experts resulted in minor vocabulary and grammatical changes. The expert consensus revealed that the questionnaire had sound face and content validity. A final version of 30 questions was framed and is arranged in the logical sequence. These 30 questions were pretested among 10 HCPs for any difficulty in answering the questionnaire and then testing and retesting was done among 70 HCPs. The median age of study participants was 23 years (22, 31) and female representation was 68.6%. Around 65% of the study subjects were aware of pharmacovigilance. (**Table I**) The response rate was more than 90% with an average time of 10 minutes and none of them had difficulty in responding during testing. Retest survey was conducted in the same 70 HCPs at a time interval of 1 day.

Study flow chart:

1. Pre-test Questionnaire

Knowledge	: 13 Questions
Attitude	: 07 Questions
Practice:	08 Questions

2. Content Validity:

Knowledge	: 15 Questions
Attitude	: 07 Questions
Practice:	08 Questions

Validated by 8 experts

3. Pretesting:

10 randomly selected HCPs

4. Testing and retesting questionnaire:

70 HCP: Medical and dental doctors, Medical and dental interns, nurses, students (Dental and Nursing) Time interval of 24 hours
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5. Analysis:

Item properties:
Proportion of missing answers
Relevance of not applicable responses
Score distributions
Reliability:
Internal consistency
Reproducibility
Validity
Construct validity,
Known group validity

6. Final questionnaire

Knowledge	: 14 Questions
On ADR reporting:	10
On Burden of ADR:	04
Attitude	: 07 Questions
Practice:	04 Questions

7. Scoring

For Knowledge : Maximum score 28
On ADR reporting: Maximum score 21
On Burden of ADR: Maximum score 07
Composite score: Percentage of Individual score over Maximum score.
➤ 66% : Adequate knowledge.
34 - 66 : Moderate knowledge
< 34 : Poor knowledge
Attitude : 07 Questions
Practice : 04 Questions

Table I: Background of the participants

Sl. No	Healthcare Professionals	Total subjects	Gender		Experience Average (years)	Aware on Pharmacovigilance	
			Male	Female		Yes	No
1	Medical Faculty	11	8	3	8.5	10	1
2	Medical Interns	10	6	4	0	9	1
3	Dental Faculty	10	6	4	7.6	6	4
4	Dental Interns	9	0	9	0	3	6
5	BDS Final Year Students	10	2	8	0	2	8
6	Nursing Staff	10	0	10	6.8	8	2
7	Nursing Final Year Students	10	0	10	0	8	2
	Total	70	22	48	NR	46	24

NR: Not relevant

Table II: Cronbach's alpha values to check for internal consistency

Sl. No.	M	C	Sl. No.	M	C	Sl. No.	M	C
K1	13.43	0.72	K8	13.80	0.74	A1	9.09	0.84
K2	13.83	0.70	K9	13.78	0.74	A2	9.17	0.82
K3	14.35	0.71	K10	13.09	0.76	A3	9.37	0.84
K4	13.98	0.72	K11	13.65	0.68	A4	9.30	0.86
K5	13.20	0.70	K12	13.43	0.78	A5	9.24	0.83
K6	13.30	0.71	K13	14.33	0.70	A6	8.39	0.84
K7	13.83	0.68	K14	13.89	0.74	A7	7.65	0.80

Table III: Cohen's kappa coefficients to assess reproducibility of knowledge questions and Paired T test to assess reproducibility of attitude questions

Knowledge						Attitude	
Sl. No.	Kappa values	Cohen's kappa P value	Sl. No.	Kappa values	Cohen's kappa P value	Sl.No	Paired T test P value
K1	0.60	<0.005	K8	0.64	<0.005	A1	0.164
K2	0.42	<0.005	K9	0.65	<0.005	A2	1.000
K3	0.70	<0.005	K10	0.72	<0.005	A3	0.785
K4	0.68	<0.005	K11	0.61	<0.005	A4	0.323
K5	0.83	<0.005	K12	0.63	<0.005	A5	0.710
K6	0.67	<0.005	K13	0.43	<0.005	A6	0.837
K7	0.64	<0.005	K14	0.78	<0.005	A7	1.000

Kappa values > 0.6: good reproducibility. Paired T test: P < 0.05 is considered significant

For internal consistency, the Cronbach's α co-efficient was 0.7 or more in all except 2 questions which were modified resulting in acceptable internal consistency (Table II). The Cohen's kappa co-efficients were 0.6 and more in all except for 2 knowledge

questions. Paired "T" test for attitude questions showed no significant differences among test and post-test responses and hence these were considered as good reproducibility (Table III).

Table IV: Differences between known group and another group: Knowledge and attitude questions

Knowledge Questions						Attitude Questions		
Sl No.	T- test	P value	Sl No.	T- test	P value	Sl.No	T- test	P value
K1	2.65	0.017*	K8	2.34	0.035*	A1	1.97	0.04*
K2	1.63	0.042*	K9	1.56	0.045*	A2	1.66	0.03*
K3	1.03	0.043*	K10	2.11	0.049*	A3	2.34	0.002*
K4	1.53	0.047*	K11	8.51	<0.001*	A4	1.50	0.004*
K5	2.15	0.049*	K12	2.01	0.48	A5	1.89	0.03*
K6	4.00	0.001*	K13	3.11	0.007*	A6	2.53	0.001*
K7	5.69	<0.001*	K14	3.81	0.002*	A7	1.599	0.04*

P < 0.05 is considered significant

Table V: Known group validity

Variable	Mean score	SD	T- test value	P value
Knowledge				
Medical practitioners	17.8	3.22	6.67	<0.001
Dental interns	9.6	1.8		
Attitude				
Medical practitioners	10.9	1.4	2.19	<0.05
Dental interns	07.6	4.1		

Table VI: Final questionnaire

K1	What do you understand by pharmacovigilance?
K2	What percentage of ADR leads to hospitalization?
K3	What percentage of in-patients experience ADR?
K4	Are the entire ADRs known before the drug is released into the market?
K5	What type of ADR is necessary to report? A. Untreatable ADRs B. Serious ADRs C. New ADRs D. Known ADRs E. All ADRs
K6	What constitutes serious adverse event? (Mention at least two)
K7	Who gets benefit of reporting an ADR?
K8	Should the reactions due to blood transfusion be reported?
K9	Should the reactions due to vaccination be reported?
K10	Who can report an ADR? D:Doctor N:Nurses P:Patients G:General Population
K11	To whom does an ADR have to be reported?
K12	ADR reports should be sent to AMC within how many days of suspected ADR?
K13	Does your hospital have an ADR monitoring center?
K14	Mention any familiar drug withdrawn from the market due to ADR reporting?
A1	One should be certain of the ADR due to particular drug
A2	One should have a suspicion of possible ADR during treatment
A3	ADR reporting by one person can make a significant difference to the community
A4	ADR reporting in the hospital by healthcare professional should be voluntary
A5	ADR reporting in the hospital should be mandatory
A6	ADR reporting in the hospital should be financially rewarded
A7	ADR reporting in the hospital is not required
P1	How many times have you reported the ADR?
P2	What will you do when you come across any ADR?
P3	How frequently do you include ADR as a differential diagnosis?

P4	What factors discourage you from reporting ADRs? (tick all that apply) Not aware that I need to report Don't know where to report Don't know how to report Problem with diagnosing ADR. Problem of confidentiality with patient's data. Management of patients was more important than reporting. Fear of negative impact. Legal liability issues Others
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Known group validity was measured between medical practitioners, who are aware of pharmacovigilance and dental interns, who are unaware of pharmacovigilance. Medical practitioners had better score than dental interns and it was found to have a significant difference between groups $p < 0.05$. (Table IV and Table V)

A final set of 25 questions are framed of which 14 are to assess knowledge, 7 and 4 are to assess attitude and practice respectively. The question numbers K2, K3, K4 and K14 represents the knowledge on burden of ADR and the remaining questions represent for knowledge on

Table VII: Average composite score regarding knowledge on ADR reporting and burden of ADR among healthcare professionals

Sl. No	Healthcare professionals	Average composite score on knowledge on ADR reporting	Average composite score on knowledge on ADR burden
1	Medical Faculty	66.66	47.14
2	Medical Interns	39.28	34.28
3	Dental Faculty	46.28	45.71
4	Dental Interns	35.44	33.33
5	B.D.S. Final Year Students	34.76	42.85
6	Nursing Staff	48.57	27.14
7	Nursing Final Year Students	40.47	14.28

Discussion:

Validation of questionnaire is an important step in any questionnaire based study. Many questionnaire based observational studies on ADR reporting have been conducted till date but the information obtained from these studies is variable even with the similar objectives. The format and framework of questionnaire used in many of these studies conducted for KAP were not in uniformity to produce consistent results. ⁽¹¹⁻¹⁵⁾ Hence, this study

reporting ADR and pharmacovigilance. The attitude questions include their opinions about reporting an ADR and includes the agreement towards preformed scale consisting agree, disagree and don't know. The practice questions collect the information regarding the approach to ADR or adverse event in their clinical experience (Table VI).

The results regarding average composite score and the knowledge on ADR reporting and burden of ADR among healthcare professionals are given in Table VII & VIII.

was conducted to prepare a questionnaire which is validated to obtain information of KAP regarding ADR reporting.

Inputs regarding the clarity and authenticity were continuously discussed with the experts throughout the study. The target population for this study was the HCPs, viz. qualified doctors, nursing staff, dentists, interns and students. They were selected as they are the first to come in contact with patients of any adverse effects and can distinguish better between the adverse effects of a drug and disease itself.

Table VIII: Knowledge on ADR reporting and burden of ADR among healthcare professionals

Sl. No	Health care professionals	No. of subjects						
		Total	Knowledge on ADR reporting			Knowledge on ADR burden		
			A	M	P	A	M	P
1	Medical Faculty	11	8	3	0	1	8	2
2	Medical Interns	10	0	7	3	1	5	4
3	Dental Faculty	10	0	8	2	3	4	3
4	Dental Interns	9	0	5	4	0	5	4
5	BDS Final Year Students	10	0	5	5	2	4	4
6	Nursing Staff	10	1	8	1	1	2	7
7	Nursing Final Year Students	10	0	8	2	0	0	0
	Total	70	9	44	17	9	28	24

A = Adequate knowledge, M = Moderate knowledge, P = Poor knowledge

Moreover, sensitizing these HCPs on ADR reporting and its associated interventions to report the ADR will yield good result.^{6, 10, 14}

The questionnaire on ADR reporting and pharmacovigilance among healthcare workers is mainly composed of open ended questions to assess knowledge and practice which can avoid the guessing and hence prevent false impression. However, for information on the attitude, statements were framed and the respondents were asked to indicate their agreement towards preformed scale which includes agree, disagree and don't know as the options.¹⁹ For assessing the knowledge, questions were framed to know their understanding on pharmacovigilance, ADRs, its problem in the society and in hospital, serious adverse events and the method of its reporting and benefits of reporting ADRs. During testing, the practice part of the questionnaire was written as "not applicable" by the final year students and interns and hence was not included for analysis. Twenty six subjects felt it difficult to answer the question, 'what happens after reporting an ADR' and was removed as suggested by the subjects and decided by the expert committee. The investigators did not notice any difficulty in the interpretation or comprehension of the other questions by the participants.

For internal consistency, the Cronbach's α co-efficient of 2 questions was less than 0.7 and hence modified. The question 'who gets benefit of reporting an ADR?' with options of patients, doctors, hospital and community were confusing as doctors and patients are included within hospital and hospital belongs to community and hence it was converted to an open ended question. For the question 'to whom an ADR has to be reported?' the responses were doctors, hospital and AMC. As the 1st two responses are overlapping, the score for doctor was also given equal score of 1 as that of hospital. With this modification Cronbach's α coefficient increased to 0.72 and considered acceptable internal consistency. For reproducibility, Cohen's kappa co-efficient was not significant for the response on 'what percentage of ADR leads to hospitalization' and 'does your hospital have an ADR monitoring center?' The variations were expected as the subjects updated their knowledge after discussing among their colleagues. Known group validity was analyzed between medical practitioners who had previous exposure to pharmacovigilance and dental interns who have no exposure to pharmacovigilance. Concurrent validity was not used as we couldn't find the validated questionnaire for knowing KAP on ADR reporting in India. For responsiveness of an intervention, already a validated questionnaire is available. So,

the same questionnaire can be used to check the responsiveness of an intervention.¹⁰

Composite scoring was used for categorizing the knowledge which will help in knowing the final outcome. The categorization was based on expected responses given by subject experts for adequate and moderate knowledge.

Study Strengths and Limitations: Study was conducted in a standardized manner, using an accepted methodology and statistical tests.^{19, 20} Sample size of 70 HCPs was statistically calculated and was a good number for validation of questionnaire. Since there is a continuous change in the regulations by the concerned authorities, it needs to be updated on a regular basis.

Future: The data obtained with this validated questionnaire covering important aspects of ADR reporting can be used by different investigators to assess KAP on ADR reporting and also to assess the usefulness of any interventional strategies. This helps in pooling of valid data from different centers and hence will help the policy makers to form any new interventions if required to improve reporting of ADR.

Conclusion:

Availability of the questionnaire which can give a consistent result is a hallmark of this study. Since there was no such validated questionnaire available regarding KAP on reporting ADR by healthcare professionals, this is a step towards providing reproducible results.

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