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Original Research

Evaluation of patient comprehension and quality of consumer medicine information

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Abstract

Background: Consumer medicine information (CMI) is voluntarily produced by pharmaceutical manufacturers in Thailand, but quality assessment of Thai-CMI is not routinely performed. **Objective:** This study aimed to evaluate the content and design quality of CMI available in Thailand and assess patient understanding of the medicine information provided. **Methods:** A cross-sectional study that consisted of two phases. Phase 1 was expert assessment of CMI using 15-item content checklists. Phase 2 was patient assessment of CMI by user-testing and the Consumer Information Rating Form. Participants (n=130) were outpatients aged 18 years or older with an educational level of less than grade 12. Self-administered questionnaires were distributed to patients at two university-affiliated hospitals in Thailand. **Results:** A total of 60 CMI produced by 13 Thai pharmaceutical manufacturers were included in the study. Most of the CMI contained essential information about the medicines, but lacked information about serious adverse effects, maximum dose, warnings, and use in specific patient groups. Of 13 CMI selected for user-testing, none met the passing criteria with only 40.8% – 70.0% of answers found in the correct position and answered correctly. The mean values of patients' rating the CMI were between 2.5 (SD=0.8) and 3.7 (SD=0.5) for utility on a 4-point scale, and 2.3 (SD=0.7) to 4.0 (SD=0.8) for comprehensibility and 2.0 (SD=1.2) to 4.9 (SD=0.3) for design quality on a 5-point scale. Eight CMI were rated as poor (less than 3.0) for font size. **Conclusion:** More safety information about medications should be included in Thai CMI and the design quality must be improved. CMI needs to be evaluated before distribution to consumers.

Keywords: assessment; consumer health communication; patient safety

INTRODUCTION

Patients receive medical information from their healthcare professionals that help them gain knowledge about their illnesses and satisfaction with their medications.[1] While information leaflets are inserted into every medicine package, the information provided is often more suited to healthcare professionals than it is to patients due to the use of technical language and unattractive designs.[2] These consumer medicine information (CMI) contains essential information about the medicine and its indications, how to take the medicine, precautions about taking the medicine, possible adverse drug reactions (ADRs), and storage of the medication.[3] To gain the most benefit from providing these leaflets with every medicine, they should be organized and written in language suitable for lay people to understand.

Guidelines on the preparation and assessment of CMI have been developed in the United States and Europe.[4,5] These guidelines specify that CMI must include the risks and benefits of the medicine to help make patients aware of unwanted effects and to promote the appropriate use of the medication.[6] In addition, the guidelines specify that CMI should be user-friendly and have a well-organized format that allows patients to easily find and understand the information.[7] User-testing tests the consumer's ability to locate information in a CMI and their ability to understand that information and has been widely used for the quality control of CMI in many regions and countries around the world.[8]

In Thailand, all medicines are registered with the Thai Food and Drug Administration (FDA) and pharmaceutical companies must provide leaflets with all medicines that include the basic details about the medication plus any warnings, and they must be written in the Thai language.[9] However, the provision of CMI by manufacturers and pharmaceutical companies remains voluntary and there is very little quality control of the CMI that are provided. This study aimed to assess the content and design quality of CMI produced by Thai pharmaceutical manufacturers, and assessed patient satisfaction with the comprehensibility, utility, and design quality of the CMI.

METHODS

Study design and setting

Cross-sectional study was carried out in 2 phases. Phase 1 assessed the content and design characteristics of CMI produced by manufacturers using a checklist. Phase 2 assessed the comprehensibility, utility, and design quality of the CMI

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by user testing and the Consumer Information Rating Form (CIRF). This study was conducted at outpatient clinics of the Srinagarind University Hospital and Queen Sirikit Heart Center in the northeast of Thailand for 12 months. The study was approved by the Ethics Committee for Human research, Khon Kaen University (HE591091).

Participants

Outpatients at Srinagarind Hospital and Queen Sirikit Heart Center aged 18 years or older with a maximum educational level of grade 12 were eligible for the study if they could read and complete the questionnaire by themselves and had no history of receiving CMI. As the required participants for user testing was ten per each CMI.[10] The total number of participants for user-testing in this study was 130. Participants were recruited into the study by purposive sampling.

Study instruments

Checklists for assessing CMI content and design

The content and design checklists were based on the Thai Guidelines for Leaflet Development and European Union regulations.[11,12] The 15-item content checklist included the name of product, what is in the medicine, what is this medicine used for, when should you not take this medicine, what other medicines or food should be avoided whilst taking this medicine, how much and how often should you use this medicine, what should you do if you miss a dose, signs and symptoms of overdose, what to do when you take more than the recommended dosage, action that should be taken when taking this medicine, when should you consult your doctor, undesirable effects, how should you store this medicine, the name of the manufacturer, importer, or marketing authorization holder and the date of latest revision. The 10-item design checklist included landscape orientation, three columns, A4-paper size, Tahoma font style, clear font color, font size at least 11 Tahoma, number of pages, Thai language, Arabic number use.

User-testing and the Consumer Information Rating Form

Thirteen multiple choice questions covering information about drug name, indication, precautions before use, how to take the medicines, possible side effects and what to do if the side effects occur, and how to store the medicines, were validated by three experts who had experience in medicine information. The 17-item of CIRF was used for assessing patients' perceptions of CMI in three dimensions: comprehensibility, utility, and design quality.[13]

Data collection

For phase 1, 16 manufacturers were contacted and asked to send their Thai language CMI. Sixty CMI were received from 13 manufacturers. Six CMI were collected from 6 manufacturers that produced one CMI, and 54 CMI were collected from the remaining 7 manufacturers. All 60 CMI were evaluated using the content and design checklists.

In phase 2, one CMI was selected from each manufacturer for a total of 13 CMI. For the seven manufacturers that produced more than one CMI, CMI were randomly selected after grouping them according to the pharmacological classification of the medicines. One CMI was distributed to each participant and returned within the same day. The participants were asked to review the CMI and complete the user-testing questions and the CIRF.

Data analysis

All quantitative data were analyzed using IBM SPSS for Windows version 19.0 and are reported using descriptive analysis; mean (standard deviation; SD), percentage, or median (range) as appropriate. For phase 1, a binary scoring system was applied based on the content or design of the CMI that met the criteria checklists (1 = presence, 0 = absence). The scores were calculated as the percentage of total available information.

For user testing, participants were asked to locate information in a CMI and answer questions about the medicine information provided. The percentage of participants who could correctly locate the information in the CMI and the percentage of participants who could provide the correct answer were calculated. In order for a CMI to pass user-testing, the information must be located correctly by at least 90% of participants and at least 90% of these participants must then correctly answer the question, corresponding to 81% of participants locating the correct answer at the correct location.[11]

The CIRF measures patients' perceptions of the comprehensibility of CMI across 5 categories (reading, understanding, remembering, and finding information and storing the CMI) using a 5-point rating scale ranging from 1 = very hard to 5 = very easy. The CIRF utility score is a composite score of information quantity (0 = too little or too much information, or 1 = suitable amount of information) and usefulness (1 = not useful to 3 = very useful) for a range score of 1-4 across 8 categories. The CIRF assessment of the design quality of the CMI was scored on a 5-point rating scale from 1 = worst to 5 = best across 9 categories.

RESULTS

Checklist assessment of CMI from Thai manufacturers

Content assessment

All 60 CMI included the brand name of the medicine, active ingredients, indications, administration, contraindications, side effects, drug interactions, storage, and name of manufacturer. More than three-quarters contained information about overdosage and overdose management (n=59, 98.3%), precautions (n=57, 95.0%), patient-specific advice (n=54, 90.0%), missed dose management (n=49, 81.7%), and duration of medication therapy (n=46, 76.7%). Information about serious ADRs (n=43, 71.7%), warnings (n=38, 63.3%), and maximum dose (n=26, 43.3%) were found less frequently. Side effects were mainly presented as verbal descriptions of symptoms without associated frequencies (n=44, 73.3%) (Table 1).

Design assessment

All CMI were written in Thai language with Arabic numerals in clear font colors. More than half of the CMI had a font size

Table 1. Contents of consumer medicine information (CMI) in Thailand (N=60)

Information	Number of CMI (%)
Brand name	60 (100.0)
Active ingredients	60 (100.0)
Indications	60 (100.0)
Mechanism of actions	19 (31.7)
Administration	60 (100.0)
Duration of medication therapy	46 (76.7)
Maximum dose	26 (43.3)
Overdose management	59 (98.3)
Missed dose management	49 (81.7)
Contraindications	60 (100.0)
Precautions	57 (95.0)
Warnings	38 (63.3)
Side effects	60 (100.0)
Verbal descriptions[a]	44 (73.3)
Numeric descriptions[b]	21 (35.0)
No frequency description	34 (56.7)
Serious adverse drug reactions	43 (71.7)
Drug interactions	60 (100.0)
Patient-specific advice	54 (90.0)
Pregnancy	54 (90.0)
Lactation	53 (88.3)
Children	28 (46.7)
Elderly	12 (20.0)
Storage	60 (100.0)
Manufacture information	60 (100)
Date of updated version	54 (90.0)

[a]Verbal descriptions were defined as "very common", "common", "uncommon", "rare", and "very rare."
[b]Numeric descriptions were defined as "frequency>10%", "1-10%", "0.1-1%", "0.01-0.1%", "<0.01%."

of less than 11 Tahoma. Less than one-fourth of the CMI used layouts in landscape orientation (n=9, 15.0%), or with three columns (n=1, 1.7%), or at A4 page size (n=13, 21.7%). Tahoma style font was not used in any of the examined CMI. The CMI had either 1 page (n=25, 41.7%) or 2 pages (n=35, 58.3%). The results of the design assessment are presented in Table 2.

Patient comprehension and evaluation of CMI

Demographic data

A total of 130 participants were included in this study. Most participants were female (n=95, 73.1%), with a mean age of 40.18 (SD=10.55) years (range 18-67 years). Most of the participants were employed in either agriculture (n=53, 40.8%) or in private businesses (n=40, 30.8%). Most participants had either a sixth or ninth grade education level (n=55 each, 84.6%). A high number of participants reported that they always read the leaflet before using their medications (n=91, 70.0%), with

Table 2. Design of CMI in Thailand (N=60)

Information	Number of CMI (%)
Clear font color	60 (100.0)
Tahoma font style	0 (0.0)
Font size	
Smaller than size 11 Tahoma	37 (61.7)
Size 11 Tahoma or equivalent	23 (38.3)
Landscape orientation	9 (15.0)
Number of pages	
1	25 (41.7)
2	35 (58.3)
Number of columns	
1	9 (15.0)
2	41 (68.3)
3	1 (1.7)
4	6 (10.0)
5	3 (5.0)
CMI size	
Smaller than A4 page	34 (56.7)
A4 page	13 (21.7)
Bigger than A4 page	13 (21.7)
Thai language	60 (100.0)
Arabic numerals	60 (100.0)
Pictograms	8 (13.3)

48.5% (n=63) reporting that they read all the contents. Most participants kept their CMI at least some of the time, with 50 participants reporting that they always kept their CMI and 50 participants reporting that they sometimes kept their CMI (77%) (Table 3). The average time taken to read CMI was 11.05 (SD=15.44) minutes (range 1.0–160.0 minutes).

User-testing of CMI

Thirteen CMI were selected: amiodarone, perindopril, atorvastatin, metformin, loperamide, apixaban, budesonide plus formoterol fumarate dehydrate inhalation, ciclesonide nasal spray, isotretinoin, betahistine, meloxicam, tenofovir disoproxil fumarate, and drospirenone plus ethinyl estradiol. Each CMI was assessed by ten participants. The participants located the relevant medicine information at the correct position for 44.6% to 74.6% of the questions (58–97 questions from a total of 130 questions) and provided the correct answer for 46.2% to 73.8% of the questions (60-96 questions from a total of 130 questions). None of the CMI achieved the 81% passing criteria of user-testing. Only 40.8% to 70.0% of participants located the correct answer at the correct location (Table 4 a&b).

The CMI for loperamide achieved the highest user testing score (70.0%), followed by betahistine (67.7%), and amiodarone and perindopril (both 65.4%), while the lowest user testing score was for the meloxicam CMI (40.8%). The maximum number of

Table 3. Characteristics of participants in user-testing process (N=130)	
Characteristics of participants	**Number of participants (%)**
Female	95 (73.1)
Age (years); Mean ± SD (Min - Max)	40.18 ± 10.55 (18 – 67)
Occupation	
Agriculture	53 (40.8)
Employee	40 (30.8)
Own business	15 (11.5)
None	10 (7.7)
Civil servants	5 (3.8)
Others[a]	7 (5.4)
Educational level	
Fourth grade	10 (8.5)
Sixth grade	55 (42.3)
Ninth grade	55 (42.3)
Twelfth grade	9 (6.9)
Having underlying disease	77 (59.2)
Frequency of reading drug leaflets before using medicines	
Always	91 (70.0)
Sometimes	29 (22.3)
Never	10 (7.7)
Contents of drug leaflets that usually read	
Read all contents of leaflets	63 (48.5)
Read only important contents	29 (23.8)
Read only interested contents	36 (27.7)
Keeping the drug leaflets after reading	
Always	50 (38.5)
Sometimes	50 (38.5)
Never	30 (23.1)

[a]Others = Students (n=5, 3.8%), private officer (n=1, 0.8%), others (n=1, 0.8%)

questions that met the criteria for any individual CMI was four (loperamide, budesonide plus formoterol fumarate dehydrate inhalation, isotretinoin, and betahistine). None of the questions from the atorvastatin and tenofovir disoproxil fumarate CMI met the criteria. The most common question that met the criteria was storage information, which met the criteria in eight CMI, followed by duration of using the medication, overdose management and use in specific patients, which met the criteria in three CMI, and indications, adverse drug reactions, and precautions, which met the criteria in two CMI. The remaining six questions achieved the criteria for only one CMI each. These questions were about the generic name, drug interactions, contraindications and precautions from the fact questions and missed-dose management and how to take the medication from the action required questions.

Consumer Information Rating Form (CIRF)

The results of the user evaluations using the CIRF are presented in Table 5 a&b. Participants rated the comprehensibility of each CMI on a scale of one to five in five aspects: how easy it was to read, understand, remember, find, and keep. The average scores for the comprehensibility aspects for each CMI were low to moderate ranging from 2.3 (SD=0.7) to 4.0 (SD=0.8) (range 1-5). For utility, participants rated the CMI on a scale of one to four for eight aspects (Table 5). The average scores for the utility aspects ranged from 2.5 (SD=0.8) to 3.7 (SD=0.5) (range 1-4). Most CMI were rated as moderate to good for usefulness and containing an adequate amount of information. Six CMI were rated as moderate for "adverse drug reactions" and five CMI were rated as moderate for "contraindications". In contrast, all CMI were rated as good for drug name, specific directions about how to take the medication, and storage. The design of each CMI was rated by the participants on a scale of one to five across nine aspects. The average scores for the design aspects of each CMI ranged from 2.0 (SD=1.27) to 4.9 (SD=0.3) (range 1-5). The CMI scored moderately favorable for design aspects, but eight CMI scored poorly in terms of font size.

Participants rated the CMI for loperamide (overall score 38.4 (SD=5.0) out of 45), isotretinoin (35.9 SD=8.5)), and atorvastatin (35.2 (SD=8.5)) as having a good level of overall design quality. The CMI for loperamide scored favorably in all items, except font size. The lowest overall design score was for the CMI for budesonide plus formoterol fumarate dehydrate inhalation (25.5 (SD=5.4)). The design quality of the CMI for budesonide plus formoterol fumarate dehydrate inhalation was rated as low for 6 of the 9 checklist items and the drospirenone plus ethinyl estradiol CMI was rated as low for 5 of the 9 checklist items.

DISCUSSION

The information provided in CMI can have an important impact on patient compliance, knowledge, and the effectiveness of the drug.[14,15] The current study evaluated the content of sixty CMI produced by Thai manufacturers. Unfortunately, no CMI contained all the topics listed in the checklist. All CMI included clear information about the brand name, active ingredients, indications, administration, contraindications, side effects, drug interactions, storage, and manufacturer information. However, the dosage instructions and administration topics were usually unclear, with unhelpful sentences like "take this medicine following your doctor's recommendation" or "use milligrams instead of number of tablets". Previous evidence has shown that patients are more likely to misunderstand this type of information, especially patients with low literacy.[16,17] More than one-quarter of all CMI lacked content about serious ADRs, warnings, and maximum dose of medication. A study in Thailand conducted in 2013 found that only 4% of nonsteroidal anti-inflammatory drug products had CMI and none of them covered all checklist items, and with only half including safety information such as contraindications, precautions, and ADRs.[18]

Including information about serious ADRs is important for

Table 4a. User-testing of the CMI

Questions	Cardiovascular system						Alimentary tract and metabolism				Respiratory system			
	Amiodarone		Perindopril		Atorvastatin		Metformin		Loperamide		Budesonide plus formoterol fumarate dehydrate inhalation		Ciclesonide nasal spray	
	F	U	F	U	F	U	F	U	F	U	F	U	F	U
Fact														
Generic name	8	8	9	9	7	7	8	6	5	6	7	6	4	4
Indication	9	9	8	8	7	8	4	7	6	8	8	7	8	8
Drug interaction	8	8	7	6	7	7	2	2	7	6	5	4	7	7
Contraindication	6	6	6	6	5	7	4	5	7	7	7	4	2	5
Duration	4	4	6	8	7	7	6	5	10	9	6	6	2	2
ADRs	6	6	7	6	4	7	10	10	6	6	8	9	6	7
Precaution	8	8	4	3	8	8	7	7	7	6	9	8	8	8
Action required														
Overdose	5	5	5	5	7	8	3	4	10	10	10	8	8	6
Missed dose	9	9	8	8	6	6	5	6	8	8	4	4	9	6
How to take	6	6	7	8	4	6	6	7	4	4	10	8	8	7
Storage	10	10	8	8	8	8	8	8	9	9	10	10	9	8
Explanation of action														
Use in specific patients	7	7	7	7	1	1	1	1	9	9	6	5	2	2
Precaution	2	1	9	10	3	3	7	7	7	8	7	7	7	6
Number of questions that met the criteria (n, %)	88 (67.7)	87 (66.9)	91 (70.0)	92 (70.8)	74 (56.9)	83 (63.8)	71 (54.6)	75 (57.7)	95 (73.1)	96 (73.8)	97 (74.6)	86 (66.2)	80 (61.5)	76 (58.5)
% Correct locating and answers[a]	65.4		65.4		56.9		43.8		70.0		64.6		55.4	
No. of questions that met criteria	3		2		0		1		4		4		1	
Average time of reading the CMI (minutes, mean (SD))	9.5 (5.8)		13.2 (13.2)		11.8 (7.8)		8.5 (8.3)		5.9 (2.8)		11.7 (7.9)		5.5 (3.9)	

Table 4b. User-testing of the CMI (Continue)

Questions	Blood and blood-forming organs		Dermatological system		Sensory organs		Musculo-skeletal system				Genito-urinary system and sex hormones		No. of CMI met criteria
	Apixaban		Isotretinoin		Betahistine		Tenofovir disoproxil fumarate		Meloxicam		Drospirenone plus Ethinyl estradiol		
	F	U	F	U	F	U	F	U	F	U	F	U	
Fact													
Generic name	7	7	5	6	6	6	6	4	3	2	4	3	1
Indication	9	9	6	8	6	7	6	6	3	4	8	8	2
Drug interaction	6	6	7	6	9	8	5	5	6	4	4	3	1
Contraindication	3	2	7	7	8	7	10	10	4	5	8	8	1
Duration	4	2	10	9	9	8	5	4	6	6	6	6	3

ADRs	4	4	6	6	5	6	8	6	5	6	10	10	2
Precaution	4	4	7	6	8	8	2	2	7	7	8	5	1
Action required													
Overdose	8	8	10	10	7	6	6	9	1	1	2	4	3
Missed dose	7	7	8	8	4	3	7	7	5	4	6	5	1
How to take	3	3	4	4	5	5	4	7	2	4	8	6	1
Storage	7	7	9	9	10	10	10	10	8	8	10	9	8
Explanation of action													
Use in specific patients	5	5	9	9	10	9	5	3	3	3	1	1	3
Precaution	2	1	7	8	7	7	9	8	5	6	3	3	2
Number of questions that met the criteria (n, %)	69	65	95	96	94	90	83	81	58	60	78	71	-
	(53.1)	(50.0)	(73.1)	(73.8)	(72.3)	(69.2)	(63.8)	(62.3)	(44.6)	(46.2)	(60.0)	(54.6)	
% Correct locating and answers[a]	46.9		58.5		67.7		50.0		40.8		44.6		-
No. of questions that met criteria	1		4		4		3		0		2		-
Average time of reading the CMI (minutes, mean (SD))	7.8 (7.2)		5.9 (2.8)		8.0 (4.4)		21.8 (48.8)		10.7 (9.2)		17.1 (11.4)		-

Table 5a. Consumer ratings of the CMI using the consumer information rating form

	Consumer medicine information (mean (SD))						
Item	**Cardiovascular system**			**Alimentary tract and metabolism**		**Respiratory system**	
	Amiodarone	**Perindopril**	**Atorvastatin**	**Metformin**	**Loperamide**	**Budesonide plus formoterol**	**Ciclesonide nasal spray**
Comprehensibility[a]							
Read	3.2 (0.6)	3.7 (0.8)	3.6 (0.8)	3.0 (0.7)	3.4 (0.7)	2.7 (0.7)	3.4 (0.8)
Understand	3.1 (0.6)	4.0 (0.8)	2.9 (1.0)	2.8 (0.6)	3.5 (0.9)	3.1 (0.6)	3.9 (0.6)
Remember	3.0 (0.8)	3.7 (0.8)	2.7 (1.1)	2.5 (0.7)	3.4 (0.7)	2.5 (0.7)	3.7 (1.0)
Find	3.0 (0.8)	3.3 (1.1)	2.7 (1.3)	2.9 (0.7)	3.1 (1.0)	3.3 (1.2)	3.4 (1.3)
Keep	3.2 (1.0)	3.9 (0.1)	3.6 (1.2)	3.5 (0.7)	3.6 (1.0)	3.4 (1.0)	3.9 (1.0)
Total (range 5-25)	15.5 (2.6)	18.6 (3.3)	15.5 (3.7)	14.7 (2.1)	17.0 (3.3)	15.0 (2.4)	18.3 (3.7)
Utility[b]							
Name	3.4 (0.5)	2.9 (0.7)	3.2 (1.0)	3.3 (0.7)	3.2 (0.8)	3.5 (0.5)	3.3 (0.7)
Indication	3.6 (0.5)	3.3 (0.8)	3.1 (0.7)	3.2 (0.6)	3.7 (0.5)	3.4 (0.5)	3.1 (0.7)
Contraindication	3.0 (1.1)	3.1 (0.9)	2.8 (0.8)	3.1 (0.7)	3.3 (0.7)	3.0 (0.7)	3.0 (0.9)
Precaution	3.3 (0.7)	3.3 (0.7)	3.3 (0.7)	3.0 (0.5)	3.0 (0.7)	3.3 (0.5)	3.2 (0.8)
Instructions	3.3 (0.5)	3.2 (0.8)	3.2 (0.8)	2.5 (0.8)	3.7 (0.5)	3.0 (0.7)	3.2 (0.8)
Actions required	3.3 (0.7)	3.3 (0.7)	3.1 (1.1)	3.0 (0.9)	3.4 (0.7)	3.3 (0.5)	3.3 (0.8)
ADRs	2.9 (0.7)	2.9 (0.6)	3.1 (1.0)	3.0 (0.8)	3.2 (0.9)	3.2 (0.6)	2.8 (1.0)
Storage	3.4 (0.5)	3.4 (0.7)	3.1 (0.7)	3.2 (0.8)	3.5 (0.7)	3.1 (0.7)	3.3 (0.7)
Total (range 8-32)	26.2 (3.9)	25.4 (3.4)	24.9 (5.0)	24.3 (2.9)	27.0 (3.7)	25.8 (3.4)	25.2 (5.3)
Design quality[c]							
Layout	3.2 (1.1)	3.9 (0.9)	4.6 (0.7)	3.4 (1.2)	4.0 (1.2)	3.3 (0.7)	3.3 (1.2)
Attractiveness	3.7 (1.3)	4.2 (0.9)	4.5 (1.1)	3.2 (1.2)	4.6 (0.5)	3.6 (1.2)	3.5 (1.2)
Paper size	3.0 (1.3)	3.8 (1.0)	3.9 (1.0)	3.3 (1.4)	4.2 (1.0)	2.9 (1.6)	3.3 (1.3)

Number of pages	3.5 (0.5)	3.5 (0.9)	3.6 (1.6)	3.1 (1.1)	4.2 (1.2)	2.6 (1.2)	3.4 (1.4)
Font size	2.5 (1.2)	3.0 (1.2)	3.2 (1.5)	2.3 (1.1)	3.0 (1.4)	2.3 (1.3)	2.9 (1.4)
Font style	3.3 (1.2)	3.6 (0.8)	3.9 (1.4)	3.1 (1.0)	4.5 (0.9)	2.8 (1.1)	3.2 (1.1)
Font clearness	3.4 (1.5)	3.7 (1.1)	3.6 (1.2)	3.1 (0.7)	4.5 (1.0)	2.1 (0.9)	3.8 (1.1)
Line space	3.4 (1.3)	3.5 (1.2)	4.0 (1.3)	3.0 (0.7)	4.5 (0.9)	2.6 (1.0)	3.3 (0.9)
Border space	3.8 (0.9)	4.0 (0.9)	3.9 (1.4)	3.1 (1.0)	4.9 (0.3)	3.3 (0.9)	3.2 (1.1)
Total (range 9-45)	29.8 (7.6)	33.2 (7.6)	35.2 (8.5)	27.6 (6.5)	38.4 (5.0)	25.5 (5.4)	29.9 (9.3)

Table 5b. Consumer ratings of the CMI using the consumer information rating form (Continue)

Item	Consumer medicine information (mean (SD))						
	Blood and blood forming organs	**Dermatological system**	**Sensory organs**	**Musculo-skeletal system**		**Genito-urinary system and sex hormones**	**Total**
	Apixaban	**Isotretinoin**	**Betahistine**	**Tenofovir disoproxil fumarate**	**Meloxicam**	**Drospirenone plus ethinyl estradiol**	
Comprehensibility[a]							
Read	3.0 (0.8)	2.6 (0.8)	3.0 (0.9)	2.7 (0.7)	3.3 (1.2)	2.6 (1.0)	3.1 (0.9)
Understand	3.0 (1.2)	3.1 (0.7)	3.3 (1.1)	2.8 (0.6)	3.7 (0.8)	3.5 (1.3)	3.3 (0.9)
Remember	3.0 (0.9)	3.2 (0.6)	3.0 (0.7)	2.5 (0.8)	3.1 (1.1)	2.7 (0.9)	3.0 (0.9)
Find	3.5 (0.9)	3.4 (0.8)	3.4 (0.8)	2.7 (0.8)	3.3 (1.3)	2.3 (0.7)	3.1 (1.0)
Keep	3.6 (0.7)	3.5 (1.2)	3.2 (0.8)	3.6 (1.0)	3.7 (1.3)	3.3 (1.2)	3.5 (1.0)
Total (range 5-25)	16.1 (3.3)	15.8 (2.6)	15.9 (3.3)	14.3 (2.3)	17.1 (3.8)	14.4 (2.9)	16.0 (3.2)
Utility[b]							
Name	3.7 (0.5)	3.0 (0.7)	3.4 (0.5)	3.0 (0.8)	3.3 (0.8)	3.0 (0.5)	3.3 (0.7)
Indication	3.4 (0.7)	2.9 (0.6)	3.2 (0.6)	2.8 (1.0)	3.2 (0.4)	2.7 (0.8)	3.2 (0.7)
Contraindication	3.3 (0.8)	2.6 (0.8)	2.9 (0.6)	2.9 (1.0)	2.9 (0.9)	3.0 (0.7)	3.0 (0.8)
Precaution	3.5 (0.7)	2.6 (0.8)	2.9 (0.6)	3.3 (0.7)	3.4 (0.7)	2.7 (1.2)	3.1 (0.7)
Instructions	3.5 (0.5)	3.3 (0.7)	3.3 (0.7)	2.8 (1.1)	3.5 (0.7)	3.0 (1.1)	3.2 (0.8)
Actions required	3.7 (0.5)	3.1 (0.7)	3.1 (0.3)	3.0 (0.5)	3.2 (0.8)	3.0 (0.8)	3.2 (0.7)
ADRs	3.6 (0.7)	2.8 (1.0)	2.8 (0.8)	3.0 (0.7)	3.0 (0.9)	2.9 (0.9)	3.0 (0.8)
Storage	3.5 (0.7)	3.1 (0.6)	3.2 (0.6)	3.4 (0.5)	3.6 (0.7)	3.2 (0.6)	3.3 (0.7)
Total (range 8-32)	28.2 (3.6)	23.4 (3.5)	24.8 (3.3)	24.4 (4.5)	26.1 (4.1)	23.5 (4.8)	25.3 (4.0)
Design quality[c]							
Layout	4.1 (0.7)	4.3 (1.1)	3.9 (1.2)	3.5 (1.2)	4.1 (1.1)	3.4 (1.4)	3.8 (1.1)
Attractiveness	3.7 (1.3)	4.3 (0.9)	4.0 (1.2)	3.7 (1.6)	3.9 (1.2)	3.3 (1.6)	3.9 (1.2)
Paper size	3.7 (1.1)	4.0 (1.2)	4.0 (1.3)	3.5 (1.8)	3.9 (1.6)	3.4 (1.4)	3.6 (1.3)
Number of pages	3.6 (1.6)	4.0 (0.9)	3.9 (1.4)	3.0 (1.7)	3.2 (1.2)	2.8 (1.4)	3.4 (1.3)
Font size	2.3 (1.3)	3.6 (1.3)	2.7 (1.6)	2.1 (1.3)	3.2 (1.8)	2.0 (1.2)	2.7 (1.4)
Font style	3.8 (1.3)	3.7 (1.3)	2.9 (1.5)	2.9 (1.4)	4.0 (1.3)	2.2 (1.1)	3.4 (1.3)
Font clearness	3.0 (1.2)	4.0 (1.2)	2.5 (1.5)	2.6 (1.6)	3.9 (1.5)	2.9 (1.6)	3.3 (1.4)
Line space	3.9 (1.2)	3.9 (1.1)	2.9 (1.6)	3.4 (1.3)	4.4 (1.4)	2.6 (1.1)	3.5 (1.3)
Border space	3.9 (1.2)	4.1 (1.3)	3.7 (1.6)	3.8 (1.3)	4.1 (1.4)	3.5 (1.5)	3.8 (1.2)
Total (range 9-45)	32.0 (7.3)	35.9 (8.5)	30.5 (9.0)	28.5 (10.9)	34.7 (10.6)	26.1 (9.0)	31.3 (8.8)

CMI as it can be helpful for patients to correctly perceive and manage when an ADR is occurring.[19] However, providing this type of information in leaflets can make patients anxious about side effects and stop taking their medication despite no ADR occurring.[20] Presenting side effects with verbal descriptions such as "common", "rare", or "very rare" can cause patients to overestimate risk, which can cause them to stop taking their medication.[21,22] Therefore, numerical descriptors such as "frequency>10%", or "1 in 1000" are favored as patients provided with these more accurate estimates show increased consumer satisfaction.[23,24] Only one-third of the CMI examined in the current study presented numerical side-effect risk information, which is similar to the 28% rate reported in a previous study.[25]

The percentage of leaflets in the current study that presented information about use in paediatric and elderly patients was 46.7% and 20.0%, respectively, which is similar to previous studies (44% and 13% of leaflets, respectively).[25,26] One study of CMI for medications used in the treatment of type 2 diabetes and cardiovascular disease found that 15% of the CMI included information specific for older patients,[27] whereas another study found this information was included in more than 80% of pamphlets.[28] The design aspects of the CMI examined in the current study did not meet the quality criteria for font size, page layout, number of columns, and size of paper corresponding with a previous study that found that the text font and print sizes of CMI were generally too small for elderly patients to read.[27] A previous study suggested a leaflet with good design characteristics could improve the acceptability of the CMI.[14]

For user-testing, 13 CMI were selected – one from each manufacturer. All of them did not meet the 90% passing criteria of user-testing. CMI should be revised, improved and subjected to repeat testing until they meet the criteria.[29] Other studies have found that user testing scores for finding the information range from 60% to 100%, and scores for understanding the information range from 40% to 100%.[29,30] Retesting until the CMI achieve acceptable user testing scores is required to assure their quality before distributing them to consumers.

The CMI evaluated in this study were rated only "moderate" for comprehensibility - easiness to read, understand, remember, find information, and keep the CMI for future use. This is different from a previous user-testing study of information leaflets of selective serotonin reuptake inhibitors that showed the CMI were well accepted by patients with all the comprehensibility, utility and design aspects rated at good to very good.[31] Only the utility aspect in the current study showed good levels (more than 24); with average scores from 25.2 (SD=5.3) to 28.2 (SD=3.6) (range 8–32). The design of the Thai-produced CMI was rated as low to moderate by patients for many CMI, with particularly low scores for font type and size.

LIMITATION OF THE STUDY

This is the first study evaluating CMI produced in Thailand that used a structured checklist combined with patient assessment. Patients were selected by purposive sampling and the characteristics of the participants might not be generalized for all types of patients in Thailand.

CONCLUSION

Overall, this study shows that the CMI currently produced by manufacturers in Thailand are inadequate in aspects of contents and design. All contents in the CMI should be revised to inform essential information, particularly benefit and safety information of the medications. Results of user testing showed none of the CMI achieved the passing criteria of user testing. Most CMI were evaluated rather difficult to understand but moderate in utilization and design aspects. Consumers as the medicine users are in a target position to engage in evaluating written information of medicines. The Thai FDA should encourage pharmaceutical manufacturers to perform user-testing for all CMI before providing them to consumers.

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DECLARATION OF INTEREST

No conflicts of interest.

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AUTHOR'S CONTRIBUTION

Conceptualization and supervision: NJ and TP, Data collection, data curation and formal analysis: SP, writing – original draft: KW, Writing – review and editing: KW and NJ. All authors read and approved the final manuscript.

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