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INTRODUCTION Antibiotics are chemical substances produced by microorganisms that can inhibit or kill bacteria (Fair & Tor, 2014). Antibiotics usage for an infection in the low and middle-income countries has increased up to 65% from 2010-2015 (Klein et al., 2018). An increase has followed the increase in usage in bacterial resistance. The irrational use of antibiotics, such as treating viral infections and usage on the farm and fisheries, correlates with bacterial resistance (Economou & Gousia, 2015).

Furthermore, the patient's compliance in taking their oral antibiotics also contributed to bacterial resistance prevalence (Moradi et al., 2013). 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 (Jin et al., 2008). 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 that remain and compares to the prescription's instruction (Lam & Fresco, 2015). The 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 cannot be used in an everyday situation. Besides, pill count cannot describe specifically the aspects of compliance, such as timing, dosing, and taking compliance (Williams et al., 2013).

Hence, a subjective method such as using a questionnaire is preferable because of less cost, non-judgmental, non-threatening, quick, and comfortable in collecting results (Lam & Fresco, 2015; Llor et al., 2013; Ponto, 2015). 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 et al., 1986; Thompson et al., 2000; Duong et al., 2001).

However, the questionnaires have not been translated and validated into Bahasa Indonesia for measuring compliance with oral antibiotics treatment in Indonesia. A study has been conducted to validate the English version of Morisky 3, 4, and 5-item questionnaires in assessing oral antibiotics compliance (Treibich & Ventelou, 2017). In Indonesia, measuring oral antibiotics compliance usually uses pill count. Therefore, there has been no questionnaire 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, viz internal and external validity (Bolarinwa, 2015). Internal

validity includes content validity that measures the degree to which the instrument comprehensively assesses the construct of interest usually conducted before external validity.

Therefore, this study was conducted to record the developed questionnaire's content validity 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 short-course oral antibiotics usage compliance.

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 contained ten questions to evaluate whether the patients understood the dosage regimens and took their dosage correctly or not and the reasons behind their action in taking the dosage. Section two rated the patient's understanding, compliance, and the reasons in how many times they took the dosage daily through five questions.

In the third section, it was assessed how patients gave an interval between their dosages and the reasons why they did it. In the last section, the patient's understanding of 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 in 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 three and ten experts (Polit & 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 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 as well as community pharmacy at Universitas Airlangga and Akademi Farmasi Surabaya). After getting their approval, the researcher sent an

informed consent form, an information cover letter, and the questionnaire attached to the evaluation criteria.

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 the 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). The 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 Universitas Airlangga and Akademi Farmasi Surabaya. All experts are deliberately selected from Surabaya to facilitate communication. The mean age of the experts was 41.5 (SD=9.16) years. After the validation process, the number of question items in the 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 as shown in Table I. Table I. Result for the content validation of 20-KAO questionnaire

Section	Item Number	Question description	Expert Raters	I-CVI
Section I	Q1	Knowledge of prescribed antibiotic dose at one time	4 3 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	4 4 4 4 3 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 stopped 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 = 0.95a S-CVI= 0.98 \_\_ aNumber of items that achieved the I-CVI of 1.00 divided by the total number of items to be validated in the questionnaire Table I showed that the questionnaire had excellent content validity in measuring oral antibiotic compliance.

However, the experts gave some editorial revisions to make the sentences more comfortable to be understood, as presented in Table II. Table II. Editorial revision of 20-KAO questionnaire Item Question description Original Question Sentences (Bahasa Indonesia) After Editorial Revision (Bahasa Indonesia) After Editorial Revision (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 mengonsumsi 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 persepsian dokter? \_How many times should you take your antibiotic as prescribed in one day? \_\_Q12 \_Experience in taking more frequent \_Apakah Anda pernah mengonsumsi 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 mengonsumsi 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 stopped 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, the only item with I-CVI less than 1.00 and significant editorial revision was Q11. The 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. Changes in the structure of the questions were then carried out after consultation with these experts.

The final form of the 20-KAO questionnaire after the content validity process was shown in Table III.

Table III. The 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 comorbidities ? If YES, please mention it)  
\_:..... \_ Apakah anda mengonsumsi **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) \_ Berapa jumlah tablet/ kapsul antibiotik yang seharusnya anda konsumsi tiap  
kali minum? (How many pills of antibiotic should you take at one time?)  
\_:..... \_ Apakah Anda pernah  
mengonsumsi obat antibiotik lebih dari jumlah tersebut tiap kali minum? (Have you  
taken more antibiotic pills than that at one time?) \_: Ya (Yes) \_: Tidak (No) \_ Apa Alasan  
Anda ? (Please explain your reasons) .....

\_ \_ Apakah Anda pernah mengonsumsi obat antibiotik kurang dari jumlah tersebut  
tiap kali minum? (Have you taken less antibiotic pills than that at one time?) \_: Ya (Yes) \_:  
Tidak (No) \_ Apa Alasan Anda ? (Please explain your reasons)  
..... \_ \_ Berapa jumlah tablet/ kapsul antibiotik yang  
seharusnya anda konsumsi dalam satu hari? (How many pills of antibiotics should you  
take in one day?) \_:..... \_ \_ Apakah  
Anda pernah mengonsumsi obat antibiotik lebih dari jumlah dalam satu hari? Have you  
taken more antibiotic pills than that in one day? \_: Ya (Yes) \_: Tidak (No) \_ Apa Alasan  
Anda ? (Please explain your reasons) .....

\_ \_ Apakah Anda pernah mengonsumsi obat antibiotik kurang dari jumlah tersebut  
dalam satu hari? (Have you taken less antibiotic pills than that in one day?) \_: Ya (Yes) \_:  
Tidak (No) \_ Apa Alasan Anda ? (Please explain your reasons)  
..... \_ Bagian 2 (Section 2) \_ Berapa kali dalam satu hari  
seharusnya Anda minum antibiotik dari puskesmas sesuai resep dokter? (How  
many times should you take your antibiotic as prescribed in one day?)  
\_:..... \_ Apakah Anda pernah  
mengonsumsi lebih dari itu dalam satu hari? (Have you taken more frequently than  
that?) \_: Ya (Yes) \_: Tidak (No) \_ Apa Alasan Anda ? (Please explain your reasons)  
.....

\_ \_ Apakah Anda pernah mengonsumsi kurang dari itu dalam satu hari? (Have you  
taken less frequently than that?) \_: Ya (Yes) \_: Tidak (No) \_ Apa Alasan Anda ? (Please

explain your reasons) ..... \_ \_Bagian 3 (Section 3) \_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) \_Sejak kapan Anda minum  
antibiotik? (Since when you take your antibiotics course?)  
\_ : ..... \_ \_Apakah Anda telah berhenti  
meminum antibiotik Anda sebelum hari ini? Have you stopped your antibiotic course  
before today? \_ : Ya (Yes) \_ : Tidak (No) \_Apa Alasan Anda ? (Please explain your reasons)  
.....

\_ \_ \_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 Kandrotaitė et al. (2013) developed a 91-items questionnaire adapted from ASK-20, SF-12, and Morisky scale questionnaire to identify the risk of nonadherence antibiotics treatments.

It was said that the developed questionnaire covered the identification of the five-dimension adherence model developed by World Health Organization (Kandrotaitė et al., 2013). However, although the developed questionnaire had been discussed with nine professionals, it had not been validated yet. Besides, one of the studies in Indonesia that used questionnaires to measure antibiotics compliance was the study by Muljabar and Supadmi (2014) that used 8-items MMAS.

However, the study did not validate the questionnaire directly to patients receiving antibiotics. Therefore, the questionnaire developed in this study could be tested for construct validity and reliability tests. Construct validity is the degree to which an instrument measures the trait or theoretical construct intended to measure, while reliability test is the extent to which a questionnaire produces consistent results on repeated trials (Boateng et al., 2018; Kimberlin & Winterstein, 2008).

Construct validity for the 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 The 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 to analyze the respond of targeted respondents and the consistency of the questionnaire.

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