Original Article

Adaptation and Validation of the Screening Tool of Older People's Prescriptions Instrument for the Indonesian Population

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Abstract

Objective: In this study, we aimed to prepare and validate an Indonesian version for the Screening Tool of Older People's Prescriptions (STOPP), which is an instrument to identify inappropriate medications for elderly patients. **Methods:** The Indonesian version of STOPP (STOPP_INA) was developed using modified transcultural adaptation guidelines from the American Academy of Orthopedic Surgeons. Our method consisted of translating original STOPP into Indonesian (forwardly translation), synthesis of forward translation, translation into English and synthesis of back translation, a review by the copyright holder of STOPP, a review by the expert team, pretest, revision of STOPP_INA, field test, and psychometric analysis of the final version of the questionnaire. The study design for this part was quasi-experimental with purposive sampling for members of the translator's team, expert's team, and respondents in the pretest, but they were different from field testing that used purposive and postsurvey sampling for respondents. Content validity and face validity were used to construct the validity of STOPP_INA by assessing item-level content validity and correlation between items and total values. Internal consistency was measured with Cronbach's alpha coefficient. **Findings:** The expert panel agreed on a list of 81 criteria. Five (62.50%) of expert team members agreed and could be continued to the field test without revision of STOPP_INA and 3 (37.50%) agreed with a revision. The research subjects in the psychometric test had 230 respondents, 5 (2.17%) resigned, with an average of item-level content validity index of 0.99. The construct validity analysis showed that 5-item criteria are "not valid," namely in A1, A3, B7, B10, and C3. Reliability analysis showed the Cronbach's Alpha and Cronbach's Alpha Based on Standardized Items were 0.978 and 0.979. **Conclusion:** The expert team was be agreed on 81 criteria (100%) of adaptation of STOPP version 2 criteria. There were 5 criteria that not valid statistically, they could not be removed from the instrument because they can influence content and construct of the instrument. The STOPP_INA has been developed for the Indonesian population, currently being tested in clinical practice against elderly patients undergoing hospitalization.

Keywords: *Elderly population, inappropriate medications, Indonesia, prescription, screening tool, transcultural adaptation, validation*

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Introduction

In 2014, the prevalence of morbidity for the elderly in Indonesia reached 25.05%, and 66.01% of them consumed medicines.[1] A change and decrease in various physiological, hormonal, and organ functions could result with increasing age. This caused susceptibility

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the body to disease. The ageing process in the elderly also resulted in changes in body composition, pharmacokinetic and pharmacodynamics that could increase sensitivity to certain drugs.[2,3]

Multimorbidity and the use of large amounts of medicines caused potentially inappropriate medications (PIM), polypharmacy,[4] hospitalization, adverse drug reactions,[5,6] and fall in elderly patients.[7,8] This resulted in an increase of treatment costs.[9] An effort to reduce the use of inappropriate drugs was by providing clinical guidance through the development of explicit treatment criteria because it will benefit practitioners in providing the best care for patients according to the latest evidence and giving an assurance of health for patients.[10,11] Some instruments have been developed in various countries, one of which was the Screening Tool of Older Persons' Prescriptions (STOPP) and the Screening Tool to Alert Doctors to Right Treatment (START) criteria. The STOPP/START criteria were developed in Ireland and the United Kingdom in 2008 and revised in 2014.[12,13] The STOPP/START instrument was validated using the Delphi method by 20 expert team members.[13]

The identification of appropriate medications in elderly patients was critically important because they were susceptible to diseases.[1] STOPP had been used in several studies in Indonesia[6,14] but was never adapted to Indonesian. At present, Indonesia does not have instruments yet that function the same as STOPP. Therefore, it was necessary to develop an instrument for identifying inappropriate medications to the Indonesian version (STOPP_INA). This study aimed to adapt the English version of STOPP to Indonesian culture and to measure the validity and reliability of the instrument. The development of the instrument was carried out through the adaptation process of the STOPP version 2 criteria. The questions in this study are: was STOPP version 2 adaptation in Bahasa Indonesia acceptable? Was the STOPP_INA valid and reliable as an instrument of the identifier inappropriate medications in elderly patients?

Methods

The adaptation of the STOPP version 2 criteria got permission from Denis O'Mahony as the copyright holder and ethical clearance from the Ethics Committee of the Faculty of Medicine, The University of Indonesia (No. KET-850/UN2.F1/ETIK/PPM.00.02/2019). Informed consent was given to subjects before participating. The research was conducted on a multicenter of Indonesian hospitals.

The STOPP consisted of 81 criteria which were grouped into 13 sections such as A: Indications of the drug (A1–3); B: Cardiovascular system (B1–13); C: Coagulation System (C1–11); D: Central nervous system (D1–14); E: Renal system (E1–6); F: Gastrointestinal system (F1–4); G: Respiratory system (G1–5); H: Musculoskeletal system (H1–9); I: Urogenital system (I1–2); J: Endocrine system (J1–6); K: Medications that are predicted to increase the risk of falls (K1–4); L: Analgesic medicine (L1–3); and M: Antimuscarinic/anticholinergic drugs (M1).[13]

The adaptation of the STOPP was developed with the cross-cultural adaptation guidelines from the American Association of Bone Surgeons Committee.[15] The prose stage consisted of translation of the original STOPP into Indonesian language (forward translated), synthesis of forward translation, back translation into English, synthesis of back translation, a review from the copyright holder of STOPP, a review by the expert team, pretest, revision of STOPP_INA, field test, and psychometry of the final version of the questionnaire.[16]

Translation of STOPP (forward and back translation) involved 5 translators. They were independent translators, didn't know each other, were fluent in Indonesian and English and had different scientific backgrounds. The synthesis of the forward translation and back translation was undertaken by the researcher and translators through confirmation and discussion for the differences of

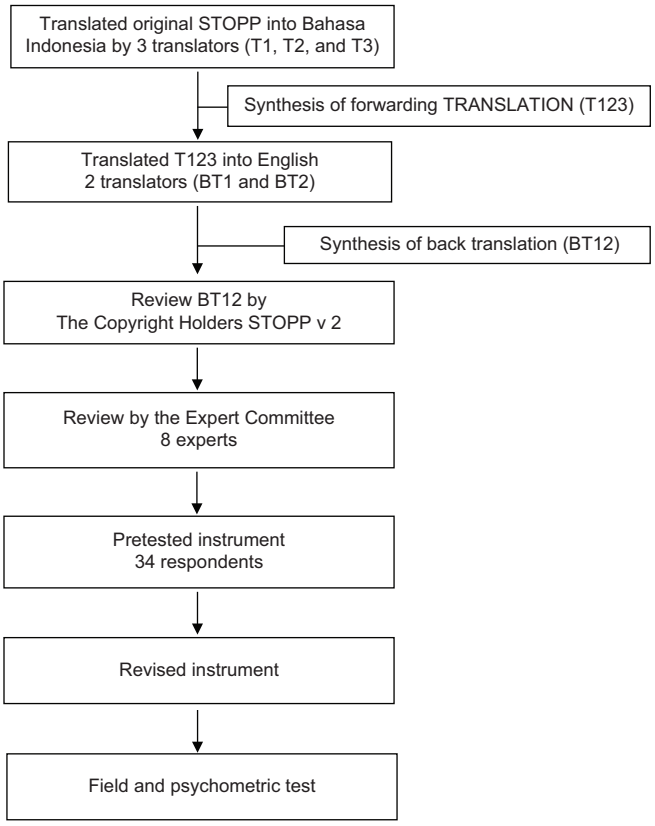

Figure 1: Flowchart of adaptation of instrument in the Indonesian version

meanings. Each correction of translation was recorded as data in the translation process. The stage of adaptation of instrument is presented as follows: [Figure 1].

The questionnaire was presented in a paper format with two choices, namely: "agree" if the statement was relevant and "disagree" if it was not relevant. The papers were sent to members of the expert team for initial reviewing, followed by an expert panel, and were sent back to review more. The composition of this expert team consisted of two geriatricians, one pharmacologist, one endocrinologist, one cardiologist, one neurologist, one clinical pharmacist, and one linguist who was also a translator member. They were assessed using three feasibility options, namely: 1 = "the instrument could be used to testing without revision," 2 = "could be used to testing with revision," and 3 = could not be used to testing. The study design in the pretest was a quasi-experimental study with the test–retest method. Respondents were pharmacists who met the inclusion and exclusion criteria and were chosen using a purposive sampling technique in March 2019. The minimum number of the needed subjects was 30 respondents.[15] Eligible participants of the study were hospital pharmacists, who served in pharmaceutical care for >1-year, from secondary or tertiary hospitals in Indonesia, and were willing to be respondents in this study. Hospital pharmacists who served in managerial pharmacy or served outside the hospital pharmacy installation were excluded. Respondents completed the paper of our self-administered questionnaire, which consisted of sheets of informed consent, demographic characteristics, STOPP_INA paper, and an opinion form. The STOPP_INA was presented in five Likert scales: 1 = "strongly disagree," 3 = "don't know," and 5 = "strongly agree."

The design of this part of our study was quasi-experimental with the one-shot method. The data were taken using a purposive sampling technique through survey post in July–October 2019. Respondents were a pharmacist who required of the inclusion and exclusion criteria, such as pretest respondent qualification. The minimum needed subjects were 220 respondents at a significance level of 95% (d = 0.05) and proportion (P) 80%.[17] Respondents completed a questionnaire paper that consisted of informed consent, demographic characteristics, and a final STOPP_INA which were obtained in four Likert scales, 1 = "strongly disagree" and 4 = "strongly agree."

We used the IBM® SPSS® Statistics, International Business Machiner Corp. version 22.0 for data analysis, and a $P < 0.05$ was considered statistically significant. The data analysis was presented qualitatively for the modified criteria. Descriptive analysis was presented as a percentage (%). The demographic characteristics of respondents with mean ± standard deviation, the content validity and face validity with an average of item-level content validity index (I-CVI/ave), and internal consistency form pretest data. The construct validity and reliability were tested and reported with a Pearson correlation and Cronbach's alpha coefficient.[18,19]

Results

There were 30 (37.04%) of 81 criteria that gave different meanings in the translation process. An overview of the needed modifications of items of the STOPP questionnaire is presented in Table 1. The instrument feasibility assessment showed that 5 (62.50%) expert team members agreed to be continued the field test without revision and 3 (37.50%) expert team members agreed to be continued the field test with the revision.

I-CVI values were >0.7 for each item and an I-CVI/ave value was 0.99.[20]

The total number of subjects at the pretest stage was 34 respondents. The basic characteristics of respondents are presented in Table 2. The internal consistency showed that 14-item criteria were not relevant. Therefore, a retest was carried out on these items. The internal consistency of the first test and retest is presented in Table 3.

In the field test stage, respondents were pharmacists from 320 hospitals in Indonesia and obtained 230 (71.88%) respondents. Five respondents did not complete the questionnaire, and the characteristics of respondents are

Table 1: Overview of adaptation of the Screening Tool of Older People's Prescriptions version 2 instrument to the Indonesian language

Modification type	Expert team review	Criterion	Type of equalization
Use of specific words	The term was more commonly used in medicine Causing the wrong meaning with the word "blocker" or vice versa	A3, B3, IB4, B5, B11, B12, C3-11, D4, F2, H8, I2, and J3	Semantic, idiomatic, conceptual
Remove the name of the drug from the criteria	Medicine is not available in Indonesia	B10, D3, J1, K4, and L1	Experiential, conceptual
Rewrite and use specific words	The term was more commonly used in medicine	B13 and D11	Semantic, idiomatic, conceptual
Add information	Except for glimepiride	J1	Experiential, conceptual

Table 2: Basic demographic characteristics of respondents

Characteristics	Pretesting (*n*=34)	Field test (*n*=230)
The region		
Regional 1	34 (100.00)	135 (58.69)
Regional 2	0 (0.00)	47 (20.61)
Regional 3	0 (0.00)	29 (12.72)
Regional 4	0 (0.00)	4 (1.75)
Regional 5	0 (0.00)	15 (6.58)
Hospital level		
Tertiary hospital	0 (0.00)	28 (12.17)
Secondary hospital	34 (100.00)	222 (97.37)
Gender		
Male	5 (14.70)	38 (16.67)
Female	29 (85.30)	192 (83.47)
Age (years)		
20-30	11 (32.36)	124 (54.39)
31-40	16 (47.06)	80 (34.78)
41-50	6 (17.65)	23 (10.00)
>50	2 (5.88)	3 (1.32)
Last education		
Pharmacist	29 (85.30)	194 (85.09)
Magister of pharmacy	5 (14.70)	36 (15.65)
Time of duty in the pharmaceutical service (years)		
>1	6 (17.65)	65 (28.51)
2-5	8 (23.53)	79 (34.65)
5-10	13 (38.23)	51 (22.37)
>10	8 (23.53)	35 (15.22)

Data are expressed in *n* (%). Regional 1=Banten, DKI Jakarta, West Java, Central Java, East Java, DI Yogyakarta, Regional 2=West Sumatra, Riau, South Sumatra, Lampung, Bali, West Nusa Tenggara, Regional 3=Nanggroe Aceh Darussalam, North Sumatra, Jambi, Bengkulu, Riau Islands, North Sulawesi, Central Sulawesi, Southeast Sulawesi, Gorontalo, West Sulawesi, South Sulawesi, Regional 4=South Kalimantan, Central Kalimantan, Regional 5=Bangka Belitung, East Nusa Tenggara, East Kalimantan, North Kalimantan, Maluku, North Maluku, Papua, West Papua

presented in Table 2. A mean score of each item criterion was more than 3 points, except for Item_1 (2.86 ± 0.95), Item_2 (2.86 ± 0.89), and Item_10 (2.96 ± 0.73). The construct validity was 5-item criteria that were "not valid," namely in Item_1/A1 (r = 0.262; P = 0,000), Item_3/A3 (r = 0.423; P = 0,000), Item_10/B7 (r = 0.401; P = 0,000), Item_13/B20 (r = 0.373; P = 0,000), and Item_19/C3 (r = 0.442; P = 0,000). The Cronbach's alpha was 0.978 and Cronbach's alpha based on standardized items was 0.979.

Discussion

This study used a different validation method from the study of Luz *et al*. and Samaranayake *et al*. They used the Delphi two-round method.[21,22] The forward translation process involved three translators, one translator was an educator who understood pharmacy and clinical pharmacy well, and the other two were educators who were experts in the languages and cultures of both countries (English and Indonesian). It aimed to get the right word selection and reduce the ambiguous meanings, so produced a better instrument equivalence.[15] Our study also conducted a review of the results of the back translation obtained from the authorities, which provides corrections to 5 criteria related to the replacement of terms, an affirmation of statements in sentences, replacement of words, improvement of wording, and an affirmation of subgroups of drugs. This process aimed to reduce errors in translation results, correct sentences to be easily understood, and assess the quality of translations with the original version.[23]

The expert team review stage begun with the submission of the manuscript, to be reviewed every for all item in

Table 3: Internal consistency of the first test and retest of 14-item criteria

Criteria	First test		Retest	
	Corrected item-total correlation	Cronbach's alpha if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
Item_8 (B5)	0.383	0.982	0.807	0.962
Item_9 (B6)	0.266	0.982	0.830	0.961
Item_17 (C1)	0.353	0.982	0.867	0.960
Item_18 (C2)	0.400	0.982	0.812	0.961
Item_19 (C3)	0.419	0.982	0.787	0.962
Item_20 (C4)	0.360	0.982	0.838	0.961
Item_26 (C10)	0.415	0.982	0.715	0.964
Item_39 (D12)	0.252	0.982	0.867	0.960
Item_40 (D13)	0.345	0.982	0.771	0.962
Item_41 (D14)	0.394	0.982	0.776	0.963
Item_59 (H4)	0.400	0.982	0.804	0.962
Item_61 (H5)	0.393	0.982	0.776	0.962
Item_79 (L2)	0.375	0.982	0.864	0.960
Item_81 (M1)	0.337	0.982	0.729	0.963

STOPP_INA and responded in writing; forming panels, to share their opinions and opinions with one another; and sending the text of the reconciliation results from any difference of opinion in the panel, to be reviewed and responded to in writing. This process was carried out to obtain semantic equality, idiomatic equality, experiential equality, and conceptual equality between STOPP_INA instruments and the original version.[23] The description of the field test respondents showed that the data collection was quite good.

Data were obtained from regional 1 to regional 5, which means that it could represent the entire territory of Indonesia. Respondents' assessment of STOPP_INA used four Likert scales. This aimed to eliminate the answer to the middle value, which is "don't know."

The measurement of content validity in this study was obtained from qualitative and quantitative measurements. Qualitative measurements resulted from the consideration of the expert team (validity by assumption),[24] which resulted in a modification in the STOPP criteria as in Table 1. Quantitative measurements were obtained from two subjects, namely from the expert team and respondents in the pretest stage. The content validity of the expert team review was measured with the I-CVI and the I-CVI/ave value, which means that there was a match between each measurement item with the contents of the measured variable.[20,24]

The content validity of the pretest respondents was measured using correlation between test factors[24] that 14 items had a low conformity with a correlation value <0.45,[25] which means that they had a low alignment and consistency of items to the instrument.[26] Therefore, these items were retested at the same respondent to improve internal consistency. The face validity qualitatively showed that a correlation was obtained from the reviews and opinions of the expert team, related to the consistency of the style and format of the writing, while from respondents in the pretest stage, related to the readability and clarity of the language, not confusing, unambiguous, a sentence was not too long or too short.[24,27] Quantitative measurements were obtained from descriptive eligibility both from the expert team and from pretest respondents, which showed that the instrument could be accepted.

The construct validity qualitatively ("validity by assumption") was obtained from content validity and face validity, which results in a modification of STOPP_INA before field testing.[24] The quantitative, carried out empirically using field test data, through measurement of internal consistency (Cronbach's alpha), Item to Total items correlations, Inter-Item Correlation, Cronbach's Alpha if Item Deleted.[26] The reliability test analysis showed a high value of internal consistency degree for each item and all items in the instrument, which means that the STOPP_NA instrument was reliable for repeated measurements. Based on the item's correlation value to the total Item it shows 5 Item "not valid" criteria because it gave a correlation value <0.45.[25] Their item showed a low correlation value to other items, as in Item_1 (A1) with each item in the instrument, except for Item_2 (A2), while in Item_3 (A3), Item_10 (B7), Item_13 (B13), and Item_19 (C3), each has a low correlation with each other item. Therefore, they could be considered to be removed from the STOPP_INA instrument. Criteria of "not valid" did not remove from the instrument because they have related to other criteria, even though removing the criteria could increase the Cronbach's alpha significantly. This was being caused by some matter, among others: in criterion A1, had an incomplete sentence. The correction was an inserting the word "and" in-between words "indications based"; in criterion A3, had no relevance between the sentence of a statement and an explanation. The correction was a changing word "a new drug" became "other drugs of the same class/group"; in criterion B7, had been influenced ability and experience of respondents in clinical practice of geriatric care. In old age, oedema can occur due to poor circulation (sitting too often), so causing a buildup of fluid in the lower body, especially at the ankles and feet. The correction was a using of criterion that had been agreed by the expert team; in criterion B10, had an imperfection of sentence order. The correction was an inserting of explanation sentence before the word "except"; in criterion C3: had not given the name of medicines. The correction of C3 was an adding of the name of medicines. The Adaptation and validation of STOPP version 2 for Indonesian population could be accepted 81 criteria (100.00%), was different from the STOPP-START adaptation study for the Sri Lanka population that had been rejected 8% item of original instruments.[22]

The Indonesian version of STOPP criteria has been developed. We hope the instrument can be used in clinical practice and research on medication among the elderly. Currently, the STOPP_INA are being tested in clinical practice against elderly patients undergoing hospitalization for ensuring the capability of the instrument as a tool of identification PIM. The final adapted and validated version of the questionnaire is available online in the journal's website as a Supplement Table 1.

Authors' Contribution

All authors contributed to the design, the questionnaire developing, data collection, and analysis. All authors

participated in the editing, reviewing, and approval of the final version of the manuscript.

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Conflicts of interest

There are no conflicts of interest.

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