Patient’s Compliance with Oral Antibiotics Treatments at Community Health Centers

by Ilil Maidatuz Zulfa

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Patient's Compliance with Oral Antibiotics Treatments at Community Health Centers in Surabaya: A 20-KAO Questionnaire Development

Ilil Maidatuz Zulfa [1*]

Widya Handayani [2]

[1]Department of Community Pharmacy, Akademi Farmasi Surabaya, Surabaya, East Java, Indonesia

[2]Departement of Clinical Pharmacy, Akademi Farmasi Surabaya, Surabaya, East Java, Indonesia

*Email: ililmaidatuz@gmail.com

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Abstract

The irrational and in compliance use of antibiotics has been correlated to bacterial resistance. Several methods evaluated the patient's compliance with oral antibiotics have been conducted. However standard questionnaire for evaluating oral antibiotics compliance in *Bahasa Indonesia* has not been developed yet. This study was conducted to record the content validity of a developed questionnaire called 20-KAO assessing compliance with oral antibiotics. A validity content test was conducted through six experts review using the Item Content Validity Index (I-CVI) and Scale-Content Validity Index (S-CVI). The experts were also requested to provide recommendations for each item either revisions or deletion. After the review process, the number of questions remained unchanged. There were 19 out of 20 items that had an I-CVI of 1.00 and S-CVI was calculated at 0.98. Therefore, 20 items of the 20-KAO questionnaire had excellent content validity. However, future construct validity and reliability tests to analyze the response of targeted respondents, and the consistency of the questionnaire are needed.

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INTRODUCTION

Antibiotics are chemical substances produced by a microorganism that can inhibit or kill bacteria (Denyer, Hodges and Gorman, 2008). The usage of antibiotics for an infection in the low and middle-income countries has increased up to 65% from 2010-2015 (Klein *et al.*, 2018). The increase in usage has followed by an increase in bacterial resistance. The irrational use of antibiotics such as for treating viral infections, in the farm, and fisheries has been correlated to bacterial resistance (Shimizu, 2017). Furthermore, the patient's compliance in taking their oral antibiotics also contributed to the prevalence of bacterial resistance (Moradi *et al.*, 2015).

Several studies evaluated the patient's compliance with oral antibiotics have been conducted using various methods. Measuring compliance using objective or subjective methods has its particular limitations. Examples of objective methods in assessing patient compliance are pill count and Medication Event Monitoring System (MEMS). Pill count is a physical count of the number of pills remains and compares to the prescription's instruction (Lam and Fresco, 2015). MEMS is a medication container contains a microelectronic chip that records the date and time of opening of every bottle (Llor *et al.*, 2013). Although MEMS measures compliance accurately, it can not be used in a regular situation. In addition, pill count can not describe specifically the aspects of compliance such as timing, dosing, and taking compliance. Hence, a subjective method such as using a questionnaire is

preferable because of less cost, non-judgmental, non-threatening, also quick and easy in collecting results (Llor *et al*., 2013; Wibowo and Soedibyo, 2016).

Various questionnaires such as Medication Adherence Questionnaire (MAQ), Medication Adherence Rating Scale (MARS), Patient Medication Adherence Questionnaire (PMAQ), Morisky Medication Adherence Scale (MMAS), etc. have been developed and validated to measure compliance (Morisky, Green and Levine, 1986; Thompson, Kulkarni and Sergejew, 2000; Duong *et al.*, 2001). However, the questionnaires have not been translated and validated into *Bahasa Indonesia* for measuring compliance with oral antibiotics treatment. A study has been conducted to validate the English version of Morisky 3,4, and 5-item questionnaires in assessing oral antibiotics compliance (Treibich and Ventelou, 2017). In Indonesia, measuring oral antibiotics compliance usually uses pill count. Therefore, there has no questionnaire been developed yet. Hence, developing a standard questionnaire for evaluating oral antibiotics compliance in *Bahasa Indonesia* is essentials. In developing a questionnaire, validity tests are needed in order to evaluate whether it measures what it is supposed to measure or not (Setia, 2017). Validity tests are classified into two broad categories namely internal and external validity (Bolarinwa, 2015a). Internal validity includes content validity that measures the degree to which the instrument fully assesses the construct of interest that is usually conducted before external validity. Therefore, this study was conducted to record the content validity of the developed questionnaire assessing compliance with oral antibiotics.

MATERIALS AND METHODS

This study was conducted observationally from August to September 2020 to establish the evidence of content validity of the developed questionnaire namely 20-KAO from experts.

20-KAO Questionnaire

The 20-KAO questionnaire was developed in *Bahasa Indonesia* and aimed to assess the compliance of short-course oral antibiotics usage. The name 20-KAO was developed from 20 items in assessing compliance with oral antibiotics or in *Bahasa Indonesia - Kepatuhan Antibiotik Oral* (KAO). The questionnaire was developed in four sections and contained 20 questions. Section one, it was contained 10 questions to evaluate whether the patients understood about the dosage regimens and took their dosage correctly or not and the reasons behind their action in taking the dosage. Section two, it was rated the patient's understanding, compliance, and the reasons in how many times they took the dosage daily through 5 questions. The third section, it was assessed how patients gave an interval between their dosages and the reasons why they did it. The last section, it was observed the patient's understanding on the duration of taking the antibiotics, and whether they had stopped taking the antibiotics before it should be stopped, and their reasons to do so. Additionally, patients were also asked to fill the number of pills left in the questionnaire and if they used other non-prescribed medication.

Content validation

The literature shows that the ideal number of content experts needed in a validation study is still controversial. However, the suggestions are between 3 and 10 experts (Polit and Beck, 2006). In this study, a total of six experts were selected. Three of them were academic experts while three remained were registered pharmacists. These experts proportion were designed intentionally so that the review results would reflect academic and practical opinions. The academic experts were selected based on their experiences in developing a

questionnaire and the pharmacists' experts' experiences in giving patient consultation in order to improve the patient's compliance. The experts were invited from educational institutions and community health centers in Surabaya (they were registered pharmacists in Wonokromo, Gayungan, and Kalirungkut Community Health Centers and academic lecturers in clinical and community pharmacy at Airlangga University and Pharmacy Academy of Surabaya). After getting their approval, we sent an informed consent form, information cover letter, and the questionnaire attached to the evaluation criteria form. The evaluation form contained an explanation of the validation procedure. The experts were asked to assess the relevance of each question in the questionnaire. The relevance meant whether all the items in 20-KAO questionnaire referred to measure the antibiotics usage compliance in dose, frequency, and the duration of therapy. To determine the relevance of each item, a four scale was used (1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, 4 = highly relevant). The experts were also requested to provide recommendations for each item either revisions or deletion. The maximum time for validating the questionnaire for each expert was two weeks and they were requested to return the result through email or in-person to the researcher. The response from the experts was analyzed through Content Validity Index (CVI) specifically Item Content Validity Index (I-CVI) and Scale-Content Validity Index (S-CVI). I-CVI was calculated in every item from the number of experts giving 3 or 4 scores divided by the total number of experts while S-CVI was computed as the average of I-CVI from all the items. The questionnaire would qualify to be content valid if the S-CVI greater than 0.90.

RESULTS AND DISCUSSION

All of the six experts invited were agreed to participate. They were registered pharmacists in Wonokromo, Gayungan, and Kalirungkut Community Health Centers and academic lecturers in clinical and community pharmacy at Airlangga University and Pharmacy Academy of Surabaya. The mean age of the experts was 41.5 (SD=9.16) years. After the validation process, the number of question items in 20-KAO questionnaire remained unchanged. There were 19 out of 20 items that had an I-CVI of 1.00. Therefore, S-CVI was calculated at 0.98.

Table I. Result for the content validation of 20-KAO questionnaire

Section	Item Number	Question description	Expert Raters						I-CVI
			1	2	3	4	5	6	
Section I	Q1	Knowledge of prescribed antibiotic dose at **one time**	3	4	4	3	4	3	1.00
	Q2	Experience in taking a **higher** dosage at **one time**	4	3	4	3	4	3	1.00
	Q3	Reasons for Q2 Answer	4	3	4	3	4	3	1.00
	Q4	Experience in taking a lower dosage at **one time**	4	3	4	3	4	3	1.00
	Q5	Reasons for Q4 Answer	4	3	4	3	4	3	1.00
	Q6	Knowledge of prescribed antibiotic **dose daily**	3	4	4	4	4	3	1.00
	Q7	Experience in taking **higher** dosage **daily**	4	4	4	3	4	3	1.00
	Q8	Reasons for Q7 Answer	4	4	4	3	4	3	1.00
	Q9	Experience in taking **lower** dosage **daily**	4	4	4	3	4	3	1.00
	Q10	Reasons for Q9 Answer	4	4	4	3	4	3	1.00

Section II	Q11	Knowledge of times taken prescribed antibiotics daily	4	4	4	2	4	2	0.67
	Q12	Experience in taking **more** frequent	4	3	4	3	4	3	1.00
	Q13	Reasons for Q12 Answer	4	3	4	3	4	3	1.00
	Q14	Experience in taking **less** frequent	3	3	4	3	4	3	1.00
	Q15	Reasons for Q14 Answer	3	3	4	3	4	3	1.00
Section III	Q16	The time interval between dose	3	3	4	4	4	3	1.00
Section IV	Q17	Knowledge of prescribed antibiotics duration	3	4	4	4	4	3	1.00
	Q18	Whether has stoped their antibiotics course	4	3	4	4	4	3	1.00
	Q19	Reasons for Q19 Answer	4	3	4	4	4	3	1.00
	Q20	The number of pills remaining	4	4	4	4	4	3	1.00
	Total agreement = 0.95[a]						S-CVI= 0.98		

[a] Total agreement= the number of items that achieved the I-CVI of 1.00 divided by the total number of items to be validated in the questionnaire

Table 1 showed that the questionnaire had excellent content validity in measuring oral antibiotic compliance. However, there were some editorial revisions given by the experts in order to make the sentences easier to be understood (Table2).

Table II. Editorial revision of 20-KAO questionnaire

Item Number	Question description	Original Question Sentences (in *Bahasa Indonesia*)	After Editorial Revision (in *Bahasa Indonesia*)	After Editorial Revision (in English)
Q1	Knowledge of prescribed antibiotic dose at **one time**	*Berapa tablet/kapsul antibiotik dari puskesmas yang seharusnya anda konsumsi **tiap kali minum**?*	*Berapa jumlah tablet/kapsul antibiotik yang seharusnya anda konsumsi **tiap kali minum**?*	How many pills of antibiotic should you take at one time?
Q2	Experience in taking **higher** dosage at **one time**	*Apakah Anda pernah mengkonsumsi **lebih** dari jumlah tersebut **tiap kali minum**?*	*Apakah Anda pernah mengkonsumsi obat antibiotik **lebih** dari jumlah tersebut **tiap kali minum**?*	Have you taken more antibiotic pills than that at one time?
Q3	Reasons for Q2 Answer	*Apa alasan Anda?*	-	Please explain your reasons.
Q4	Experience in taking lower dosage at **one time**	*Apakah Anda pernah mengkonsumsi **kurang** dari jumlah tersebut **tiap kali minum**?*	*Apakah Anda pernah mengkonsumsi obat antibiotik **kurang** dari jumlah tersebut **tiap kali minum**?*	Have you taken less antibiotic pills than that at one time?
Q5	Reasons for Q4 Answer	*Apa alasan Anda?*	-	Please explain your reasons.
Q6	Knowledge of prescribed antibiotic **dose daily**	*Berapa tablet/kapsul antibiotik dari puskesmas yang seharusnya anda konsumsi **dalam satu hari**?*	*Berapa jumlah tablet/kapsul antibiotik yang seharusnya anda konsumsi **dalam satu hari**?*	How many pills of antibiotic should you take in one day?
Q7	Experience in taking **higher** dosage **daily**	*Apakah Anda pernah mengkonsumsi **lebih** dari jumlah tersebut **dalam satu hari**?*	*Apakah Anda pernah mengkonsumsi obat antibiotik **lebih** dari jumlah **dalam satu hari**?*	Have you taken more antibiotic pills than that in one day?
Q8	Reasons for Q7 Answer	*Apa alasan Anda?*	-	Please explain your reasons.
Q9	Experience in taking **lower** dosage **daily**	*Apakah Anda pernah mengkonsumsi **kurang** dari jumlah tersebut **dalam satu hari**?*	*Apakah Anda pernah mengkonsumsi obat antibiotik **kurang** dari jumlah tersebut **dalam satu hari**?*	Have you taken less antibiotic pills than that in one day?
Q10	Reasons for Q9 Answer	*Apa alasan Anda?*	-	Please explain your reasons.
Q11	Knowledge of times taken prescribed antibiotics daily	*Berapa kali seharusnya Anda minum antibiotik dari puskesmas beberapa hari yang lalu **dalam satu hari**?*	*Berapa kali **dalam satu hari** seharusnya Anda minum antibiotik dari puskesmas sesuai peresepan dokter?*	How many times should you take your antibiotic as prescribed in one day?

Q12	Experience in taking **more** frequent	*Apakah Anda pernah mengkonsumsi **lebih** dari itu **dalam satu hari**?*		Have you taken more frequently than that?
Q13	Reasons for Q12 Answer	*Apa alasan Anda?*		Please explain your reasons.
Q14	Experience in taking **less** frequent	*Apakah Anda pernah mengkonsumsi **kurang** dari itu **dalam satu hari**?*		Have you taken less frequently than that?
Q15	Reasons for Q14 Answer	*Apa alasan Anda?*		Please explain your reasons.
Q16	The time interval between dosage	*Bagaimana Anda memberi jeda waktu dalam meminum antibiotik Anda?*		How do you give interval between your antibiotic dosage?
Q17	Knowledge of prescribed antibiotics duration	*Untuk berapa hari seharusnya Anda minum antibiotik Anda?*	*Sejak kapan Anda minum antibiotik?*	Since when do you take your antibiotics course?
Q18	Whether has stoped their antibiotics course	*Apakah Anda telah berhenti meminum antibiotik Anda sebelum hari ini?*		Have you stopped your antibiotic course before today?
Q19	Reasons for Q19 Answer	*Apa alasan Anda?*		Please explain your reasons.
Q20	The number of pills remaining	*Berapa antibiotik anda yang tersisa?*	*Berapa Jumlah antibiotik anda yang tersisa?*	How many pills of antibiotics do you have left?

Among the 20 items validated, Q11 was the only item have I-CVI less than 1.00 and significant editorial revision. Q11 was developed to assess whether the patients understand how many times they should take their antibiotics or not. Two of the six experts suggested changing the sentence structured because the original sentence was too complicated. The final form of 20-KAO questionnaire after the content validity process was shown in Table III.

Table III. 20-KAO Questionnaire

Identities			
Nama atau Inisial (Name or Initials)	:……		
Jenis Kelamin (Gender)	: ☐ **Perempuan** (Female)	☐ **Laki-laki** (Male)	
Usia dalam tahun (Age in y.o)	:……		
Apakah anda memiliki riwayat penyakit ? Jika IYA, harap sebutkan. (Do you have comorbids ? If YES, please mention it)	:……		
Apakah anda mengkonsumsi obat lain selain yang diresepkan untuk anda ? Jika IYA, harap sebutkan. (Do you take any other medications out of prescribed? If YES, please mention it)	:……		
20-KAO Questionnaire			
Bagian 1 (Section 1)	**1. Berapa jumlah tablet/ kapsul antibiotik yang seharusnya anda konsumsi tiap kali minum?** (How many pills of antibiotic should you take **at one time?)**	:……	
	2. Apakah Anda pernah mengkonsumsi obat antibiotik lebih dari jumlah tersebut tiap kali minum?	: **Ya** (Yes) ☐	: **Tidak** (No) ☐ **3. Apa Alasan Anda ?** (Please explain your reasons)

	(Have you taken **more** antibiotic pills than that **at one time**?)			…….
	4. Apakah Anda pernah mengkonsumsi obat antibiotik kurang dari jumlah tersebut tiap kali minum? (Have you taken **less** antibiotic pills than that **at one time**?)	: **Ya** (Yes) ☐	: **Tidak** (No) ☐	**5. Apa Alasan Anda ?** (Please explain your reasons) …….
	6. Berapa jumlah tablet/ kapsul antibiotik yang seharusnya anda konsumsi dalam satu hari? (How many pills of antibiotics should you take in **one day**?)	:……		
	7. Apakah Anda pernah mengkonsumsi obat antibiotik lebih dari jumlah dalam satu hari? Have you taken **more** antibiotic pills than that in **one day**?	: **Ya** (Yes) ☐	: **Tidak** (No) ☐	**8. Apa Alasan Anda ?** (Please explain your reasons) …….
	9. Apakah Anda pernah mengkonsumsi obat antibiotik kurang dari jumlah tersebut dalam satu hari? (Have you taken **less** antibiotic pills than that in **one day**?)	: **Ya** (Yes) ☐	: **Tidak** (No) ☐	**10. Apa Alasan Anda ?** (Please explain your reasons) …….
Bagian 2 (Section 2)	**11. Berapa kali dalam satu hari seharusnya Anda minum antibiotik dari puskesmas sesuai peresepan dokter?** (How many times should you take your antibiotic as prescribed in **one day**?)	:……		
	12. Apakah Anda pernah mengkonsumsi lebih dari itu dalam satu hari? (Have you taken **more** frequently than that?)	: **Ya** (Yes) ☐	: **Tidak** (No) ☐	**13. Apa Alasan Anda ?** (Please explain your reasons) …….
	14. Apakah Anda pernah mengkonsumsi kurang dari itu dalam satu hari? (Have you taken **less** frequently than that?)	: **Ya** (Yes) ☐	: **Tidak** (No) ☐	**15. Apa Alasan Anda ?** (Please explain your reasons) …….
Bagian 3 (Section 3)	**16. Bagaimana Anda memberi jeda waktu dalam meminum antibiotik Anda?** (How do you give an interval between your antibiotic dosage?)	☐	**Pagi-Siang-Sore/Malam (Jam tidak tentu)** (Morning – Afternoon – Evening (No exact time))	
		☐	**Tiap 8 jam tepat** (Every 8 hours)	
		☐	**Pagi-Sore/Malam (Jam tidak tentu)** (Morning – Evening (No exact time))	
		☐	**Tiap 12 jam tepat** (Every 12 hours)	
Bagian 4 (Section 4)	**17. Sejak kapan Anda minum antibiotik?** (Since when you take your antibiotics course?)	:……		

	18. Apakah Anda telah berhenti meminum antibiotik Anda sebelum hari ini? Have you stopped your antibiotic course before today?	: **Ya** (Yes) ☐	: **Tidak** (No) ☐	**19. Apa Alasan Anda ?** (Please explain your reasons) ……
	20. Berapa Jumlah antibiotik anda yang tersisa? (How many pills of antibiotics do you have left?)	:……		

To our knowledge, there had no reported studies developing a questionnaire that evaluated oral antibiotics compliance in Indonesia. A study in Lithuania by Kandrotaite et.al (2013) developed a 91-items questionnaire adapted from ASK-20, SF-12 and Morisky scale questionnaire to identify the risk of nonadherence to antibiotics treatments. It was said that the developed questionnaire covered the identification of five dimension adherence model developed by WHO (Kandrotaite *et al.*, 2013). However, although the developed questionnaire had been discussed with nine professionals, it had not been validated yet. In addition, one of the studies in Indonesia that used questionnaires as an instrument in measuring antibiotics compliance was the study by Muljabar et.al (2014) that used 8-items MMAS. However, the study did not validate the questionnaire directly to patients receiving antibiotics (Muljabar and Supadmi, 2014). Therefore, the questionnaire developed in this study was the potential to be tested for construct validity and reliability tests.

Construct validity is the degree to which an instrument measures the trait or theoretical construct that it is intended to measure while reliability test is the extent to which a questionnaire, produces consistent results on repeated trials (Bolarinwa, 2015b). Construct validity for 20-KAO questionnaire is essentials to measure how well the targeted respondents give answers as the questionnaire aims to measure while the reliability test is useful to assess whether the questionnaire will give consistency in results. Future construct validity and reliability test for 20-KAO questionnaire can be done through distribution to the patient's prescribed antibiotics and then analyze their responses.

CONCLUSION

20-KAO questionnaire was found to have excellent content validity based on six experts' reviews. Future construct validity and reliability tests for 20-KAO are needed to be conducted in order to analyze the respond of targeted respondents and the consistency of the questionnaire.

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