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Research Article

Development and Validation of a Questionnaire for the Assessment of the Factors that Influence ADR Reporting by Pharmacists

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Abstract

Drug safety is a significant concern in many countries, as side effects (AE) and adverse drug reactions (ADR) have caused many deaths worldwide. One of the reasons is the low contribution of pharmacists in spontaneously reporting AE/ADR. This study aims to develop a questionnaire to assess factors that correlate with spontaneous reporting by pharmacists. A questionnaire pilot was tested on 30 pharmacist respondents who worked in type C hospitals in Surabaya and Sidoarjo, Indonesia. Respondents' responses were then evaluated for face validity, construct validity, and reliability. The results showed that the face validity of the questionnaire was ideal. Then, the results of the construct validity of the knowledge section using point biserial correlation showed that two items were invalid because the r-value was smaller than the r-table (r = 0.361). Then, construct validity uses the factor analysis method for psychological, environmental, and practical variables by paying attention to the Kaiser-Mayer-Olkin Measure (KMO) value, which must be greater than 0.5, the significance of the Bartlett test, which must be less than 0.05 and the factor loading value which conditions must be greater than 0.5. As a result, most of the psychological, environmental, and practical variables show valid and reliable results. However, further consideration should be given to eliminating some items that do not meet the requirements. In conclusion, this validated questionnaire can be used to obtain additional information regarding factors influencing spontaneous reporting by pharmacists.

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INTRODUCTION

Drug safety is a significant concern in several countries, monitored and evaluated through pharmacovigilance systems. Pharmacovigilance is an activity related to detecting, evaluating, understanding, and preventing adverse drug reactions (ADR)[1]. Pharmacovigilance activities include periodic security update reports, commonly called spontaneous reporting. Spontaneous reporting of adverse events (AE)/ADR is one element of pharmacovigilance activities that help overcome safety concerns after drug administration[2]. This reporting activity provides actual information regarding the safety profile of real-life clinical practices compared to the results of clinical trials using only a few samples and the safety of drugs studied in a limited time[3]. Spontaneous reporting is a cost-effective, flexible, and highly effective method of gathering information because health workers voluntarily submit AE/ADR case reports to the National Pharmacovigilance Center of the Food and Drug, The Indonesian Food and Drug Authority (*Badan Pengawas Obat dan Makanan Republik Indonesia*, BPOM RI) for analysis, which will later help to reduce the potential for AE/ADR in patients[4].

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Spontaneous reporting is a method that contributes significantly to the improvement of pharmacovigilance in some countries[5]. Several regulators in other countries have designed easy systems for spontaneous reporting intending to increase the participation of health workers in spontaneous reporting, but in reality, the rate of spontaneous AE/ADR reporting is still low[6,7]. Spontaneous reporting of AE/ADR in several less progressive countries is of particular concern, considering that these less developed countries contribute to 80% of the disease burden in the world. However, they only participate in AE/ADR reports in less than 1% of all global reports (11,824,804)[8].

Little participation in AE/ADR reporting in less developed countries such as Indonesia cannot be explained because the law does not require it. Spontaneous reporting of AE/ADR, reporting still needs to be improved[9]. The low level of AE/ADR reporting is caused by several factors, such as not caring about patient safety, feeling they have no responsibility to report, complicated reporting procedures, and poor knowledge and attitudes of health workers, which impacts AE/ADR reporting practices[10]. However, research on factors that correlate with spontaneous reporting practices in Indonesia still needs to be improved.

Therefore, research related to this needs to be done. Because research related to the factors that influence the practice of spontaneous reporting is still new, it requires instruments with good validity and reliability so that the data collection process is accurate and precise. Research instruments for observational research that look at the factors that influence a person generally use questionnaires because questionnaires are relatively easy to collect data in research and policy evaluation. Information containing knowledge, attitudes, opinions, behavior, and facts will be easily collected using a questionnaire[11]. Of course, a questionnaire with good validity and reliability requires a development process first from evaluating the validity and reliability of test results[12].

Validity and reliability are the two most essential and fundamental features in evaluating any measurement instrument or tool for good research, one of which is a questionnaire. Without assessing the reliability and validity of the study, it will be difficult to describe the effects of measurement errors on the theoretical relationships being measured[13]. Research with a valid questionnaire will produce data that follows the construct built by the researcher. As for reliability, it serves to minimize measurement errors from questionnaires when taking data. Reliability is an indicator of questionnaire consistency when measuring certain concepts[12].

Given the importance of validity and reliability testing for a research questionnaire, it should be a priority before taking data. However, a review of articles from 748 studies found that one-third did not attach procedures to establish validity (31%) or reliability (33%). Meanwhile, developing accurate and precise questionnaires is needed to decrease measurement errors, namely mismatches between respondent attributes and survey responses[14]. Validity and reliability tests must be carried out before data collection to reduce measurement errors and measure the questionnaire's reproducibility, and the results will be evaluated later. Therefore, this study aims to test the validity and reliability of a questionnaire developed to measure pharmacists' knowledge and management of spontaneous reporting.

MATERIALS AND METHODS

Materials

The instrument in this study was a questionnaire created by researchers based on World Health Organization (WHO) and BPOM RI pharmacovigilance guidelines[15-20]. In addition, the results of expert consultation were considered. The questionnaire consisted of five parts: pharmacist demographic characteristics, knowledge included in individual variables, psychological variables, environmental variables, and the practices that pharmacists engaged in spontaneous reporting. For the demographics section, there were 15 question items. For the part of knowledge included in individual variables, there were 13 questions. For psychological variables, there were 14 questions. Environmental variables totaled nine questions, and practice summed 19 questions. The total number of questions in the questionnaire was 55 questions (**Table I**). The questionnaire was validated in two stages: the first stage was face validation for the overall appearance of the questionnaire, and the second stage was construct validation to see whether the questionnaire could produce data following the construct developed by the researcher. Constructing validation in this questionnaire was divided into two methods. The first method was biserial point correlation for the knowledge section because the answer scale was the Guttman scale or dichotomy[21].

Because the answer scale used an ordinal scale, the factor analysis method was applied for psychological, environmental, and practice factors[22].

Table I. Question items in each instrument domain.

Variable	Questions	Number in questionnaire
Knowledge	One of the points in pharmacovigilance activities is the detection and prevention of AE/ADR so that additional reactions that are detrimental to the patient do not occur.	1
	Adverse drug reaction monitoring applies to drugs that have been around for a long time, such as captopril, simvastatin, and the like	2
	Drug reconstitution that is carried out haphazardly and without sterility has the potential to cause adverse events (AE) in patients.	3
	Adverse Drug Reactions (ADR) are part of adverse events whose causes are known from the drugs consumed by the patient.	4
	As health workers, pharmacists should report any AE/ADR encountered as part of their professional responsibility.	5
	The spontaneous reporting of AE/ADR can only be done manually via a yellow form sent by post to the pharmacovigilance centre of Balai POM.	6
	Post-Immunization Adverse Events during vaccine use are not required to be reported to BPOM.	7
	The institution that acts as the national pharmacovigilance centre in Indonesia is BPOM.	8
	Spontaneous reporting is only those that are unexpected (Unexpected Adverse Reaction).	9
	AE/ADR is one of the contributors to the highest number of deaths in various countries.	10
	Decreased absorption of omeprazole due to drug interactions with antacids does not need to be reported.	11
	Incidents of side effects due to drug overdose or medication errors need to be reported.	12
	The withdrawal of the Albothyl product in 2018 and the call to improve the drug's indications so that it is not used for mouth ulcers is an example of implementing pharmacovigilance activities so that the public can avoid serious drug side effects.	13
Psychological	Pharmacists in healthcare facilities play an essential role in pharmacovigilance activities.	14
	Pharmacists in health service facilities must regularly update their knowledge regarding pharmacovigilance.	15
	If a drug side effect occurs in their practice, the pharmacist is not obliged to report it.	16
	Pharmacists in health service facilities are the public's first reference in reporting AE/ADR.	17
	Pharmacists must receive special training regarding pharmacovigilance.	18
	Spontaneous reporting of AE/ADR must be done voluntarily or as part of professionalism.	19
	Reporting and monitoring of AE/ADR will be beneficial for patients.	20
	AE/ADR that occur due to over-the-counter drugs/limited over-the-counter and over-the-counter drugs must also be reported.	21
	Reporting AE/ADR will add more insight regarding the side effects of drugs encountered in practice.	22
	Reporting AE/ADR experienced by patients is a sign that their concerns are being taken seriously.	23
	Spontaneous reporting of AE/ADR is part of pharmaceutical care.	24
	AE/ADR must be reported even if the impact does not result in hospitalization, life-threatening conditions, disability, or death.	25
	All adverse events/ESOs that occur as a result of drugs that have just received distribution permits and medicines that have been on the market for a long time must be reported.	26
	AE/ADR reporting must be done immediately, especially for dangerous or unexpected events (Unexpected Adverse Reaction).	27
Environment	The pharmacist where I practice applies a regular shift work system.	28
	In one work shift, the pharmacist at my workplace practices according to the specified working hours.	29
	The pharmacists' working hours where I work follow the given workload.	30
	My workplace will give rewards/awards to pharmacists if they make innovations in their work or succeed in achieving specific targets.	31
	Promotions at my workplace are carried out objectively based on the achievements and contributions of a pharmacist.	32
	The income I get from my workplace is enough for me because it matches my workload.	33
	My workplace will provide additional income if there is extra work or overtime provided	34
	The portion of work at my workplace is proportional enough to do other work without needing overtime.	35
	I complete work while at work and never do work at home/outside of my working hours	36
Practice	The frequency with which I encounter reports of drug side effects or adverse events from patients at work.	37
	The frequency with which the hospital where I work reports drug side effects or adverse events to the BPOM National Pharmacovigilance Center	38

	I immediately report all drug side effects or adverse events reported by the patient to the unit head/head of pharmacy installation/pharmacist responsible for spontaneous reporting to BPOM.	39
	I document all reports of drug side effects or adverse events from patients, both unexpected and expected.	40
	I report and document all actions and interventions I provide to patients according to the patient's complaints.	41
	Suppose there is a complaint that a patient has a dry cough due to using the drug captopril. In that case, I will report it to the unit head/head of pharmacy installation/pharmacist responsible for spontaneous reporting to BPOM.	42
	Suppose there is a complaint that a patient experiences extrapyramidal syndrome due to the use of the drug metoclopramide. In that case, I will report it to the unit head/head of pharmacy installation/pharmacist responsible for spontaneous reporting to BPOM.	43
	Suppose there is an incident of decreased absorption of the drug omeprazole as a result of drug interactions with antacids. In that case, I will report it to the unit head/head of pharmacy installation/pharmacist responsible for spontaneous reporting to BPOM.	44
	I carried out a causality analysis first with the doctor who provided therapy to the patient to ensure the causality of the side effects of the medication experienced by the patient.	45
	I include information in the form of reporting data, data on patients who submit complaints, complaints felt by patients, and data on suspected drugs in every report I submit to the head of the unit/head of the pharmacy installation/pharmacist responsible for spontaneous reporting to BPOM.	46
	I discussed with the doctor who provides therapy to treat patients who experience side effects from drugs.	47
	I take my time at work to handle drug safety incident complaints from patients immediately.	48
	I take the time to do documentation and report cases of drug side effects or adverse events encountered in patients.	49
	I prioritize work related to patient safety while undergoing therapy.	50
	I apply all points of clinical pharmacy services, including monitoring drug side effects (MESO) following the Minister of Health Regulations, where I practice.	51
	I actively participate in the spontaneous reporting of drug side effects or adverse events as a form of professionalism and compliance with regulations.	52
	I have a spontaneous reporting account at e-meso.pom.go.id or the e-meso mobile smartphone application and operate it actively.	53
	I provide a yellow form for spontaneous reporting of drug side effects to BPOM manually at my practice.	54
	I participated in multilevel pharmacovigilance training held by BPOM as the national pharmacovigilance centre.	55

Methods

Design and participant

This study was conducted between September and October 2023 in pharmacists working full-time at type C hospitals in Surabaya and Sidoarjo, East Java, Indonesia. Type C hospitals were chosen because the number of type C hospitals is the largest in Indonesia, but the contribution of reports of adverse drug reactions is low[16,23]. There were 30 samples recommended by Hertzog[24]. The Health Research Ethics Commission (KEPK), Faculty of Dentistry, Universitas Airlangga, issued the certificate of ethical eligibility for this study, with number 987/HRECC. FODM/VIII/2023.

Face validity

The method used to assess face validity was to provide a suggestion and improvement column at the end of the questionnaire to comment on all parts of the questionnaire in terms of language, font size, font, and word choice. Face validity was a subjective assessment of the operation of a construct. A test was valid if its content seemed relevant to the person working on it. It evaluated the appearance of the questionnaire in terms of feasibility, readability, consistency of style and format, and clarity of the language used. In other words, face validity referred to the researcher's subjective assessment of the presentation and relevance of the measuring instrument, whether the items appeared relevant, reasonable, clear, and transparent[25].

Data analysis

Construct validity test

The construct validity test used two methods to determine the questionnaire's construct conformity. The first method used the biserial point correlation for the knowledge section, and the second used factor analysis for psychological,

environmental, and practice variables questionnaires. For biserial point correlation to check the validity of the knowledge section, the method using Microsoft Excel tools to show the difference between the r-value and the r-table, in which Rpb was biserial point correlation coefficient, xi was average total score of respondents who answered correctly, xt was average total score of all respondents, Pi was proportion of correct answers item i, Qi was 1-Pi, and St was standard deviation of the total score, as shown in **Equation 1**. **Equation 1** was used to calculate the r-value to show the validity of the questionnaire item[26]. This calculation was applied to each knowledge question item. The question item was considered valid if the computed r-value offered a value greater than the r-table, and vice versa.

$$Rpb = \frac{xi-xt}{St}\sqrt{Pi}/q \qquad [1]$$

The second method was factor analysis using several indicators using IBM SPSS Statistics 26 (https://www.ibm.com/support/pages/downloading-ibm-spss-statistics-26). The first indicator was the Kaiser-Meyer-Olkin (KMO) measurement. This parameter compared the correlation coefficient value with the partial coefficient value. The requirement for factor analysis was that the KMO value had to be higher than 0.5. Bartlett's Test of sphericity tested the dependence between the variables being tested. This parameter helped indicate the absence of correlation between variables with each other in the community. The significance value in Bartlett's Test had to be less than 0.05 so that the process could continue for factor analysis. The following indicator showed the result of the calculation of the anti-image correlation. Grades with 'A' indicated the Measure of Sampling Adequacy (MSA) value. If the MSA number for a variable was below 0.5, then the variable had to be excluded, and variable selection had to be repeated. The last indicators were the Component Matrix and Rotated Component Matrix, which helped explain the spread of variables into factors formed. The Component Matrix confirmed whether or not there was a correlation between items and components. A high correlation value showed a solid relationship between the items and the components so that the items could be used as a factor. In a complex matrix, interpreting these factors was quite rare because it was difficult. Therefore, the factor alteration used in matrix factor rotation was converted into a more friendly form to understand. The steps for factor analysis in SPSS were selecting the analysis menu, selecting dimension and factor reduction, selecting the variables to be analyzed, selecting the descriptive option, checking the initial solution, KMO, Bartlett's Test of sphericity, and anti-image, selecting OK, then selecting the rotation menu to select varimax and check rotated solution and loading plots, and finally selecting OK for the analysis process[27].

Reliability test

Reliability testing aimed to see how consistent a questionnaire was when used for data collection. The method used was to look at the value of Cronbach α, which had to be greater than 0.6 for qualified reliability[28]. However, another theory was that if the Cronbach α value was 0.5-0.7, the questionnaire could be considered moderately reliable and still be used for research data collection[29,30]. The way to carry out reliability analysis in IBM SPSS Statistics 26 tools was to select the analyze menu, click scale and select reliability analysis, then choose the variable to be measured, click the statistics menu, and check the scale if the item deleted option, then clicked ok to process the analysis, later the results would display the Cronbach α value of analyzed variables.

RESULTS AND DISCUSSION

This questionnaire pilot test found 30 pharmacist respondents who worked in type C hospitals in Surabaya and Sidoarjo. The majority of respondents were 28 (93.3%) female. Most respondents were 28 (93.3%) from type C hospitals in Surabaya and 2 (6.6%) from type C hospitals in Sidoarjo. Face validity shows that overall, the pilot test respondents said that the grammar of the questionnaire was excellent and easy to understand, and the sentence structure was not ambiguous so that respondents could understand the meaning of the questions on the questionnaire. The font size and typeface used are also ideal, according to respondents. The form validation method is similar to testing the validity of questionnaires conducted in India when testing the validity of work-related stress questionnaires (TAWS-16)[31].

The results of construct validation of the knowledge question item section that is included in individual variables can be seen in **Table II**. The calculation results in **Table II** are interpreted by comparing the calculated r-value with the r-table. The question item is arguably valid if the calculated r-value exceeds the r-table[32]. Based on the data above, two knowledge

question items show invalid results because the calculated r-value is smaller than the r-table: question items number 4 and 13. Several factors can cause the invalidity of the question item. The first possibility is that the question item contains a sentence that leads the respondent to lean toward one answer choice, or the other option is that the question item cannot describe the intention the researcher wants to ask. Hence, the respondent gives an inappropriate response[33].

Table II. Knowledge question item validation results.

Number	R table	R-value	Interpretation of results	Number in Questionnaire
1	0.361	0.559027	Item valid	1
2	0.361	0.374257	Item valid	2
3	0.361	0.455515	Item valid	3
4	0.361	-0.2747*	Item not valid	4
5	0.361	0.403602	Item valid	5
6	0.361	0.488807	Item valid	6
7	0.361	0.52928	Item valid	7
8	0.361	0.421993	Item valid	8
9	0.361	0.548176	Item valid	9
10	0.361	0.471245	Item valid	10
11	0.361	0.397606	Item valid	11
12	0.361	0.569651	Item valid	12
13	0.361	0.268317*	Item not valid	13

* invalid item

The next validity test is for psychological, environmental, and practical variables, using factor analysis methods. The first indicator shows the value of the KMO Measure and the significance values of psychological, environmental, and practice variables. The KMO and Bartlett's tests are data suitability tests that must be performed before interpreting the factor analysis results. The MSA is a statistical value that indicates the proportion of diversity in the variables on which factor analysis is based[34]. If the MSA value >0.50, It is concluded that the questionnaire can be used to measure respondents' answers precisely. If it shows a KMO value of more than 0.5 and a significance value of less than 0.05, the variable can be used for further data collection and analysis[27].

Bartlett's test examines whether the indicators used correlate and are suitable for factor analysis. If the value of Bartlett's test is less than 0.05, it is concluded that the indicators used are correlated and ideal for factor analysis. The KMO values of psychological, environmental, and practice variables are 0.535 each, 0,582, and 0.634, with each significant value below 0.05. These results show that the indicators used in this study are correlated and appropriate for factor analysis[27].

Factor analysis requires the data matrix to correlate factor analysis. The correlation value is shown in the anti-image correlation matrix. The MSA value on the diagonal anti-image correlation with the sign is expected to be above 0.5[27]. **Table III** shows that each variable has a question item whose value is less than 0.5. The first of the psychological variables shows that items 4, 8, and 13 have values less than 0.5, which are 0.229, 0.386, and 0.306. The second environmental variable is shown in item number 3; whose value is less than 0.5, which is 0.4[35]. Finally, from the practice variables, there are four items whose value is less than 0.5: items 1, 13, 18, and 19. Based on these results, question items with an MSA value of less than 0.5 cannot be continued for the data retrieval process, while other items with an MSA value of more than 0.5 can be used for the data retrieval process[22].

The results of the subsequent construct validation can be seen in **Table IV**. **Table IV** presents loading factor coefficient data explaining the connection between the origin variable and the factor. A significant correlation value denotes a solid relationship between the factor and the original variable, which means that the variable can be used as a factor. In a complex matrix, interpreting these factors is quite rare because it is difficult. Therefore, the factor alteration used in matrix factor rotation is converted into a more friendly form to understand[36].

Rotated Component Matrix is the value of the distribution of variables that have been extracted into factors that are formed based on the loading factor after the transformation process to a form that is easier to understand. The loading factor value could turn after the process rotation. Component variables with a loading factor of less than 0.5 are deemed not to contribute to the factors formed significantly, so they must be eliminated from the factors formed[27]. However, for this loading factor value, there is a theory that says if the value is more than 0.3, then the item has shown a close relationship between items on the factor formed[35]. However, in this study, all items on each variable have a loading factor value of more than 0.5, meaning that all indicator items have a close relationship with the factors formed[36].

Table III. Measurement results of MSA of psychological, environment, and practice variables.

Number of items	Standard	Anti-image correlation					
		MSA value					
		Var. psychological	Number in questionnaire	Var. environment	Number in questionnaire	Var. practice	Number in questionnaire
1	0.5	0.724	14	0.628	28	0.494*	37
2	0.5	0.513	15	0.576	29	0.705	38
3	0.5	0.560	16	0.435*	30	0.719	39
4	0.5	0.229*	17	0.623	31	0.820	40
5	0.5	0.713	18	0.518	32	0.653	41
6	0.5	0.666	19	0.596	33	0.511	42
7	0.5	0.778	20	0.630	34	0.727	43
8	0.5	0.386*	21	0.616	35	0.525	44
9	0.5	0.529	22	0.547	36	0.544	45
10	0.5	0.517	23			0.719	46
11	0.5	0.555	24			0.651	47
12	0.5	0.777	25			0.705	48
13	0.5	0.306*	26			0.443*	49
14	0.5	0.541	27			0.620	50
15	0.5					0.628	51
16	0.5					0.675	52
17	0.5					0.667	53
18	0.5					0.161*	54
19	0.5					0.492*	55

* item does not meet the requirement

Table IV. Results of loading factor measurement of psychological, environmental, and practice variables from the Rotated Component Matrix.

Item number	Rotated Component Matrix								
	Var. psychological			Var. environment			Var. practice		
	Loading factor value	Factor categories	Number in questionnaire	Loading factor value	Factor categories	Number in questionnaire	Loading factor value	Factor categories	Number in questionnaire
1	0.764	Factor 2	14	0.775	Factor 1	28	0.698	Factor 5	37
2	0.681	Factor 1	15	0.890	Factor 1	29	0.728	Factor 1	38
3	0.798	Factor 2	16	0.890	Factor 4*	30	0.849	Factor 1	39
4	0.889	Factor 4	17	0.660	Factor 2	31	0.905	Factor 1	40
5	0.641	Factor 2	18	0.829	Factor 2	32	0.572	Factor 3*	41
6	0.602	Factor 1	19	0.853	Factor 3*	33	0.821	Factor 4*	42
7	0.759	Factor 2	20	0.804	Factor 2	34	0.745	Factor 1	43
8	0.599	Factor 3*	21	0.780	Factor 3*	35	0.597	Factor 6*	44
9	0.805	Factor 1	22	0.530	Factor 1	36	0.682	Factor 5	45
10	0.757	Factor 1	23				0.867	Factor 1	46
11	0.799	Factor 1	24				0.724	Factor 2*	47
12	0.777	Factor 3*	25				0.733	Factor 2*	48
13	0.832	Factor 3*	26				0.918	Factor 3*	49
14	0.639	Factor 2	27				0.689	Factor 3*	50
15							0.687	Factor 2*	51
16							0.560	Factor 1	52
17							0.663	Factor 2*	53
18							0.907	Factor 6*	54
19							0.849	Factor 4*	55

* item does not meet the requirement

The calculated component transformation analysis results must support the results in **Table IV**. Suppose the component value of a variable shows a value that is large or more than 0.5. In that case, the relationship between the factors or components that make up a variable is getting closer[37]. Based on the component transformation matrix calculation, psychological variables are divided into four components. Still, component number three has a value of less than 0.5, so component number three is considered not to describe the construct of psychological variables. In **Table IV**, the psychological variables section results from factor loadings on psychological variables, which are included in factor or component 3 in items 8, 12, and 13, which are not included as components that make up psychological variables. Likewise, for environmental variables where the results of the transformation component matrix are only components 1 and 2, which have a solid correlation, meaning that the environmental variable question items included in components 3 and 4 are considered weak variable constituents, therefore environmental variable question items number 3, 6, and 8 are deemed

unable to represent environmental variables. In the last part, based on the results of the component transformation matrix, the training variables show that only components 1 and 5 have a strong correlation, meaning that the training questions included in components 2, 3, 4, and 6 cannot represent the training variables.

The reliability test aims to see how consistent a questionnaire item is when tested on several research samples. The reliability value is potentially high if each item has a close correlation[38]. The Cronbach α value must be greater than 0.6 to be eligible for reliability[28]. Nevertheless, another theory[39] says that if the value of Cronbach α is 0.4 to 0.6, it can be reliable, calculated, and used for data collection. The reliability test results in **Table V** show that the Cronbach α value of all variables is classified as reliable because the value is more than 0.6, meaning that question items from psychological, environmental, and practice variables are reproducible and worthy of being used as research instruments[28]. However, the corrected item's total correlation value is another parameter to see a question item's reliability.

Table V. Cronbach α value of psychological, environmental, and practice variables.

Cronbach α value		
Var. psychological	**Var. environment**	**Var. practice**
0.865	0.636	0.850

The function of the corrected item-total correlation value is to select items whose measuring function is under the test measuring function as the compiler desires. In other words, it is to choose an item that measures the same thing as what the test as a whole measure[40]. According to Azwar[41], a coefficient limit of >0.30 is commonly employed as a criterion for selecting items based on item-total correlation. As part of the test, all items with a correlation coefficient of at least 0.30 were certified psychometrically eligible. However, another theory[42] says that the item-total correlation value must be greater than the r-table to be reliable. After analysis, results show unqualified values based on the two theories above; in psychological variables, item 4 shows values less than 0.3 and more minor than the r-table. For environment variables, items 2, 3, 5, and 9 indicate low values, then practice items 6, 18, and 19, whose values do not qualify. Therefore, some of these items can be removed from the questionnaire.

The results of this validity and reliability test aim to select question items suitable for use in the data collection process because they relate to the purpose of the questionnaire, which is to get answers under the construct built into the questionnaire. Regarding the validity and reliability test results, there is a theory that states that every valid questionnaire question item must also have good reliability because if the item is accurate, then the reproducibility is also good. Unlike reliability, not all questionnaires with good reliability will result in valid question items because the accuracy of the answers has not been tested[43].

Based on the validity and reliability test results, several question items must be eliminated because they cannot provide accurate answers according to the variable construct created. The final form of the questionnaire, which has been evaluated for validity and reliability, can be seen in **Table VI**. From the 55 initial question items, the number was reduced to only 34, and this was because 21 question items in the questionnaire did not meet the validity and reliability requirements.

This research has limitations, and the sample size is only 30 respondents because few pharmacists in type C hospitals are willing to be pilot test respondents. This small number of respondents causes a lack of representation, potentially affecting the results' validity and reliability[44]. However, on the other hand, this research has strength. The strength of this research is that there are no open questions in the questionnaire developed, so the respondents' answers are common to process. Apart from that, the analysis used to test the construct validity of the questionnaire is relatively common because most questions use an ordinal answer scale, so the researcher can use the factor analysis method to construct validity.

Regardless of the strengths and limitations above, this questionnaire benefits researchers in finding out the factors that influence spontaneous reporting practices by pharmacists because this questionnaire can provide accurate, precise, and reproducible results. This questionnaire can be used for pharmacist respondents who work in type C hospitals in East Java. Suppose this questionnaire will be used for pharmacists in other types of hospitals or health services, such as community health centers or drug stores, or for pharmacists outside East Java. This questionnaire can be used but requires a verification process to adapt it to the pharmacist's workplace and location. Suggestions for the next step when developing a research questionnaire instrument: the researcher must start with making the correct conceptual framework design, compiling the questions that the researcher wants to make in the questionnaire, and determining what type of question-answer it looks like, then make a filter that suits the target respondent, then eliminate various potential biases and double questions in one

question item. Then, it also made a picture of what the analysis will be like and the last and main one that pilots must test before being used for research[45].

Table VI. Question items in each instrument domain after evaluation of validity and reliability results.

Variable	Questions	Number in questionnaire	Explanation
Knowledge	One of the points in pharmacovigilance activities is the detection and prevention of AE/ADR so that additional reactions that are detrimental to the patient do not occur.	1	Valid
	Adverse drug reaction monitoring applies to drugs that have been around for a long time, such as captopril, simvastatin, and the like	2	Valid
	Adverse events (AE) can occur in patients if medication reconstitution is done hastily and without an aseptic technique.	3	Valid
	Adverse Drug Reactions (ADR) are part of adverse events whose causes are known from the drugs consumed by the patient.	4	Invalid*
	As health workers, pharmacists should report any AE/ADR encountered as part of their professional responsibility.	5	Valid
	The spontaneous reporting of AE/ADR can only be done manually via a yellow form mailed to the Balai POM pharmacovigilance centre.	6	Valid
	Post-Immunization Adverse events occurring during vaccine administration are not required to be reported to BPOM.	7	Valid
	The institution that acts as the national pharmacovigilance centre in Indonesia is BPOM.	8	Valid
	Spontaneous reporting is only those that are unexpected (Unexpected Adverse Reaction).	9	Valid
	AE/ADR is one of the contributors to the highest number of deaths in various countries.	10	Valid
	Decreased absorption of omeprazole due to drug interactions with antacids does not need to be reported.	11	Valid
	Incidents of side effects due to drug overdose or medication errors need to be reported.	12	Valid
	The discontinuation of the Albothyl product in 2018 and the subsequent call to improve the drug's indications so that it is not used for mouth ulcers are examples of pharmacovigilance efforts being implemented to protect the public from significant adverse drug effects.	13	Invalid*
Psychological	Pharmacists in healthcare facilities play an essential role in pharmacovigilance activities.	14	Valid
	Pharmacists in health service facilities must regularly update their knowledge regarding pharmacovigilance.	15	Valid
	If a drug side effect occurs in their practice, the pharmacist is not obliged to report it.	16	Valid
	Pharmacists in health service facilities are the public's first reference in reporting AE/ADR.	17	Invalid*
	Pharmacists must receive special training regarding pharmacovigilance.	18	Valid
	Spontaneous AE/ADR reporting must be done willingly or as part of professionalism.	19	Valid
	Reporting and monitoring of AE/ADR will be beneficial for patients.	20	Valid
	AE/ADR that occur due to over-the-counter drugs/limited over-the-counter and over-the-counter drugs must also be reported.	21	Invalid*
	Reporting AE/ADR will add more insight regarding the side effects of drugs encountered in practice.	22	Valid
	Reporting AE/ADR experienced by patients is a sign that their concerns are being taken seriously.	23	Valid
	Spontaneous reporting of AE/ADR is part of pharmaceutical care.	24	Valid
	AE/ADR must be reported even if the impact does not result in hospitalization, life-threatening conditions, disability, or death.	25	Invalid*
	All adverse events/ESOs that occur as a result of drugs that have just received distribution permits and medicines that have been on the market for a long time must be reported.	26	Invalid*
	AE/ADR reporting must be done immediately, especially for dangerous or unexpected events (Unexpected Adverse Reaction).	27	Valid
Environment	The pharmacist where I practice applies a regular shift work system.	28	Valid
	In one work shift, the pharmacist at my workplace practices according to the specified working hours.	29	Valid
	The pharmacists' working hours where I work follow the given workload.	30	Invalid*
	My workplace will give rewards/awards to pharmacists if they make innovations in their work or succeed in achieving specific targets.	31	Valid

	Promotions at my workplace are carried out objectively based on the achievements and contributions of a pharmacist.	32	Valid
	The income I get from my workplace is enough for me because it matches my workload.	33	Invalid*
	My workplace will provide additional income if there is extra work or overtime provided	34	Valid
	The portion of work at my workplace is proportional enough to do other work without needing overtime.	35	Invalid*
	I complete work while at work and never do work at home/outside of my working hours	36	Valid
Practice	The frequency with which I encounter reports of drug side effects or adverse events from patients at work.	37	Invalid*
	The frequency with which the hospital where I work reports drug side effects or adverse events to the BPOM National Pharmacovigilance Center	38	Valid
	All drug side effects or adverse events reported by the patient are immediately reported to the unit head/head of pharmacy installation/pharmacist responsible for spontaneous reporting to BPOM.	39	Valid
	I document all reports of drug side effects or adverse events from patients, both unexpected and expected.	40	Valid
	I report and document all actions and interventions I provide to patients according to the patient's complaints.	41	Invalid*
	Suppose there is a complaint that a patient has a dry cough due to using the drug captopril. In that case, I will report it to the unit head/head of pharmacy installation/pharmacist responsible for spontaneous reporting to BPOM.	42	Invalid*
	Suppose there is a complaint that a patient experiences extrapyramidal syndrome due to the use of the drug metoclopramide. In that case, I will report it to the unit head/head of pharmacy installation/pharmacist responsible for spontaneous reporting to BPOM.	43	Valid
	Suppose there is an incident of decreased absorption of the drug omeprazole as a result of drug interactions with antacids. In that case, I will report it to the unit head/head of pharmacy installation/pharmacist responsible for spontaneous reporting to BPOM.	44	Invalid*
	I carried out a causality analysis first with the doctor who provided therapy to the patient to ensure the causality of the side effects of the medication experienced by the patient.	45	Valid
	I include information in the form of reporting data, data on patients who submit complaints, complaints felt by patients, and data on suspected drugs in every report I submit to the head of the unit/head of the pharmacy installation/pharmacist responsible for spontaneous reporting to BPOM.	46	Valid
	I discussed with the doctor who provides therapy to treat patients who experience side effects from drugs.	47	Invalid*
	I take my time at work to handle drug safety incident complaints from patients immediately.	48	Invalid*
	I take the time to do documentation and report cases of drug side effects or adverse events encountered in patients.	49	Invalid*
	I prioritize work related to patient safety while undergoing therapy.	50	Invalid*
	I apply all points of clinical pharmacy services, including monitoring drug side effects (MESO) following the Minister of Health Regulations, where I practice.	51	Invalid*
	I actively participate in the spontaneous reporting of drug side effects or adverse events as a form of professionalism and compliance with regulations.	52	Valid
	I have a spontaneous reporting account at e-meso.pom.go.id or the e-meso mobile smartphone application and operate it actively.	53	Invalid*
	I provide a yellow form for spontaneous reporting of drug side effects to BPOM manually at my practice.	54	Invalid*
	I participated in multilevel pharmacovigilance training held by BPOM as the national pharmacovigilance centre.	55	Invalid*

* invalid item

CONCLUSION

Evaluation of validation results on knowledge question items found two invalid items and four question items could not represent psychological variables. There are three invalid items for environmental variables, and then for practice variables, there are twelve invalid items. Thirty-four question items can still be used to acquire further data.

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DATA AVAILABILITY

None.

CONFLICT OF INTEREST

There are no conflicts of interest.

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