# Modification and Evaluation of Tools for Pharmaceutical Care of Patients with Schizophrenia in Non-psychiatric Hospitals

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<td>Pharmaceutical care tools, schizophrenia, antipsychotic medications, extrapyramidal symptoms</td>
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Original Article

Modification and Evaluation of Tools for Pharmaceutical Care of Patients with Schizophrenia in Non-psychiatric Hospitals

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Abstract

Nowadays, the hospital pharmacists in Thailand still lack tools for using in the pharmaceutical care of patients with schizophrenia. The objectives of this study were to modify and evaluate the tools for this purpose. Four tools which were the Pharmacy Mental Status Examination, the Modified Simpson Angus Scale, the Modified Barnes Akathisia Rating Scale, and the Modified Abnormal Involuntary Movement Scale were modified from the original tools by selecting the items which were related to the context of the pharmaceutical care provided by hospital pharmacists. The evaluation methods were also modified. All of them have been modified by two experienced psychiatrists and one experienced pharmacist. One hundred and fifty six volunteer patients were involved in the evaluation of the modified tools. The results showed that all tools had acceptable content validity and internal consistency which represented by the values of Item Objective Congruence Index and Cronbach’s alpha coefficient, respectively. The concurrent validity represented by Spearman rho values indicated that all tools had a strong relationship with the original tools. The inter-rater reliability represented by quadratic-weighted kappa values showed at least good agreement between the experienced psychiatrist and pharmacist. It can be concluded that all modified tools had good validity and reliability and would be useful for the routine work of the hospital pharmacists in non-psychiatric hospital settings.

Keywords: Pharmaceutical care tools, schizophrenia, antipsychotic medications, extrapyramidal symptoms

1. Introduction

Schizophrenia is a chronic and severe mental disorder that affects patient’s perception, thought, mood, behavior and interpersonal relationship. The common
symptoms of schizophrenia include delusion, hallucination, thought disorders and movement disorders (The National Institute of Mental Health, 2016). The prevalence of schizophrenia in Thais was approximately 500,000 people (Phanthunane et al., 2010). Most of them need to be treated with antipsychotic medications for at least two years to control the symptoms and prevent the relapse (Lortrakul, 2012).

Normally, patients with schizophrenia will receive their treatment in psychiatric hospitals at the initial state before referring them back to their community hospitals to continue their treatment for preventing the relapse of symptoms. The pharmaceutical care should be provided to patients during their stay in the community hospitals to prevent and solve drug related problems. They need to be assessed for the effectiveness and the adverse reactions of the antipsychotic medications continuously throughout the treatment with medicines. However, most of healthcare professionals in the non-psychiatric community hospitals lack of specific knowledge on the antipsychotic medications. Therefore, the psychotic symptoms and the most common adverse reactions of typical antipsychotic medication, extrapyramidal symptoms (Lortrakul et al., 2012), are not assessed. This problem leads to the patient nonadherence to the medication, resulting in the relapse of symptoms. Finally, these patients have to be sent back to receive their treatment again in the psychiatric hospitals.

Pharmaceutical care (van Mil et al., 2013), thus, is helpful for safety and effectiveness of the antipsychotic medications. It can reduce the number of drug related problems, and increase knowledge of schizophrenia, adherence to antipsychotic use and quality of life in the physical and mental domain (Kanjanasilp et al., 2016). However, hospital pharmacists in Thailand encounter the problem of lacking tools for pharmaceutical care of patients with schizophrenia such as tools for assessing the
antipsychotic treatments both their adverse reactions and effectiveness. Although the direct face-to-face interview is the primary tool psychiatrists used for assessment of psychiatric patients, structured interviews, standardized data forms, questionnaires, and rating scales can also be useful tools for diagnosis and evaluation of the treatment outcome (Work Group on Psychiatric Evaluation, 2006).

The psychiatric assessment tools may help the interviewer create the complete structured questions and receive information on all issues within a determined period of time. However, tools for assessment available thus far such as the Positive and Negative Syndrome Scale Thai version (PANSS-T) (Nilchaikovit et al., 2000), the Psychogenic Movement Disorders Scale (Hinson et al., 2005), the Simpson-Angus Scale (SAS) (Simpson et al., 1970), and the Abnormal Involuntary Movement Scale (AIMS) (Guy, 1976) are mostly used only in research, but not for routine work since it takes a long time to interview and evaluate the patients. This study aims to modify and evaluate tools used for pharmaceutical care of patients with schizophrenia in non-psychiatric hospitals and pharmacists can use the proposed tools for their routine practice.

2. Materials and Methods

Modification of tools for pharmaceutical care of patients with schizophrenia

There were four tools modified in this study including the Pharmacy Mental Status Examination (PMSE), the Modified Simpson-Angus Scale (Mod-SAS), the Modified Barnes Akathisia Rating Scale (Mod-BARS), and the Modified Abnormal Involuntary Movement Scale (Mod-AIMS). The PMSE was modified for the pharmacists in non-psychiatric hospitals to use for the evaluation of the effectiveness of antipsychotic treatment in all schizophrenic patients who receive medication counseling or acute care service. In case the patient develops movement disorders during
antipsychotic treatment, the Mod-SAS, the Mod-BARS, and the Mod-AIMS are used for monitoring of parkinsonism, akathisia, and tardive dyskinesia, respectively.

All of these tools have been modified by two psychiatrists who have experience in the treatment of patients with schizophrenia for more than five years, and a pharmacist who has experience in pharmaceutical care of patients with schizophrenia for more than five years and also has been trained for the interview and the assessment of psychiatric symptoms using the Mental Status Examination (MSE) by expert psychiatrist. The items which were related to the context of pharmaceutical care performed by hospital pharmacists were selected and included in the modified tools. The PMSE, the Mod-SAS, the Mod-BARS, and the Mod-AIMS were modified from the MSE Thai version (MSE-T) of Suanprung Psychiatric Hospital (Tiam-Kaew, 2012), the SAS, the Barnes Akathisia Rating Scale (BARS) (Barnes, 1989), and the AIMS, respectively. The original tools were translated into Thai language using the common and well-known vocabulary to allow the practical use of these tools. The description of each item was defined including the basis for rating. This study was conducted at Suanprung Psychiatric Hospital, Chiang Mai, Thailand.

Evaluation of the Tools

Volunteers

The inclusion criteria were patients aged 14-80 years, known case with a history of schizophrenia for 4 weeks or longer, on International Statistical Classification of Diseases and Related Health Problems 10th revision (ICD-10), code F 20.x, duration of the treatment at least 1 day with both typical and atypical antipsychotics. Patients who could not be communicated in Thai language or patients who were threatened with serious medical conditions were excluded from the study. Totally, there were 156
patients recruited into the study. All patients or their legal representatives (if any) have signed the informed consent. This study was approved by Suanprung Psychiatric Hospital Ethic Committee.

**Content validity**

The content validity is the degree to which elements of an assessing tool are relevant, and represent the target, built for a particular assessment purpose of each tool. The three experts were requested to approve the content validity of the tools with the congruence form. The level of content validity was identified by Item Objective Congruence Index (IOC). The value of IOC near 1.0 shows high content validity and the value less than 0.5 might indicate the need to improve scale content (Rovinelli et al., 1977).

**Internal consistency**

Internal consistency is expressed by the Cronbach alpha coefficient (Tang et al., 2014). Total of twenty two patients were needed for internal consistency calculated by 90% power, minimum acceptable reliability of 0.6, and minimum desirable reliability of 0.8 (Conroy, 2015).

**Concurrent validity**

Concurrent validity expressed the degree to which the scores on the test were related to the scores on another established, test administered at the same time. Concurrent validity was presented by the nonparametric version of Pearson’s correlation, Spearman’s rank-order correlation coefficient. At 90% power and $\alpha = 0.05$, total of twenty five patients were needed for concurrent validity test (Hulley et al., 2013).

**Inter-rater reliability**
The inter-rater reliability, the degree of agreement among raters, was expressed as quadratic-weighted kappa ($k_w$). This study anticipates that raters will agree about 70% of gold standard, with expected relative error of 30%, twenty three patients were needed for the inter-rater reliability (Gwet, 2008).

**Data Analysis**

All statistical analyses were carried out using STATA for Windows version 14.0 (StataCorp LP; College Station, TX).

**3. Results**

**Modification of tools for pharmaceutical care of patients with schizophrenia**

**The Pharmacy Mental Status Examination (PMSE).**

The PMSE is the tool that has been modified from the MSE-T, which was used officially by psychiatrists to examine the mental status of patients. It is composed of 15 items used for the assessment. Some items which took a long time in evaluation and were not relevant to the efficacy of the drug were excluded from the modified tool. These items were consciousness, attention and concentration, memory, and judgment. Therefore, there were only 11 items presented in the modified tool which were 1. general appearance, 2. attitude, 3. psychomotor, 4. affect, 5. mood, 6. speech, 7. thought process, 8. thought content, 9. perception, 10. orientation, and 11. insight. To evaluate the outcome, the severity level of the symptoms was classified as 0 = normal; 1 = minimal symptoms which did not affect patient’s daily life, 2 = symptoms which sometimes or little affect patient’s daily life, and 3 = symptoms which strongly affect patient’s daily life. It took about 10 minutes to complete the evaluation.

**The Modified Simpson Angus Scale (Mod-SAS)**
The Mod-SAS was modified from the SAS, which had 10 items, and was used for evaluating pseudoparkinsonism. Four items were discarded during the development stage. Two of them, which were shoulder shaking, and glabella tap, were discarded because they were not appropriate for routine evaluation by pharmacists. Another two items, which were leg pendulousness, and head dropping, were discarded because they require additional equipment and place, such as, bed and table etc. Therefore, six items were selected for the Mod-SAS, namely, 1. gait, 2. arm dropping, 3. elbow rigidity, 4. wrist rigidity, 5. tremor, and 6. salivation. Each item had 5 levels of severity (0-4). The evaluation was modified from the original one (Hawley et al., 2003). It considered the score of individual item, which was evaluated in four levels. A score of 0 means normal. A score of 1 means the patient should be monitored weekly by the pharmacist (mild symptoms). A score of 2 means the pharmacist should consult a doctor to consider the revision of treatment plan (moderate symptoms). A score of 3 to 4 means the pharmacist should consult the doctor immediately to consider treatment (severe symptoms). If the score of the evaluation was 1 or more, the patient should be monitored and evaluated for pseudoparkinsonism. It took about 5 minutes for the evaluation.

The Modified Barnes Akathisia Rating Scale (Mod-BARS)

The Mod-BARS was modified from the BARS, which was widely used in clinical study for evaluation of motor restlessness syndrome, caused by antipsychotics. The four main items of BARS were objective, subjective: awareness of restlessness, subjective: distress related to restlessness, and global clinical assessment of akathisia. They were chosen to modify the Mod-BARS, where all details of the contents in the tools were preserved. The first three items had 4 levels of severity (0-3), and another
item had 6 levels of severity (0-5). The evaluation of the Mod-BARS was modified from the original one. If the evaluation score of global clinical assessment of akathisia was 1 or more, the symptom should be monitored for akathisia by the pharmacist. The evaluation took 5 minutes to complete.

The Modified Abnormal Involuntary Movement Scale (Mod-AIMS)

The Mod-AIMS was modified from the AIMS, which was used for evaluating symptoms and severity of choreoathetoid and other movement symptoms of tardive dyskinesia (TD). It consists of 14 items, but two of them were discarded during the modification stage for the conciseness of the tools. Therefore, the Mod-AIMS consisted of 12 topics, where ten of them must rate the movement disorder as 5 levels (0-4). Those ten items include 1. muscle of facial expression, 2. lips and perioral area, 3. jaw, 4. tongue, 5. upper (arms, wrists, hands, fingers), 6. lower (legs, knees, ankles, toes), 7. neck, shoulders and hips, 8. severity of abnormal movement overall, 9. incapacitation due to abnormal movements, and 10. Patient’s awareness of abnormal movements. Another two items were evaluated by yes or no. Those two items included 11. current problems with teeth and/or dentures, and 12. Are dentures usually worn? The evaluation part was newly modified from the original one (Schooler et al., 1982). It considered the score of individual item. If the score from rating was 1 or more, the patients would be monitored and evaluated for TD. It took 10 minutes to complete the evaluation.

Evaluation of the tools for pharmaceutical care of schizophrenia patients

The demographic of the patients with schizophrenia, who volunteered to participate in this study, is shown in Table 1.
Content validity

The content validity of all four modified tools was evaluated by three experienced psychiatrists. The results indicated that every tool had an acceptable content validity or better. This can be observed from the IOC values as shown in Table 2.

Table 2 The content validity and internal consistency of the four tools for pharmaceutical care of patients with schizophrenia.

Internal consistency

The internal consistency of all four modified tools was tested by two experienced pharmacists. The results indicated that all tools had an acceptable internal consistency as shown in Table 2. In case of the PMSE, which originally had 11 items, it was found that two topics (general appearance and speech) were not correlated very well with over all items (item-rest correlation 0.159 and 0.144, respectively), and were discarded. Therefore, there were 9 items left, and the Cronbach’s alpha value was increased from 0.833 to 0.853.

Concurrent validity

The concurrent validity of all four tools was implemented by two experienced psychiatrists. The patients were evaluated independently by the original tools and the evaluation results were blinded from other assessors. At the same time, two experienced pharmacists evaluated the patients by the newly modified tools. The relationship between the original tools and the newly modified tools was analyzed with the results in Table 3, which indicated that all tools had a strong relationship in the positive direction with statistically significance.
Table 3 The concurrent validity of the four tools for pharmaceutical care of patients with schizophrenia.

Inter-rater reliability

The inter-rater reliability was implemented by allowing an experienced psychiatrist to interview the patients and the interviews were observed by an experienced pharmacist. After finishing each patient interview, both psychiatrist and pharmacist independently rated each item in the modified tools. Table 4 showed that the analysis results of the psychiatrist had a good agreement with those of the pharmacist (the PMSE and the AIMS showed very good agreement, while the Mod-SAS and the Mod-BARS showed good agreement).

Table 4 The agreement of the four tools for pharmaceutical care of patients with schizophrenia.

4. Discussion

The four tools were modified from the original tools to correspond with drug use monitoring and evaluation, as well as movement disorder symptoms caused by antipsychotics. Since the purpose of the tools was for monitoring symptoms, not for diagnostic, only some evaluation criteria of the original tool was implemented.

The results indicated that all four tools had good validity and reliability. In addition, there are many obvious advantages of these tools. Firstly, the items were selected in such a way that a pharmacist can easily use. Secondly, the evaluation results were closely related to those obtained from the original tools. Thirdly, the evaluation by each tool takes not much time. These tools would be helpful for the routine work of the pharmacists who work in the non-psychiatric hospitals. However, the pharmacists, who
used those tools, needed to be graduated the short course training program in psychiatric pharmaceutical care, so that the tools could be used effectively.

The construct validity of the tools used in this study was not tested because of the following reasons. These tools were not newly developed but they were modified from the original tools employed by psychiatrists. The target users are non-psychiatric hospital pharmacists, who have significant lower level of psychiatric knowledge and skill compared to the psychiatrists. The construct validity of the modified tools may have been changed compared to the original tools because the experts have removed some items which were not suitable for the target pharmacists.

Although the number of patients with schizophrenia participating in this study was low, it was sufficient for statistical analysis.

The limitation of this study was that this study did not apply the reverse translation by language expert, but let an experienced psychiatrist choose the words that were commonly used for each item of the tools in response to the usage in psychiatry arena. These tools should be further examined on effectiveness and feasibility in a representative sample.

5. Conclusions

This study aims to modify and evaluate four tools for pharmaceutical care of patients with schizophrenia. The results indicated that all modified tools had good validity and reliability, and can be used in routine work.

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<table>
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<tr>
<th>Patients</th>
<th>PMSE</th>
<th>Mod-SAS</th>
<th>Mod-BARS</th>
<th>Mod-AIMS</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants</td>
<td>48</td>
<td>50</td>
<td>30</td>
<td>28</td>
<td>156</td>
</tr>
<tr>
<td>Male (%)</td>
<td>52.1</td>
<td>48.0</td>
<td>56.7</td>
<td>46.4</td>
<td>50.6</td>
</tr>
<tr>
<td>Age (years)</td>
<td>42.8±13.4</td>
<td>47.0±15.6</td>
<td>42.9±14.2</td>
<td>57.6±13.5</td>
<td>46.9±15.2</td>
</tr>
</tbody>
</table>

| Duration of the illness | ≥ 4 weeks | ≥ 4 weeks | ≥ 4 weeks | ≥ 4 weeks | ≥ 4 weeks |
| Duration of the treatment | ≥ 1 day | ≥ 1 day | ≥ 1 day | ≥ 1 day | ≥ 1 day |

Table 1 Baseline characteristics of the schizophrenic patients, who participated in the study.
<table>
<thead>
<tr>
<th>Number of participants</th>
<th>IOC</th>
<th>Cronbach’s alpha</th>
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<tbody>
<tr>
<td>PMSE</td>
<td>24: 0.67-1.00</td>
<td>0.853</td>
</tr>
<tr>
<td>Mod-SAS</td>
<td>27: 1.00</td>
<td>0.801</td>
</tr>
<tr>
<td>Mod-BARS</td>
<td>27: 0.67-1.00</td>
<td>0.929</td>
</tr>
<tr>
<td>Mod-AIMS</td>
<td>27: 0.67-1.00</td>
<td>0.731</td>
</tr>
</tbody>
</table>

PMSE = Pharmacy Mental Status Examination  
Mod-SAS = Modified Simpson Angus Rating Scale  
Mod-BARS = Modified Barnes Akathisia Rating Scale  
Mod-AIMS = Modified Abnormal Involuntary Movement Scale

Table 2 The content validity and internal consistency of the four tools for pharmaceutical care of patients with schizophrenia.
<table>
<thead>
<tr>
<th>Modified tools</th>
<th>Compared tools</th>
<th>Direction</th>
<th>Spearman rho</th>
<th>P-value</th>
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<tr>
<td>PMSE</td>
<td>MSE-T</td>
<td>+</td>
<td>$r_s(34) = 0.963$</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mod-SAS</td>
<td>SAS</td>
<td>+</td>
<td>$r_s(26) = 0.777$</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mod-BARS</td>
<td>BARS</td>
<td>+</td>
<td>$r_s(29) = 0.802$</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mod-AIMS</td>
<td>AIMS</td>
<td>+</td>
<td>$r_s(26) = 1.000$</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

PMSE= Pharmacy Mental Status Examination  
MSE-T= Mental Status Examination Thai version  
Mod-SAS= Modified Simpson Angus Rating Scale  
SAS= Simpson-Angus Scale  
Mod-BARS= Modified Barnes Akathisia Rating Scale  
BARS= Barnes Akathisia Rating Scale  
Mod-AIMS= Modified Abnormal Involuntary Movement Scale  
AIMS= Abnormal Involuntary Movement Scale

Table 3 The concurrent validity of the four tools for pharmaceutical care of patients with schizophrenia.
<table>
<thead>
<tr>
<th>Number of participants</th>
<th>Weighted Kappa, quadratic</th>
<th>P-value</th>
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<tbody>
<tr>
<td>PMSE</td>
<td>24</td>
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<tr>
<td>Mod-SAS</td>
<td>23</td>
<td>0.768</td>
</tr>
<tr>
<td>Mod-BARS</td>
<td>30</td>
<td>0.783</td>
</tr>
<tr>
<td>Mod-AIMS</td>
<td>23</td>
<td>0.965</td>
</tr>
</tbody>
</table>

PMSE = Pharmacy Mental Status Examination  
Mod-SAS = Modified Simpson Angus Rating Scale  
Mod-BARS = Modified Barnes Akathisia Rating Scale  
Mod-AIMS = Modified Abnormal Involuntary Movement Scale

Table 4 The agreement of the four tools for pharmaceutical care of patients with schizophrenia.