# **Original Research**

# Assessing medication counseling skills during transitioning from pre-clinical to clinical years among medical students: using generalizability theory to optimize reliable pharmacology exam design

Sethapong Lertsakulbunlue (D), Anupong Kantiwong (D)





Received (first version): 14-Jun-2024

Accepted: 28-Aug-2024

Published online: 30-May-2025

#### Abstract

Background: Physician medication counseling (MC) skills are crucial for improving adherence, treatment outcomes, and minimizing preventable medical errors. However, studies on MC among medical students, particularly in the pre-clinical stage, are scarce. Objective: This study analyzed an MC examination to identify common errors and determine the number of assessment items and questions needed for reliable evaluation. Methods: Ninety-five third-year students took a written examination on MC at the end of their third year. The exam included 10 questions on common drugs used in different systems, each with five error types (item) that varied per question. There were eight assessment items: administration time, adverse drug reaction, drug interval, indication, drug interaction, compliance, dosage form, and drug-specific information. Each item scored 2 for 'Fully correct,' 1 for 'Partially correct,' and 0 for 'Incorrect.' A Kruskal-Wallis test was used to compare the scores for each item, and a generalizability study was conducted to determine the sources of variance and the optimal number of items and questions, Results: The Cronbach's alpha for the exam is 0.88. The unidimensionality of the questions was confirmed (Eigenvalue1:Eigenvalue2=4.95:0.97, λ=0.52-0.82). The median (IQR) score is 52 (40-63) out of 100. Significant differences were found in the mean rank of each item, H(7)=195.13, p<0.001. Items with relatively high medians (IQR) included dosage form (1.33 [1.00-1.67]) and drug interval (1.38 [1.13-1.50]), while drug interaction (1.00 [0.00-1.00]), compliance (0.80 [0.00-1.00]), and specific information (0.40 [0.00-0.80]) were lower. Most of the variance is attributable to students (11.60%), and items nested within the question are 20.70%. The current study had a Phi-coefficient of 0.85; at least eight questions are needed for reliable assessment using five items (Phi-coefficient = 0.82). Whereas utilizing all 8 items, 6 questions are required (Phicoefficient = 0.84). For optimization, at least six questions using six items are needed for reliable assessment (Phi-coefficient = 0.80).

Conclusion: This study identified MC errors and highlighted areas for improvement before transitioning from pre-clinical to clinical years. Moreover, most variance is due to items nested within questions, indicating that different types of errors should be assessed in each question, which reflects real-life counseling challenges.

Keywords: Medical students, Pre-clinical, Medication counseling, Generalizability theory, Pharmacology

## INTRODUCTION

Medication counseling (MC) is a major responsibility for physicians, with newly graduated doctors counseling in numerous inpatient and outpatient settings. Medical curricula worldwide and the Thailand Medical Council mandate that medical students meet professional MC skills standards1. Moreover, hospitalization and discharge often involve care discontinuity, multiple medication changes, and insufficient patient education on drug use, respiratory devices, disease information, and potential side effects2. This can lead to medication nonadherence, a significant problem that can compromise patient care and treatment outcomes. Pharmacists typically provide MC after the patient meets with the physician, which is known to improve adherence

Sethapong Lertsakulbunlue. Department of Pharmacology, Phramongkutklao College of Medicine, Bangkok 10400, Thailand. Sethapong.ler@pcm.ac.th Anupong Kantiwong\*. Department of Pharmacology, Phramongkutklao College of Medicine, Bangkok 10400, Thailand. anupongpcm31@gmail.com

and treatment outcomes<sup>3</sup>. However, physicians also play a significant role in MC, enhancing adherence and treatment continuity and reducing prescription errors through better medical reviews<sup>4</sup>. These errors can result in substantial health and economic impacts, with estimates indicating that preventable medication errors could cost between \$17 billion and \$29 billion annually5. Moreover, patients often express dissatisfaction with MC in various areas, including drug indications, drug interactions, adverse events, and costs, which can lead to poor communication with physicians<sup>3,6,7</sup>. Therefore, improving the effectiveness of MC can help build trust in the patient-physician relationship and enhance treatment quality8.

Given the high stakes involved, medical students must be proficient in prescription counseling before encountering patients. However, previous literature on physicians has mostly focused on prescription writing rather than counseling skills9. To the best of our knowledge, previous medication counseling training literature mostly focuses on pharmacy students using Objective Structured Clinical Examinations (OSCE)<sup>10,11</sup>. Among physicians, training typically targets senior medical students and residents, utilizing checklists for workplace-based practice or workshops<sup>1,12</sup>. To date, early exposure to clinical



context among pre-clinical years students is an innovative approach to readying them to meet with real patients<sup>13</sup>. Thus, Phramongkutklao College of Medicine (PCM) provides preclinical students with MC knowledge and conducts written exams to identify potential pitfalls in their understanding. Well-prepared written exams are essential for assessing students' original and creative thinking, written expression skills, subject knowledge, and applying knowledge and skills<sup>14</sup>. Although OSCE could provide a more realistic approach to assessing MC skills, it consumes time, personnel and resources. It may also not capture all the pitfalls in students' understanding due to their higher excitement than written exams<sup>15</sup>.

This study utilized Generalizability theory, an extension of classical reliability theory, to assess the primary variable of interest and subject performance against error variance. It statistically determines the reliability and validity of educational assessments by analyzing variance sources such as occasions, items, and students<sup>16</sup>. Generalizability theory is instrumental in evaluating and improving assessment quality. Moreover, Decision studies identify specific assessment errors and recommend optimal assessment structures, including the necessary number of questions and assessment criteria (item) for reliable results<sup>17</sup>. Given the restricted time, this approach would aid in designing both formative and summative assessments for transitioning pre-clinical students to clinical practice in medication counseling. Furthermore, to the best of our knowledge, the use of generalizability theory in this context is rare.

To the best of our knowledge, most published data focus on prescription writing errors rather than understanding prescription counseling<sup>18</sup>. Hence, this study aimed to identify common pitfalls in pre-clinical students' knowledge of various types of prescribing counseling. This insight will help improve pre-clinical students' comprehensive understanding of medication counseling before they advance to clinical training and are exposed to real patient counseling. This study also employed Generalizability theory analysis to identify sources of variance and determine the reliability of various numbers of questions and items. The findings will help establish the optimal number of items and questions for future written MC exams, providing valuable insights for institutions with a high student-to-teacher ratio and restricted time before the transition to clinical years.

# **METHODS**

## Study design and subjects

A sample size of 66 was required for an effect size of 0.64 with 80% power at a significant level of 0.05 on a Two-sample Wilcoxon rank-sum (Mann-Whitney) test using G\*Power 3.1.9.7<sup>11,19</sup>. This study retrospectively analyzed cross-sectional data from a written prescription counseling examination among 95 third-year pre-clinical medical students at Phramongkutklao College of Medicine in Bangkok, Thailand. Due to the analysis of secondary data, the study received exemption approval from the Medical Department Ethics Review Committee for

Research in Human Subjects, Institutional Review Board, Royal Thai Army (IRBRTA) (Approval no. S041h/66 Xmp).

# Written prescription counseling examination process and development

At the end of their third year, after completing all pharmacology courses in their pre-clinical years, the students were tested with ten written examination questions on common medications used in outpatient settings and instances of irrational drug use. For example, the examination covered topics such as insulin, drugs used in non-ST elevated myocardial infarction, contraceptive drugs, migraine treatments, allergic rhinitis, and ciprofloxacin, a common drug used for urinary tract infections, along with its interaction with antacids. An example of the examination format with key answers is shown in Figure 1.

The questions were developed according to the blueprint for the must-know drugs for third-year medical students at PCM, which aligns with the Thai national licensing criteria<sup>20</sup>. The overall assessment comprised eight items from reviews of medical counseling steps and errors aligning with the context of a written examination for pre-clinical students<sup>3,6,7,10,12</sup>. Each question included five items for assessment, which varied between questions (Table of specifications is shown in Figure 2). These items included:

- 1) Drug interval: The administration interval, such as once daily or as needed.
- Administration time: When the drug should be administered, such as before or after meals.
- 3) Dosage form: Explain the dosage form. For example, insulin should be explained as being administered subcutaneously.
- 4) Drug indication: Explain why the patient needs to take the drug and provide a brief mechanism of how it works in relation to the disease.
- 5) Adverse drug reaction: The possible adverse drug reactions and precautions the patient should take.
- 6) Drug interaction: Potential drug interactions and steps the patient should take to avoid them.
- 7) Compliance counseling: Instructions on how the patient should adhere to the medication, including addressing potential drug resistance in cases of nonadherence.
- 8) Drug-specific information: Information specific to the particular drug. For example, what to do if a dose is missed when taking contraceptive drugs.

Scores for each item were assigned as follows: 2 for 'Completely correct,' 1 for 'Partially correct,' and 0 for 'Incorrect.'

Three professors from PCM's pharmacology department ensured content validity using the item-objective congruence (IOC) method. They assessed content validity based on language, relevance of context and items, realism, and clarity. Each question and its corresponding items attained a content validity index exceeding 0.67 out of 1.00, indicating good



# Please write your answer for appropriate medication counseling in the space provided

Given that XX replaces the standard drug administration times, such as PC, AC, HS, or Immediately.

Question 1. Diagnosis: Urinary tract infection (Underlying disease: Peptic ulcer)

Prescription:

- Ciprofloxacin (500 mg) 1x2 PO XX
- Antacids 30 mL PO prn for dyspepsia

| Medication counseling |  |  |
|-----------------------|--|--|
|                       |  |  |
|                       |  |  |
| •                     |  |  |

| <u>KEY</u>   |                       |
|--|-----------------------|
| Items  | Counseling types      |
| Take Ciprofloxacin after a meal (2 marks)  | Drug time             |
| Adverse drug reaction (tendinitis: exercise precaution, QT prolongation: palpitation and syncope precaution) (2 marks) | Adverse drug reaction |
| Ciprofloxacin bid and Antacids as needed (prn) (2 marks)   | Drug interval         |
| Drug interactions: should not be eaten concurrently (2 marks)  | Drug interaction      |
| Antibiotic compliance and resistance (2 marks)   | Compliance            |

Figure 1. Example of medication counseling written examination format with key answer



| d.       |  |   | Error type (item) |                     |                |                    |                             |                     |            |                         |  |  |  |
|----------|--|---|-------------------|---------------------|----------------|--------------------|-----------------------------|---------------------|------------|-------------------------|--|--|--|
| Question | Diagnosis                              | Drug used   | Drug<br>interval  | Administration time | Dosage<br>form | Drug<br>indication | Adverse<br>drug<br>reaction | Drug<br>interaction | Compliance | Specific<br>Information |  |  |  |
| Q1       | Urinary tract infection                | -Ciprofloxacin<br>-Antacids                                 | •                 | •                   |                |                    | •                           | •                   | •          |                         |  |  |  |
| Q2       | Type 1<br>Diabetes                     | -Pre-mixed insulin  | •                 | •                   | •              | •                  | •                           |                     |            |                         |  |  |  |
| Q3       | NSTEMI                                 | -Aspirin<br>-Atorvastatin                                   | •                 | •                   |                | •                  | •                           |                     | •          |                         |  |  |  |
| Q4       | Family planning for contraception      | Drospirenone+Ethinylestradiol                               | •                 | •                   |                | •                  | •                           |                     |            | •                       |  |  |  |
| Q5       | Migraine without aura                  | -Mefenamic acid<br>-Dimenhydrinate                          | •                 | •                   |                | •                  | •                           |                     |            | •                       |  |  |  |
| Q6       | Acute otitis media                     | -Azithromycin<br>-Ibuprofen                                 | •                 | •                   |                | •                  | •                           |                     |            |                         |  |  |  |
| Q7       | Allergic rhinitis                      | -Loratadine<br>-Phenylephrine                               | •                 | •                   |                | •                  | •                           |                     | •          | •                       |  |  |  |
| Q8       | Insomnia due<br>to anxiety<br>disorder | -Diazepam<br>-Vitamin B complex                             |                   | •                   |                | •                  | •                           | •                   |            | •                       |  |  |  |
| Q9       | Upper respiratory tract infection      | -Amoxicyllin+clavulanic acid<br>syrup<br>-Paracetamol syrup |                   |                     | •              |                    | •                           |                     | •          |                         |  |  |  |
| Q10      | Acute<br>gastroenteritis               | -Norfloxacin<br>-Oral rehydration salt                      |                   | •                   | •              | •                  |                             |                     | •          | •                       |  |  |  |

 <sup>=</sup> Included item

Figure 2. Table of specifications for medication counseling written examination

validity (above 0.50) as assessed by the instructors.

#### **Preparation and assessments**

Before the exam, students acquired medication counseling knowledge through various classes, including interactive lectures, case-based discussion, team-based learning and problem-based learning throughout their pre-clinical years. The tests were conducted during the final block for third-year students. Subsequently, three pharmacology department teachers from PCM, each with over ten years of teaching experience, assembled and rated the students' answers. The students' written exams were simultaneously marked on a screen. In cases of disagreement, the final score was determined by a two-out-of-three vote consensus among the teachers.

#### Statistical analysis

The data were analyzed using IBM SPSS Statistics for Windows, Version 29.0. Armonk, NY: IBM Corp and StataCorp, 2021, Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC. Descriptive statistics were expressed as frequency with percentages and median with interquartile ranges (IQR). The internal consistency reliability of the assessment tool was evaluated using Cronbach's alpha. Exploratory factor analysis was also done to confirm the construct validity of the questions. The Kruskal-Wallis test compares the mean rank sum across items.

To enhance the reliability assessment of the instrument, a

generalizability theory analysis was conducted using a 3-way ANOVA with a person-by-item nested within-questions (P×(I:Q)) design was conducted. The present analysis comprised five components of variance: the main effects of persons (P), questions (Q), items nested within questions (I:Q), two-way interactions between persons and questions (PQ), and the residual error variance (PI:Q, e). This approach considered the influence of interactions among all facets and other unidentified sources of variability. The nested design was employed because each question contained different items. Items were nested within questions due to multiple items per question, with each question having unique items. The item and question facets were crossed with persons because each person responded to all items and questions<sup>21,22</sup>.

In addition, a decision study or optimization study was also calculated for each item and question combination. The absolute G-coefficient (Phi-coefficient) was selected to assess the reliability of individual facet combinations. The error term includes the Phi-coefficient, which adjusts for any systematic (primary) effects of the facets that introduce error into the estimate. The absolute coefficient was used because the students' prescription counseling scores were assessed based on predetermined criteria rather than in comparison to one another. A cutpoint of 0.80 was used to indicate good reliability for summative examinations, while a cutpoint of 0.70 was used for formative examinations<sup>16,23</sup>. The generalizability theory analysis was done using EduG version 6.0e<sup>24</sup>.



#### **RESULTS**

#### **Characteristics**

Ninety-five third-year pre-clinical medical students at PCM underwent a prescription counseling examination. Table 1 shows the scores of the students in the prescription counseling written exam. The median (IQR) score is 52 (40-63) out of 100. The median score for each question ranges between 4 and 7. Figure 3 shows the scores stratified by each item. Over half of the students answered correctly regarding the drug interval (62.1%), administration time (56.0%), and dosage form (50.9%). On the other hand, a high proportion of errors were observed in the specific information (80.1%), compliance (80.1%), drug interaction (62.6%), and adverse drug reaction (60.7%) items.

The Cronbach's alpha for the exam is 0.88 (95%CI 0.84:0.92). Exploratory factor analysis was performed with principal component analysis. The unidimensionality of the questions was confirmed (Eigenvalue component 1: Eigenvalue component 2=4.95:0.97). The Kaiser–Meyer–Olkin measure of sampling adequacy was applied, yielding an overall index of 0.88, indicating sufficient data for factor analysis. Additionally, Bartlett's test for sphericity confirmed that the intercorrelation matrix was factorable ( $\chi 2 = 412.52$ , p < 0.001). The factor loadings are good, between 0.52 and 0.82, and all are over 0.30 (Supplementary Table 1).

# Comparison of median score stratified by item types

Table 2 shows the comparison of median scores for each item. The Kruskal-Wallis test revealed significant differences in the mean rank of each item, H(7) = 195.13, p<0.001. Items with relatively high median (IQR) include dosage form (1.33 [1.00-1.67]) and drug interval (1.38 [1.13-1.50]), while drug interaction (1.00 [0.00-1.00]), compliance (0.80 [0.00-1.00]), and specific information (0.40 [0.00-0.80]) are at the lower end. Dosage form (mean rank = 524.33) and drug interval (mean rank = 500.61) have a relatively high mean rank. In contrast, specific information has the lowest mean rank (mean rank = 189.15), with post hoc analysis revealing that this item is significantly lower than all other items.

#### Generalizability study (G-study)

Table 3 shows the results from the two-facet G-study for the P×(I:Q) nested design. The analysis reveals that 11.6% of the total variance is attributable to the students (P), representing the universe score. The variance component due to the question (Q) accounts for 0%, while the items nested within the question (I:Q) account for 20.70%. Additionally, the percentage of variance due to the interaction between students' performance and questions is only 2.90%. Finally, the residual variance is relatively high, comprising 64.80%.

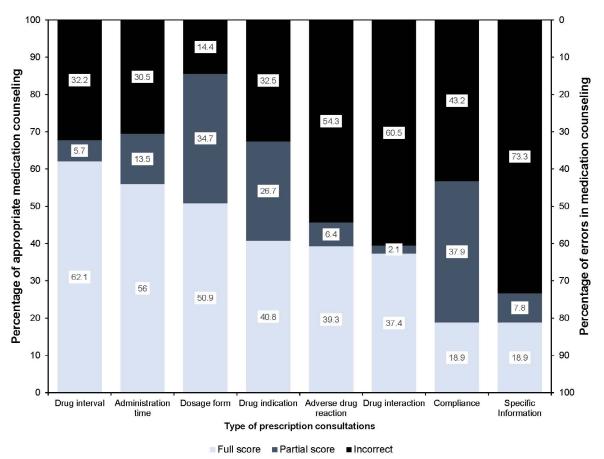


Figure 3. Percentage of appropriate medication counseling stratified by items



| Table 1. Scor | es of medi | cation counsel   | ing examination am  | nong third-yea | ar preclinical st  | tudents (N=95               | 5)                  |            |                         |            |  |  |  |  |
|---------------|------------|------------------|---------------------|----------------|--------------------|-----------------------------|---------------------|------------|-------------------------|------------|--|--|--|--|
|               |            |                  |                     |                | Ite                | ems                         | <u> </u>            |            |                         |            |  |  |  |  |
| Question      | Score      | Drug<br>interval | Administration time | Dosage<br>form | Drug<br>indication | Adverse<br>drug<br>reaction | Drug<br>interaction | Compliance | Specific<br>Information | Total      |  |  |  |  |
|               |            | n (%)            |                     |                |                    |                             |                     |            |                         |            |  |  |  |  |
| Q1            | 2          | 73 (76.8)        | 58 (61.1)           | N/A            | N/A                | 25 (26.3)                   | 44 (46.3)           | 21 (22.1)  | N/A                     |            |  |  |  |  |
|               | 1          | 8 (8.4)          | 1 (1.1)             | N/A            | N/A                | 10 (10.5)                   | 3 (3.2)             | 35 (36.8)  | N/A                     | 5 (4-7)    |  |  |  |  |
|               | 0          | 14 (14.7)        | 36 (37.9)           | N/A            | N/A                | 60 (63.2)                   | 48 (50.5)           | 39 (41.1)  | N/A                     |            |  |  |  |  |
| Q2            | 2          | 30 (31.6)        | 28 (29.5)           | 29 (30.5)      | 35 (36.8)          | 27 (28.4)                   | N/A                 | N/A        | N/A                     |            |  |  |  |  |
|               | 1          | 3 (3.2)          | 2 (2.1)             | 48 (50.5)      | 34 (35.8)          | 0 (0.0)                     | N/A                 | N/A        | N/A                     | 4 (2-5)    |  |  |  |  |
|               | 0          | 62 (65.3)        | 65 (68.4)           | 18 (19.0)      | 26 (27.4)          | 68 (71.6)                   | N/A                 | N/A        | N/A                     |            |  |  |  |  |
| Q3            | 2          | 71 (74.7)        | 26 (27.4)           | N/A            | 29 (30.5)          | 30 (31.6)                   | N/A                 | 10 (10.5)  | N/A                     |            |  |  |  |  |
|               | 1          | 0 (0.0)          | 46 (48.4)           | N/A            | 18 (19.0)          | 5 (5.3)                     | N/A                 | 36 (37.9)  | N/A                     | 5 (3-6)    |  |  |  |  |
|               | 0          | 24 (25.3)        | 23 (24.2)           | N/A            | 48 (50.5)          | 60 (63.2)                   | N/A                 | 49 (51.6)  | N/A                     |            |  |  |  |  |
| Q4            | 2          | 26 (27.4)        | 39 (41.1)           | N/A            | 60 (63.2)          | 25 (26.3)                   | N/A                 | N/A        | 23 (24.2)               |            |  |  |  |  |
|               | 1          | 3 (3.2)          | 33 (34.7)           | N/A            | 4 (4.2)            | 9 (9.5)                     | N/A                 | N/A        | 8 (8.4)                 | 4 (2-6)    |  |  |  |  |
|               | 0          | 66 (69.5)        | 23 (24.2)           | N/A            | 31 (32.6)          | 61 (64.2)                   | N/A                 | N/A        | 64 (67.4)               |            |  |  |  |  |
| Q5            | 2          | 88 (92.6)        | 46 (48.4)           | N/A            | 34 (35.8)          | 48 (50.5)                   | N/A                 | N/A        | 45 (47.4)               |            |  |  |  |  |
|               | 1          | 0 (0.0)          | 30 (31.6)           | N/A            | 2 (2.1)            | 1 (1.1)                     | N/A                 | N/A        | 1 (1.1)                 | 6 (4-8)    |  |  |  |  |
|               | 0          | 7 (7.4)          | 19 (20.0)           | N/A            | 59 (62.1)          | 46 (48.4)                   | N/A                 | N/A        | 49 (51.6)               |            |  |  |  |  |
| Q6            | 2          | 77 (81.1)        | 68 (71.6)           | N/A            | 47 (49.5)          | 58 (61.1)                   | N/A                 | 14 (14.7)  | N/A                     |            |  |  |  |  |
|               | 1          | 0 (0.0)          | 0 (0.0)             | N/A            | 10 (10.5)          | 1 (1.1)                     | N/A                 | 44 (46.3)  | N/A                     | 7 (4-8)    |  |  |  |  |
|               | 0          | 18 (19.0)        | 27 (28.4)           | N/A            | 38 (40.0)          | 36 (37.9)                   | N/A                 | 37 (39.0)  | N/A                     |            |  |  |  |  |
| Q7            | 2          | 62 (65.3)        | 82 (86.3)           | N/A            | 35 (36.8)          | 61 (64.2)                   | N/A                 | N/A        | 14 (14.7)               |            |  |  |  |  |
|               | 1          | 0 (0.0)          | 2 (2.1)             | N/A            | 52 (54.7)          | 3 (3.2)                     | N/A                 | N/A        | 5 (5.3)                 | 7 (4-8)    |  |  |  |  |
|               | 0          | 33 (34.7)        | 11 (11.6)           | N/A            | 8 (8.4)            | 31 (32.6)                   | N/A                 | N/A        | 76 (80.0)               |            |  |  |  |  |
| Q8            | 2          | N/A              | 67 (70.5)           | N/A            | 19 (20.0)          | 58 (61.1)                   | 27 (28.4)           | N/A        | 3 (3.2)                 |            |  |  |  |  |
|               | 1          | N/A              | 1 (1.1)             | N/A            | 31 (32.6)          | 2 (2.1)                     | 1 (1.1)             | N/A        | 6 (6.3)                 | 4 (2-6)    |  |  |  |  |
|               | 0          | N/A              | 27 (28.4)           | N/A            | 45 (47.4)          | 35 (36.8)                   | 67 (70.5)           | N/A        | 86 (90.5)               |            |  |  |  |  |
| Q9            | 2          | 45 (47.4)        | N/A                 | 39 (41.1)      | 47 (49.5)          | 4 (4.2)                     | N/A                 | 27 (28.4)  | N/A                     |            |  |  |  |  |
|               | 1          | 29 (30.5)        | N/A                 | 37 (39.0)      | 37 (39.0)          | 24 (25.3)                   | N/A                 | 31 (32.6)  | N/A                     | 5 (4-7)    |  |  |  |  |
|               | 0          | 21 (22.1)        | N/A                 | 19 (20.0)      | 11 (11.6)          | 67 (70.5)                   | N/A                 | 37 (39.0)  | N/A                     |            |  |  |  |  |
| Q10           | 2          | N/A              | 65 (68.4)           | 77 (81.1)      | 43 (45.3)          | N/A                         | N/A                 | 18 (19.0)  | 5 (5.3)                 | †          |  |  |  |  |
|               | 1          | N/A              | 0 (0.0)             | 14 (14.7)      | 40 (42.1)          | N/A                         | N/A                 | 34 (35.8)  | 17 (17.9)               | 6 (4-7)    |  |  |  |  |
|               | 0          | N/A              | 30 (31.6)           | 4 (4.2)        | 12 (12.6)          | N/A                         | N/A                 | 43 (45.3)  | 73 (76.8)               |            |  |  |  |  |
| Total         | 2          | 472 (62.1)       | 479 (56.0)          | 145 (50.9)     | 349 (40.8)         | 336 (39.3)                  | 71 (37.4)           | 90 (18.9)  | 90 (18.9)               |            |  |  |  |  |
|               | 1          | 43 (5.7)         | 115 (13.5)          | 99 (34.7)      | 228 (26.7)         | 55 (6.4)                    | 4 (2.1)             | 180 (37.9) | 37 (7.8)                | 52 (40-63) |  |  |  |  |
|               | 0          | 245 (32.2)       | 261 (30.5)          | 41 (14.4)      | 278 (32.5)         | 464 (54.3)                  | 115 (60.5)          | 205 (43.2) | 348 (73.3)              |            |  |  |  |  |



| Items                           | Median (IQR)                 | Mean Rank          | Test statistic | P-value | Significance<br>difference | Test<br>statistic | P-value <sup>a</sup> |
|---------------------------------|------------------------------|--------------------|----------------|---------|----------------------------|-------------------|----------------------|
|                                 | 1.38 (1.13-1.50)             | 500.61             |                |         | 5–1                        | -173.92           | <0.001               |
| 1. Drug interval                |                              |                    |                |         | 6–1                        | 194.36            | <0.001               |
| 1. Drug interval                |                              |                    |                |         | 7–1                        | 202.17            | <0.001               |
|                                 |                              |                    |                | <0.001  | 8–1                        | 311.46            | <0.001               |
| 2. Administration time          | 1.33 (1.00-1.56)             | 481.04             |                |         | 5–2                        | 154.34            | <0.001               |
|                                 |                              |                    |                |         | 6–2                        | 174.78            | <0.001               |
| z. Auministration time          |                              |                    |                |         | 7–2                        | 182.60            | <0.001               |
|                                 |                              |                    |                |         | 8–2                        | 291.88            | <0.001               |
|                                 | 1.33 (1.00-1.67)             | 524.33             |                |         | 4–3                        | 106.84            | 0.021                |
|                                 |                              |                    | 195.13         |         | 5–3                        | -197.63           | <0.001               |
| 3. Dosage form                  |                              |                    | 195.13         |         | 6–3                        | -218.07           | <0.001               |
|                                 |                              |                    |                |         | 7–3                        | -225.88           | <0.001               |
|                                 |                              |                    |                |         | 8–3                        | 335.17            | <0.001               |
|                                 | 1.11 (0.44-1.67)             | 417.48             |                |         | 6–4                        | -111.23           | 0.013                |
| 4. Drug indication              |                              |                    |                |         | 7–4                        | -119.04           | 0.005                |
|                                 |                              |                    |                |         | 8–4                        | -228.33           | <0.001               |
| 5. Adverse drug reaction        | 0.78 (0.44-1.22)             | 326.69             |                |         | 8–5                        | 137.54            | <0.001               |
| 6. Drug interaction             | 1.00 (0.00-1.00)             | 306.25             |                |         | 8–6                        | 117.10            | 0.006                |
| 7. Compliance                   | 0.80 (0.00-1.00) 298.44      |                    |                |         | 8–7                        | 109.29            | 0.016                |
| 8. Specific Information         | 0.40 (0.00-0.80)             | 189.15             |                |         |                            |                   |                      |
| Significance values have been a | adjusted by the Bonferroni c | orrection for mult | iple tests.    |         |                            |                   |                      |

| Source of Variation P×(I:Q) design | df   | SS       | MS     | Estimated Variance Component | % of Total Variance |
|------------------------------------|------|----------|--------|------------------------------|---------------------|
| Student (P)                        | 94   | 529.756  | 5.636  | 0.099                        | 11.6                |
| Question (Q)                       | 9    | 108.532  | 12.059 | -0.011                       | 0                   |
| Items:Question (I:Q)               | 40   | 694.758  | 17.369 | 0.177                        | 20.7                |
| PQ                                 | 846  | 572.728  | 0.677  | 0.025                        | 2.9                 |
| PI:Q                               | 3760 | 2082.042 | 0.554  | 0.554                        | 64.8                |
| Total                              | 4749 | 3987.816 |        | 0.844                        | 100                 |

# **Decision study (D-study)**

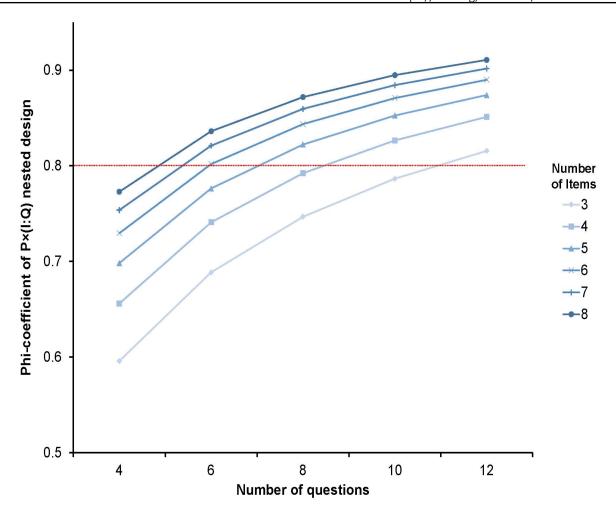
Figure 4 presents the D-study for the  $P\times(I:Q)$  nested design, forecasting the reliability of different combinations of assessment items and questions. The present study's absolute generalizability (G) coefficient (Phi-coefficient) is 0.85 for 5 items nested within 10 questions. When using 5 items, 8 questions are sufficient for reliable assessment (Phi-coefficient = 0.82). Whereas for 10 questions, at least 4 items are needed (Phi-coefficient = 0.83). When utilizing all 8 items, 6 questions are required (Phi-coefficient = 0.84). For optimization, 6 items with 6 questions are needed for a reliable summative assessment (Phi-coefficient = 0.80), while 4 items with 6 questions (Phi-coefficient = 0.74) or 3 items with 8 questions (Phi-coefficient = 0.75) are necessary. Supplementary Table 2 demonstrates the

detailed calculation of the D-study.

#### DISCUSSION

The present study successfully conducted a written examination on medication counseling among third-year medical students. The development of the examination was described, and its validity and reliability were found to be satisfactory, as evidenced by content validity, construct validity, internal consistency reliability, and generalizability theory analysis. The students demonstrated good counseling skills regarding dosage timing, intervals, and dosage forms. However, improvements may be needed in counseling about drug interactions, compliance, and specific information before they enter their





**Figure 4.** Decision study for the P×(I:Q) nested design, evaluating medication counseling among 95 pre-clinical medical students across 5 items nested within 10 questions. The coefficients indicate the projected phi-coefficient for various combinations of items and questions. The dotted line indicated an acceptable phi-coefficient of over 0.80.

clinical years. Additionally, the format with eight different types of items using five items nested within a question showed good reliability, exceeding 0.80, even with only eight questions. Furthermore, the decision study successfully estimated the reliability of different items and question combinations.

Although patient education on prescribed medications is crucial to a practitioner's role, previous studies have revealed patient dissatisfaction in some areas of physician medication counseling. In the present study, errors in medication counseling were relatively high regarding adverse drug reactions, drug interactions, compliance, and drug-specific information. This aligns with a study that identified practice gaps in these areas, revealing that information on adverse drug reactions, drug interactions, and their management is often inadequate from the patient's perspective. Additionally, a survey in Ethiopia found that patient knowledge about drug storage and precautions was low after medication dispensing. Related studies have also noted that patients need assistance incorporating medication regimens into their daily routines

and want information about medication costs<sup>7</sup>. These aspects would be valuable additions to future medication counseling examinations for clinical medical students who have experience working with real patients.

The participants in this study scored relatively higher on counseling items about dosage form, drug interval, and administration time, which are also of high concern to patients<sup>6</sup>. Despite the higher scores, some of the answers were only partially correct. Most students' information on dosage forms and drug indications was not comprehensively written. For example, the drugs were explained in terms of their name and disease, but not how their mechanisms help treat the disease. Additionally, in compliance counseling, the majority of students tend to forget to mention the probability of drug resistance in cases of nonadherence. Therefore, implementing techniques or checklists to improve the comprehensiveness of patient counseling may be advisable<sup>1</sup>.

The G-study in this research showed that most of the total variance is attributed to the items nested within the questions.



This occurred due to differences in difficulty among each type of item. These results are realistic and reflect the nature of real-life scenarios, where errors in medication counseling vary for each drug and drug combination<sup>6,7</sup>. Nevertheless, the study identified weaknesses in medication counseling among the students, and the variance may decrease if these weaknesses are addressed and improved in future assessments. On the other hand, the variance attributed to the questions is relatively low, revealing that the student's performance is less likely to be attributed to the questions. This highlights that the exam should be diverse and not limited to a single type of error.

Earlier research utilized the G-theory to investigate variance across various instructional and learning models<sup>16</sup>. This theory pinpoints potential error sources within the 'facets' of measurement conditions in the universe of permissible observations. Numerous studies assessing performance-based evaluations frequently report a significant percentage of unexplained residual variance<sup>16,23,25</sup>. The present study also exhibited a relatively high percentage of unexplained residual variance. Future investigations might need to explore different facets more extensively, including drug systems, raters, and occasions. Nevertheless, good reliability was achieved in the present study examination format.

The decision study revealed that only eight questions with five items each are adequate for a reliable summative assessment. However, the number of questions should be balanced with the learning objectives for each block or system. This information suggests that the present format could be used within a study block with less content, reducing the number of questions and learning objectives while still achieving a reliable assessment. Increasing the number of occasions with a lesser number of questions, maybe through formative examinations, could also be done to improve knowledge retention<sup>26,27</sup>. The current study also revealed that only five questions are needed for reliable formative assessment using the five-item format. Therefore, a formative peer-led mock examination is encouraged to contribute to timely and resource-efficient learning in medication counseling<sup>28</sup>.

Minimizing the number of items to three requires at least twelve questions. This approach could help focus on improving specific areas for the students, such as drug-specific information and drug interactions. Furthermore, the assessment could be more focused and less prone to errors or inconsistencies<sup>29</sup>. Having fewer criteria helps students understand the essential skills and competencies they must demonstrate. This clarity provides direction and purpose, motivating students to concentrate their efforts on what matters most<sup>30</sup>. However, the current exam, which has ten questions, takes about two hours to complete, and increasing the number of questions may not be feasible in some situations. Furthermore, the construct validity should be reconsidered once the number of items is decreased.

The current study presents a written examination assessing medication counseling. To the best of our knowledge, this is the first study to provide information on common errors in medical counseling among pre-clinical medical students.

Additionally, it provides significant insights into using G-theory to determine the number of items and questions needed for a reliable assessment. Minimizing the number of items may be beneficial to improve specific contextual knowledge. Hosting multiple occasions and reducing the number of questions to five may also enhance knowledge retention. Moreover, the present exam used in this study does not focus solely on a single system of drug prescriptions, thereby providing realistic results that represent the medication counseling errors of pre-clinical medical students from PCM. This would provide insights into what should be emphasized in future preclinical pharmacology education and identify which errors should be addressed before preclinical students transition to their clinical years and contact real patients.

This study has certain limitations. Given the context-specific nature of Generalizability theory, our results may not be generalizable to different educational environments, clinical scenarios, and instructors<sup>16</sup>. Therefore, external validation is necessary to evaluate the broader applicability of our findings across various educational settings, academic levels, clinical environments, and cultural contexts. Furthermore, this study was limited to a retrospective analysis of student answers and scores without evaluating students' confidence levels or performance during clinical years. Future research should focus on blueprinting, standard setting, consequences, quality control, prediction of later performance, and the relationship to other measures of medication counseling. Additionally, the assessments in this study were designed for written examinations and did not evaluate oral examinations or practical performance. Therefore, future assessments of real performance in OSCEs, workplace-based assessments or with simulated patients should be considered during the clinical years. Moreover, other aspects of medication counseling could be assessed in clinical years. For example, the information on the cost of drugs and the demonstration of inhalers<sup>6,7</sup>. Nevertheless, the focus on error types identified in this study could be adapted for these future assessments.

#### CONCLUSION

This study analyzes a written examination of medication counseling among pre-clinical year students. The common errors identified include providing drug-specific information, compliance counseling, drug interaction, and adverse drug reactions. These insights can help prepare students for effective medication counseling before transitioning to clinical years and counsel real patients. Furthermore, the generalizability theory analysis revealed that a major source of variance is attributed to the items nested within the questions. This indicates that each question may not need to assess the same type of errors, reflecting real-life situations where each drug combination may present different counseling challenges.

# **AUTHORS' CONTRIBUTIONS**

SL reviewed the literature, designed the study, collected the data, analyzed the data and wrote the manuscript. AK



reviewed the literature, designed the study, analyzed the data and supervised.

#### **CONFLICT OF INTEREST**

The authors declare no competing interests.

## References

- Gupta S, Shaw J. Development of medication-related counselling skills in senior medical students: a checklist-based approach. BMC Med Educ. 2019 Dec 5;19(1):335.
- 2. Sanii Y, Torkamandi H, Gholami K, Hadavand N, Javadi M. Role of pharmacist counseling in pharmacotherapy quality improvement. J Res Pharm Pract. 2016;5(2):132.
- 3. Tadesse YB, Sendekie AK, Mekonnen BA, Denberu FG, Kassaw AT. Pharmacists' Medication Counseling Practices and Knowledge and Satisfaction of Patients With an Outpatient Hospital Pharmacy Service. INQUIRY: The Journal of Health Care Organization, Provision, and Financing. 2023 Jan 22;60.
- 4. Bonnerup DK, Lisby M, Eskildsen AG, Sædder EA, Nielsen LP. Medication Counselling: Physicians' Perspective. Basic Clin Pharmacol Toxicol. 2013 Dec 26;113(6):425–430.
- 5. Gautam P. Minimizing medication errors: Moving attention from individual to system. J Anaesthesiol Clin Pharmacol. 2013;29(3):293.
- 6. Yi ZM, Zhi XJ, Yang L, Sun SS, Zhang Z, Sun ZM, Zhai SD. Identify practice gaps in medication education through surveys to patients and physicians. Patient Prefer Adherence. 2015;9:1423–30. PMID: 26557752
- Showande SJ, Laniyan MW. Patient medication counselling in community pharmacy: evaluation of the quality and content. J Pharm Policy Pract. 2022 Dec 16;15(1):103.
- 8. Crits-Christoph P, Rieger A, Gaines A, Gibbons MBC. Trust and respect in the patient-clinician relationship: preliminary development of a new scale. BMC Psychol. 2019 Dec 30;7(1):91.
- 9. Linton KateD, Murdoch-Eaton D. Twelve tips for facilitating medical students prescribing learning on clinical placement. Med Teach. 2020 Oct 2;42(10):1134–1139.
- 10. Farahani I, Farahani S, Deters MA, Schwender H, Laeer S. Training Pharmacy Students in Self-Medication Counseling Using an Objective Structured Clinical Examination—Based Approach. J Med Educ Curric Dev. 2021 Jan 31;8:238212052110164.
- 11. Garling KA, Wong B. An initial reliability analysis of a patient counseling rubric to objectively measure student pharmacist performance. Heliyon. 2023 May;9(5):e15768.
- 12. Kripalani S, Osborn CY, Vaccarino V, Jacobson TA. Development and evaluation of a medication counseling workshop for physicians: can we improve on 'take two pills and call me in the morning'? Med Educ Online. 2011 Jan 8;16(1):7133.
- 13. Tayade M, Latti R. Effectiveness of early clinical exposure in medical education: Settings and scientific theories Review. J Educ Health Promot. 2021;10(1):117.
- 14. Yuksel ME, Fidan H. A Decision Support System Using Text Mining Based Grey Relational Method for the Evaluation of Written Exams. Symmetry (Basel). 2019 Nov 19;11(11):1426.
- 15. Getu Ataro, Solomon Worku, Tsedeke Asaminew. Experience and Challenges of Objective Structured Clinical Examination (OSCE): Perspective of Students and Examiners in a Clinical Department of Ethiopian University. Ethiop J Health Sci. 2020 May 1;30(3).
- 16. Bloch R, Norman G. Generalizability theory for the perplexed: A practical introduction and guide: AMEE Guide No. 68. Med Teach. 2012 Nov 12;34(11):960–992.
- 17. Andersen SAW, Nayahangan LJ, Park YS, Konge L. Use of Generalizability Theory for Exploring Reliability of and Sources of Variance in Assessment of Technical Skills: A Systematic Review and Meta-Analysis. Academic Medicine. 2021 Nov 4;96(11):1609–1a619.
- 18. Tansuwannarat P, Vichiensanth P, Sivarak O, Tongpoo A, Promrungsri P, Sriapha C, Wananukul W, Trakulsrichai S. A 10-Year Retrospective Analysis of Medication Errors among Adult Patients: Characteristics and Outcomes. Pharmacy. 2023 Sep 1;11(5):138.
- 19. Faul F, Erdfelder E, Lang AG, Buchner A. G\*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods. 2007 May;39(2):175–191.
- 20. The Medical Council. Medical Competency Assessment Criteria for National License 2012. 2020;2:7–8. https://www.tmc.or.th/pdf/MCACNL2012-2-2563.pdf. Accessed 2 June 2024.
- 21. Brennan RL. Generalizability Theory. Educational Measurement: Issues and Practice. 1992 Dec 25;11(4):27–34.
- 22. Brennan RL. Generalizability Theory and Classical Test Theory. Applied Measurement in Education. 2010 Dec 30;24(1):1–21.
- 23. Briesch AM, Swaminathan H, Welsh M, Chafouleas SM. Generalizability theory: A practical guide to study design, implementation, and interpretation. J Sch Psychol. 2014 Feb;52(1):13–35.
- 24. Clauser BE. A Review of the EDUG Software for Generalizability Analysis. Int J Test. 2008 Aug 15;8(3):296–301.
- 25. Peeters MJ, Cor MK, Petite SE, Schroeder MN. Validation Evidence using Generalizability Theory for an Objective Structured Clinical Examination. Innov Pharm. 2021 Feb 26;12(1):15.
- 26. Lertsakulbunlue S, Kantiwong A. Development and validation of immediate self-feedback very short answer questions for



- medical students: practical implementation of generalizability theory to estimate reliability in formative examination designs. BMC Med Educ. 2024 May 24;24(1):572.
- 27. Sottiyotin T, Uitrakul S, Sakdiset P, Sukkarn B, Sangfai T, Chuaboon L, Palee P. Effective formative assessment for pharmacy students in Thailand: lesson learns from a school of pharmacy in Thailand. BMC Med Educ. 2023 May 2;23(1):300.
- 28. Braier-Lorimer DA, Warren-Miell H. A peer-led mock OSCE improves student confidence for summative OSCE assessments in a traditional medical course. Med Teach. 2022 May 4;44(5):535–540.
- 29. Al-Wardy NM. Assessment methods in undergraduate medical education. Sultan Qaboos Univ Med J. 2010 Aug;10(2):203–9. PMID: 21509230
- 30. Kusurkar RA, Orsini C, Somra S, Artino AR, Daelmans HEM, Schoonmade LJ, van der Vleuten C. The Effect of Assessments on Student Motivation for Learning and Its Outcomes in Health Professions Education: A Review and Realist Synthesis. Acad Med. 2023 Sep 1;98(9):1083–1092. PMID: 37146237



| Supplementary table 1. Exploratory factor analysis of medication counseling questions |      |  |  |  |  |  |  |
|---|------|--|--|--|--|--|--|
| Question 1  | 0.74 |  |  |  |  |  |  |
| Question 2  | 0.71 |  |  |  |  |  |  |
| Question 3  | 0.77 |  |  |  |  |  |  |
| Question 4  | 0.61 |  |  |  |  |  |  |
| Question 5  | 0.63 |  |  |  |  |  |  |
| Question 6  | 0.75 |  |  |  |  |  |  |
| Question 7  | 0.66 |  |  |  |  |  |  |
| Question 8  | 0.52 |  |  |  |  |  |  |
| Question 9  | 0.77 |  |  |  |  |  |  |
| Question 10   | 0.82 |  |  |  |  |  |  |
| Eigenvalues   | 4.95 |  |  |  |  |  |  |
| Extraction Method: Principal Components Analysis                                      |      |  |  |  |  |  |  |

| Supplem                             | Supplementary Table 2.1 Decision study of two-facet P×(I:Q) nested design medication counseling exam, among 95 medical students, 10 questions and 5 items |       |       |       |            |       |       |       |       |       |       |           |       |       |       |       |
|-------------------------------------|---|-------|-------|-------|------------|-------|-------|-------|-------|-------|-------|-----------|-------|-------|-------|-------|
| Effect                              | ect Estimate Variance Components In D-Study   |       |       |       |            |       |       |       |       |       |       |           |       |       |       |       |
| P×(I:Q)                             | n <sub>i</sub> ':nq'  | 03:04 | 03:06 | 03:08 | 03:10      | 03:12 | 04:04 | 04:06 | 04:08 | 04:10 | 04:12 | 05:04     | 05:06 | 05:08 | 05:10 | 05:12 |
| $\sigma_p^2$                        | 0.1   | 0.099 | 0.099 | 0.099 | 0.099      | 0.099 | 0.099 | 0.099 | 0.099 | 0.099 | 0.1   | 0.099     | 0.099 | 0.099 | 0.099 | 0.1   |
| $\sigma_{q}^{2}$                    | 0   | 0     | 0     | 0     | 0          | 0     | 0     | 0     | 0     | 0     | 0     | 0         | 0     | 0     | 0     | 0     |
| σ <sub>i:q</sub> <sup>2</sup>       | 0.18  | 0.015 | 0.01  | 0.007 | 0.006      | 0.005 | 0.011 | 0.007 | 0.006 | 0.004 | 0     | 0.009     | 0.006 | 0.004 | 0.004 | 0     |
| $\sigma_{pq}^{2}$                   | 0.03  | 0.006 | 0.004 | 0.003 | 0.003      | 0.002 | 0.006 | 0.004 | 0.003 | 0.003 | 0     | 0.006     | 0.004 | 0.003 | 0.003 | 0     |
| σ <sub>pi:q</sub> 2                 | 0.55  | 0.046 | 0.031 | 0.023 | 0.018      | 0.015 | 0.035 | 0.023 | 0.017 | 0.014 | 0.01  | 0.028     | 0.018 | 0.014 | 0.011 | 0.01  |
| $\hat{\sigma}^{_{\delta}}_{\delta}$ |   | 0.052 | 0.035 | 0.026 | 0.021      | 0.017 | 0.041 | 0.027 | 0.02  | 0.016 | 0.01  | 0.034     | 0.023 | 0.017 | 0.014 | 0.01  |
| $\hat{\sigma}^{2}_{\Delta}$         |   | 0.067 | 0.045 | 0.034 | 0.027      | 0.022 | 0.052 | 0.035 | 0.026 | 0.021 | 0.02  | 0.043     | 0.029 | 0.021 | 0.017 | 0.01  |
| Eρ²                                 |   | 0.654 | 0.739 | 0.791 | 0.825      | 0.85  | 0.708 | 0.784 | 0.829 | 0.858 | 0.88  | 0.745     | 0.814 | 0.854 | 0.879 | 0.9   |
| Φ                                   |   | 0.596 | 0.689 | 0.747 | 0.787      | 0.816 | 0.656 | 0.741 | 0.792 | 0.827 | 0.85  | 0.698     | 0.776 | 0.822 | 0.853 | 0.87  |
|                                     |   |       |       | C     | , /. nnaha |       | ^2    |       |       | -1-1  | ^2 -  | haal ta a |       |       | Г-?   | •     |

 $\sigma$ : Variance component,  $n_i'$ : number of items,  $n_a'$ : number of questions,  $\delta^2_{\kappa}$ : relative estimated total variance,  $\delta^2_{\kappa}$ : absolute estimated total variance,  $E\rho^2$ : relative reliability coefficient, Φ: Phi-coefficient (absolute reliability coefficient), Bold = good reliability (≥0.80)

Supplementary Table 2.2 Decision study of two-facet Px(I:Q) nested design medication counseling exam, among 95 medical students, 10 questions and 5 items

**Effect Estimate Variance Components In D-Study** 7 7 7 7 7 8 8 8 8 6 6 8 6 P×(I:Q) 4 6 4 6 8 6 8 n<sub>q</sub>′ 8 10 12 10 12 4 10 12 0.099 0.099 0.099 0.099 0.099 0.099 0.099 0.099 0.099 0.099 0.099 0.099 0.099 0.099 0.099 0.099  $\sigma_{q}^{2}$ 0 0.000 0.000 0.000 0.000 0.000 0.000 0.000 0.000 0.000 0.000 0.000 0.000 0.000 0.000 0.000 0.177 0.007 0.005 0.004 0.003 0.002 0.006 0.004 0.003 0.003 0.002 0.006 0.004 0.003 0.002 0.002 0.025 0.006 0.004 0.003 0.003 0.002 0.006 0.004 0.003 0.003 0.002 0.006 0.004 0.003 0.003 0.002 0.554 0.023 0.015 0.012 0.009 0.008 0.020 0.013 0.010 0.008 0.007 0.017 0.012 0.009 0.007 0.006 0.029 0.020 0.015 0.012 0.010 0.026 0.017 0.013 0.010 0.009 0.024 0.016 0.012 0.009 0.008 0.037 0.024 0.018 0.015 0.012 0.032 0.022 0.016 0.013 0.011 0.029 0.019 0.015 0.012 0.010 0.771 0.926  $E\rho^2$ 0.835 0.871 0.894 0.910 0.792 0.851 0.884 0.905 0.919 0.808 0.863 0.894

0.754  $\sigma$ : Variance component,  $\eta'_1$ : number of items,  $\eta'_2$ : number of questions,  $\hat{\sigma}^2_{\delta}$ : relative estimated total variance,  $\hat{\sigma}^2_{\delta}$ : absolute estimated total variance,  $\hat{E}\rho^2$ : relative reliability coefficient, Φ: Phi-coefficient (absolute reliability coefficient), Bold = good reliability (≥0.80)

0.821



0.802

0.844

0.871

0.890

0.730

0.911

0.884

0.902

0.773

0.836

0.872

0.860