

Performance of Retailers in Evaluating the Quality of Thai Traditional Non-Prescription Drug Products

นิพนธ์ฉบับ

Original Article

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วารสารไทยเภสัชศาสตร์และวิทยาการสุขภาพ 2559;11(4):119-125.

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บทคัดย่อ

Abstract

วัตถุประสงค์: เพื่อศึกษาว่าความสามารถของผู้ค้าปลีกในการระบุลักษณะทางกายภาพ ฉลาก และบรรจุภัณฑ์ที่บกพร่องของยาสามัญประจำบ้านแผนโบราณ **วิธีการศึกษา:** การวิจัยเชิงสำรวจในกลุ่มตัวอย่างผู้ค้าปลีก 73 ร้าน ที่ตั้งอยู่ในตัวอำเภอของจังหวัดนครนายก และจังหวัดปราจีนบุรีที่สุ่มตามสะดวก เก็บข้อมูลด้วยแบบสอบถามและผลิตภัณฑ์ยาที่เสื่อมสภาพทางกายภาพ (23 ข้อ) ฉลากที่บกพร่อง (9 ข้อ) และบรรจุภัณฑ์ที่บกพร่อง (4 ข้อ) โดยผู้วิจัยอ่านแบบสอบถามผู้ร่วมวิจัยระบุการเสื่อมสภาพหรือการบกพร่องดังกล่าว แล้วให้คะแนนข้อละ 1 คะแนน วิเคราะห์และนำเสนอข้อมูลด้วยค่าความถี่พร้อมร้อยละ และค่าเฉลี่ยพร้อมส่วนเบี่ยงเบนมาตรฐาน วิเคราะห์ความต่างของคะแนนตามปัจจัยคัดสรรด้วย **ผลการศึกษา:** ผู้ค้าปลีกมีคะแนนความสามารถในการระบุลักษณะการเสื่อมสภาพทางกายภาพของยาสามัญประจำบ้านแผนโบราณเป็น 15.60 ± 5.32 คะแนน (ตอบได้ถูกต้องคิดเป็น 67.83% ของ 23 คะแนน) และคะแนนนี้ไม่แตกต่างกันตามปัจจัยคัดสรร คือ วุฒิการศึกษา ระยะเวลาที่เปิดกิจการจนถึงปัจจุบัน ประเภทของผู้ค้าปลีก และการเคยหรือไม่เคยเข้ารับการอบรมเกี่ยวกับยาสามัญประจำบ้านแผนโบราณ คะแนนความสามารถในการระบุความบกพร่องของฉลากยาเป็น 4.96 ± 2.33 คะแนน (55.11% ของ 9 คะแนน) โดยผู้ที่มีการศึกษาสูงกว่าปริญญาตรีมีคะแนนสูงสุด (6.20 คะแนน) และม.6 หรือต่ำกว่ารวมถึงปวช. มีคะแนนต่ำสุด (3.67 คะแนน) อย่างมีนัยสำคัญทางสถิติ ($P = 0.048$) คะแนนความสามารถในการระบุลักษณะบรรจุภัณฑ์ที่บกพร่องเป็น 3.16 ± 0.97 คะแนน (79% ของ 4 คะแนน) สรุป: ผู้ค้าปลีกมีความสามารถในการประเมินคุณภาพของผลิตภัณฑ์ยาสามัญประจำบ้านแผนโบราณไม่สูงนัก หน่วยงานที่เกี่ยวข้องสามารถใช้โอกาสในการให้ความรู้และฝึกหัดผู้ค้าปลีกโดยใช้สื่อที่มีประสิทธิภาพต่อไป **คำสำคัญ:** ประเมินคุณภาพ, ผลิตภัณฑ์ยาสามัญประจำบ้านแผนโบราณ, ความสามารถ, ผู้ค้าปลีก

Objective: To determine retailers' performance in assessing the product problems regarding physical properties, labels and packaging. **Methods:** In this survey study, 73 retail stores in the provinces of Nakhonnayok and Prachinburi were recruited by means of convenience sampling and the data were collected using a questionnaire and samples of defective products (23 questions), incomplete labels (9 questions) and damaged packages (4 questions). The researcher read each question with the corresponding sample for the retailer to identify the problem. A score of one was given for each correct answer. The results were presented as frequency with percentage, and mean with standard deviation. Differences in scores by select factors were also tested. **Results:** The mean performance score for identifying the physically defective products was 15.60 ± 5.32 , or 67.83% of a total of 23. The score did not differ by educational level, business operation period, type of retailer, or experience in academic training on these products. The mean performance score on identifying incomplete labels was 4.96 ± 2.33 , or 55.11% of a total of nine. The mean score in those with postgraduate degrees (6.20 points) was higher than those with a high school diploma or an associate degree (3.67) with a statistical significance ($P = 0.048$). The mean performance score of identifying damaged packages was 3.16 ± 0.97 , or 79.00% of a total of four. **Conclusion:** The retailer performance in identifying problems with Thai traditional non-prescription drug products was not at a high level. Various involving parties had the opportunity to educate these retailers.

Keywords: quality evaluation, Thai traditional non-prescription drug products, performance, retailers

Introduction

There has been a trend of using herbal products for basic therapeutic purposes.¹ With their acceptable safety profile, when used appropriately, many of these herbal entities have been legally listed as the Thai traditional non-prescription drug products. These products are for treating basic and non-serious illnesses. As a result, they are readily accessible for the public, not only at the drugstores but also the retail stores, even on street vendors.

Thai traditional non-prescription drug products come in various dosage forms² such as tablets, capsules, pills,

infusions, creams, and balms, etc. Among those listed, a few have been tremendously popular. For example, turmeric and andrographis. This popularity is attributable in part to the governmental promotional campaign with the One-Tambon One-Product policy (OTOP), a grass-root level development program to promote various kinds of commercial products from sub-district (Tambon) level in each province throughout the country.

Despite the popularity, knowledge and skills to select safe and effective Thai traditional non-prescription drug

products among most consumers are questionable. Thus the task in a large part inevitably depends on the retailers' capability to procure quality products ready for the customers. The retailers are thus subject to acquiring such knowledge and skills to identify quality of the products. This study aimed to determine the retailers' their performance in assessing the problems with the Thai traditional non-prescription drug products, regarding physical properties, labels and packages.

Methods

In this survey research, the study population was retailers in the provinces of Nakhonnayok and Prachinburi, and the study sample was those retailers willing to participate in the study by means of convenience sampling method. The retailer participants were those locating mostly in the central parts of each district of the two provinces. The number of retailers in each district was determined by a quota basis. The informants were individuals in the eligible retailers who were able to communicate in Thai. The person making the most decision to select products to the store were preferred.

A sample of 171 retailers was estimated based on a large population by Cochran (1963) equation³, $n_0 = Z^2 p (1 - p) / e^2$ where n_0 was the estimated sample size, and p was set as 0.5 to account for the largest variability from the unknown proportion of the population characteristics of interest. Such pre-determined values allowed for the largest sampling error and hence the largest sample size. A critical value (Z) was in accordance with a two-tailed type I error of 5% (or a P-value of 0.05). A sampling error (e) was set at 0.075 to reflect a rather large sampling error of 7.5%, as this study was an exploratory research where a sampling error of greater than 5% was deemed appropriate.

Products samples

A set of Thai traditional non-prescription drug products was selected representing popular herbs and dosage forms. The products included andrographis tablets (*Andrographis paniculata*), turmeric capsules (*Curcuma longa*), phlai creams (*Zingiber montanum*), indian gooseberry cough syrups (*Phyllanthus emblica*), aloe vera gels, and snake plant balms (*Clinacanthus nutans*). For each of these products, one well known merchant was purchased.

The preparation of the defective products, incomplete labels and damaged packages

To prepare defective products, various methods for given products were applied. Specifically, andrographis tablets were partially cracked, freckled, color-faded, malodorous, swollen and mold-stained.^{4,5} Turmurin capsules were distorted, retracted, breached, swollen, powder-clumped, and malodorous. Phlai creams were layer-separated, and darkened.⁴⁻⁶ Indian gooseberry cough syrups were malodorous and precipitated. Snake plant balms were layer-separated, less viscous, color-changed, and malodorous. Finally, aloe vera gels were layer-separated, less viscous, and malodorous.⁴⁻⁶

Incomplete labels were prepared as guided by the Thai Food and Drug Administration's regulations on labels stated in the Thailand Drugs Act B. E. 2510. Based on the three products of turmeric capsules, andrographis tablets and aloe vera gels, a total of 9 incomplete labels were created. These included absences of herbal name, registration number, content amount, date of manufacturing, batch number, manufacturer and address, "Thai traditional drug products" label, "external use only" label when indicated, and "non-prescription drug" label. To prepare damaged packages, we made them color-faded, breached, distorted, retracted, cap-loosen, plastic seal-breached on the boxes of andrographis tablets and turmeric capsules and a bottle of Indian gooseberry cough syrups.⁷

The development of the instruments to assess the retailers' performance

In accordance with the defective products, incomplete labels and damaged packages described above, 23, 9 and 4 candidate questions assessing such problems were listed respectively. This set of questions was tested for content validity using item of objective congruence index (IOC) by four experts on herbal product standards and one expert on questionnaire development. Based on an IOC criteria cut-off of 0.5 or greater, all questions were qualified. Comments and suggestions from the experts were also used to improve the questions. After revisions, to further test for understanding, these questions were tested with three individuals comparable to the prospective participants by means of cognitive interview. Results were used to further revise the questions.

Regarding the internal consistency reliability, the questionnaire was tested on thirty third- and fourth-year pharmacy students as a test sample. It was found that questions to assess the performance on defective products (23 items) and incomplete labels (9 items) were with an acceptable reliability with Cronbach's alpha coefficients of 0.733 and 0.896, respectively. On the other hand, reliability on a set of questions assessing performance on damaged packages (4 items) was low with a Cronbach's alpha coefficient of 0.316. After the survey on actual participants, reliability was also in an acceptable level for the first two sets of questions with Cronbach's alpha coefficients of 0.883 and 0.726, respectively. The reliability of the 4 questions on damaged packages was improved but still in a low level (Cronbach's alpha coefficient of 0.509).

In addition to the questions assessing the retailer's performance on the defective products, incomplete labels, and damaged packages, we also asked them about type of retailer (1st class drugstore, 2nd class drugstore, Thai traditional medicine drugstore, general health product store, and others), experience as a merchant buyer (in years), and the training in the use of the Thai traditional medicine.

The study proposal had been approved by the Ethics Committee of the Faculty of Pharmacy, Srinakharinwirot University (IRB number: 003/2560, issue date: October 10, 2016). The survey started after the approval.

Data collection procedure

Data collection survey was conducted during October 15 – 30, 2016. Before the survey, ten research assistants were trained by the investigators. At the candidate retailer, to obtain consent to participate in the research, the candidate informants were given objective, the interview process, and the voluntary nature of the study by the researcher (NS.) and research assistants. Once agreed, the written informed consent was obtained.

Before completing the questionnaire, the investigation team had two products for the informant to identify their status of the Thai traditional non-prescription drug. The answer for these two screening questions was that one was a Thai traditional non-prescription drug and the other was not. The informants who correctly identify the status of the two products could further complete the questionnaire. The researcher and research assistants read the questions with the corresponding samples of the defective products, incomplete labels and

damaged packages for the informant to identify the problem. A score of one was given for each problem correctly identified. However, for informants

Data analysis

Descriptive results were presented as frequency with percentage, and mean with standard deviation to depict participant characteristics and related variables. Statistical significance for all tests was set at a two-tailed type I error of 5%. Binary test was used to examine equal proportion (50:50) of those who correctly identified each problem correctly and those who did not. The total scores of the correct answers of 23 questions on the defective products, 9 questions on incomplete labels, and 4 questions on damaged packages were calculated. We also examined the differences of the total scores by select factors including educational level, number of years of business operation, type of retailer, and having the training in the use of Thai traditional non-prescription medicines. For such analyses on mean differences, independent t-test or Mann-Whitney U test was used when appropriate for two-group comparisons, and analysis of variance (ANOVA) or Kruskal-Wallis test, when appropriate, for multiple-group comparisons.

Results

Of the 140 candidate retailers, 90 agreed to participate and all were eligible resulting in a response rate of 64.28%. Of these 90 retailers, 73 of them answered the screening question correctly and were considered the final sample of participants. Of these 73 retailers, the majority were first-class drugstores (48 retailers or 65.75%), followed by second-class drugstores (10 retailers) (Table 1). The rest were 4 Thai traditional medicine stores, 5 health product stores, and 6 other kinds of stores (beauty salon, grocery stores, spa salon, street vendor, and a health product kiosk in a hospital). Among these 73 retailers, the majority of the informants were those making a buying decision (80.82%). One-third of them had been a buyer for 1 – 5 years and more than 10 years (37.29% each). It was found that 27.39% had training in the use of the Thai traditional non-prescription medicines.

Table 1 Characteristics of the retailer participants (N = 73).

รายละเอียด	N (%)
Educational level	
High school or equivalent	15 (20.55)
Associate degree (vocational education)	2 (2.74)
Bachelor's degree	46 (63.01)
Higher than Bachelor's degree	10 (13.70)
Number of years of business operation	
< 1	8 (11.96)
1 – 5	20 (27.40)
5 – 10	17 (23.29)
> 10	28 (38.36)
Type of retailer	
First class drugstore	48 (65.75)
Second class drugstore	10 (13.70)
Thai traditional medicine drugstore	4 (5.48)
General health product retailer	5 (6.85)
Others	6 (8.22)
Decision maker as merchant buyer	
Yes	59 (80.82)
No	14 (19.18)
Number of years as merchant buyer	
< 1	5 (8.47)
1 – 5	22 (37.29)
5 – 10	10 (16.95)
> 10	22 (37.29)
Having the training in the use of Thai traditional non-prescription medicines	
Yes	20 (27.39)
No	53 (72.60)

Performance of the retailers in determining defective products

Of the 23 questions concerning the physical defects of the Thai traditional non-prescription medicine products, the retailer participants could detect 15.60 ± 5.32 of such problems by average. In other words, 67.83% of all 23 questions were answered correctly. The widest range of answering correctly was found, i.e., from 0 to 23 questions (Table 2). The total scores were slightly higher in those with higher educational level, more years of business operation, and having training experience, but not statistically significant; while no difference regarding type of retailers (data not shown in table).

The most correctly answered question was the crack on andrographis tablets (95.89%), followed by the precipitation of the Indian gooseberry cough syrups (89.00%), color change of the aloe vera gels (89.00%), and powder clumping of turmeric capsules (86.30%) (Table 2). The least correctly determined was the change in viscosity of the snake plant balms (27.40%), followed by the viscosity change of the aloe vera gels (34.25%), and the fading of turmeric capsule color (50.68%).

Table 2 Performance of the retailer participants in determining physical defects in the Thai traditional non-prescription medicine products (N = 73).

Physical defects by given products	Number of participants (%)		
	Correct	Incorrect	P-value*
Andrographis tablets			
cracked	70 (95.89)	3 (4.11)	< 0.001
freckled	45 (61.64)	28 (38.36)	0.060
mold-stained	45 (61.64)	28 (38.36)	0.060
swollen	42 (57.53)	31 (42.47)	0.242
color-faded	55 (75.34)	18 (24.66)	0.009
malodorous	41 (56.16)	32 (43.84)	0.349
Turmeric capsules			
distorted and retracted	60 (82.19)	13 (17.81)	< 0.001
breached	55 (75.34)	18 (24.66)	< 0.001
swollen	54 (74.00)	19 (26.00)	< 0.001
color-faded	37 (50.68)	36 (49.32)	1.000
malodorous	55 (75.34)	18 (24.66)	< 0.001
powder-clumped	63 (86.30)	10 (13.70)	< 0.001
Phlai creams			
layer-separated	44 (60.27)	29 (39.73)	0.101
darkened	59 (80.82)	14 (19.18)	< 0.001
Indian gooseberry cough syrups			
malodorous	46 (63.00)	27 (37.00)	0.340
precipitated	65 (89.00)	8 (11.00)	< 0.001
Snake plant balms			
layer-separated	39 (53.42)	34 (46.58)	0.640
less viscous	20 (27.40)	53 (72.60)	< 0.001
color-changed, or malodorous	63 (86.30)	10 (13.70)	< 0.001
Aloe vera gels			
layer-separated	40 (54.79)	33 (45.21)	0.483
less viscous	25 (34.25)	48 (65.75)	0.010
color-changed	65 (89.00)	8 (11.00)	< 0.001
malodorous	51 (69.86)	22 (30.14)	0.001

* Binary test

Performance of the retailers in determining incomplete labels

Of the 9 questions concerning the incomplete labels of the Thai traditional non-prescription medicine products, the retailer participants could detect 4.96 ± 2.33 of such problems by average. In other words, 55.11% of all 9 questions were answered correctly. The widest range of answering correctly was found, i.e., from 0 to 9 questions (Table 3). Among various select factors, the total scores were slightly higher in those with post-graduate degree (6.20 points) compared with those with high school or associate vocational degree (3.67), with a statistical significance ($P = 0.048$, Kruskal-Wallis test); while no distinct difference was found among the other factors (data not shown in table).

The most correctly answered question was the absence of manufacturing date (83.56%), followed by the absences of herbal name precipitation (80.82%), and manufacturer and address (75.34%) (Table 3). The least correctly determined

was the absence of “external use only” label (21.92%), followed by the absences of batch number (35.62%) and “Thai traditional drug products” label (36.99%).

Table 3 Performance of the retailer participants in determining incomplete labels in the Thai traditional non-prescription medicine products (N = 73).

Absence of	Number of participants (%)		
	Correct	Incorrect	P-value*
herbal name	59 (80.82)	14 (19.18)	< 0.001
registration number	53 (72.60)	20 (27.40)	< 0.001
content amount	29 (39.73)	44 (60.27)	0.101
date of manufacturing	61 (83.56)	12 (16.44)	< 0.001
batch number	26 (35.62)	47 (64.38)	0.019
manufacturer and address	55 (75.34)	18 (24.66)	< 0.001
“Thai traditional drug products” label	27 (36.99)	46 (63.01)	0.034
“external use only” label	16 (21.92)	57 (78.08)	< 0.001
“non-prescription drug” label.	36 (49.32)	37 (50.68)	1.000

* Binary test

Performance of the retailers in determining damaged packages

Of the 4 questions concerning the damaged packages of the Thai traditional non-prescription medicine products, the retailer participants could detect 3.16 ± 0.97 of such problems by average. In other words, 79.00% of all 4 questions were answered correctly. The widest range of answering correctly was found, i.e., from 0 to 4 questions (Table 4). The total scores were not different regarding select factors (data not shown in table).

The most correctly answered question was the loosening of the bottle cap with the breached plastic seal -breached (97.26%), followed by the breaching of the box (84.93%) (Table 4). The least correctly determined was the fading of the package color (57.53%, followed by the distortion and retraction of the package (76.71%).

Table 4 Performance of the retailer participants in determining damaged packages in the Thai traditional non-prescription medicine products (N = 73).

The damage of the package	Number of participants (%)		
	Correct	Incorrect	P-value*
color-faded	42 (57.53)	31 (42.47)	0.242
breached	61 (84.93)	11 (15.07)	< 0.001
distorted, retracted	56 (76.71)	17 (23.27)	< 0.001
cap-loosen, plastic seal-breached	71 (97.26)	2 (2.74)	< 0.001

* Binary test

Discussions and Conclusion

In our survey on the performance of the retailers in the provinces of Nakhonnayok and Prachinburi, the ability to determine the quality of the Thai traditional non-prescription medicine products was in, if not the highest, a moderate level. We found that 67.83%, 55.11% and 79.00% of the 23, 9 and 4 questions regarding defective products, incomplete labels and damaged packages, respectively.

Regarding the defective products, the retailers could answer correctly only 67.83% which was lower than 80%. With this low percentage of correct answers, these retailers could be considered a considerably poor proxy for the consumers especially on these health products. To be able to directly help the consumers, their ability to detect such defects should be urgently improved. In addition, it was found that the total score made by the informants of the first class drugstore was 15.10 which was lower than that of the other retailers (18.33). This could be attributable to the fact that most of the informants of the first class drugstores were not pharmacists, but the relatives or employees of the owners. As expected that the change in viscosity and the color could be the most difficult defects to detect, the percentages of the informants who could identify the lower viscosity of the snake plant balms and aloe vera gels, and discoloration of the turmeric capsules were low. Without the presence of normal products for comparison, to detect such changes could be too difficult. For example, to detect a color change, one might need to see the normal specimens of the actual capsules or tablets, not the whole nontransparent package, of the test product. In addition, to detect the change in viscosity, one might need to feel the actual viscosity of the normal product and viscosity could also differ from brand to brand. Last, the fact that some informants were probably unfamiliar to the brands of the defective products could also be a reason of such low performance.

With a considerably low performance, one could suspect the informants' unfamiliarity on the test defective products. On the contrary, all informants were familiar with most of the test products, except for the snake plant balms. We therefore were somewhat confident that the findings on performance to determine defective products were reliable, while the finding on the snake plant balms should be interpreted with caution. In terms of the extent of reliability, this low performance could be overestimated. Since the

standard laboratory acceleration methods⁸⁻¹² were not used to create the defective products, the physical appearances of the test products in our study could be overly obvious to determine. More subtle specimens made by the standard acceleration methods are encouraged for future studies. Finally, the overestimated findings further suggested an even lower performance of the retailers in determining the defective products. We thus could conclude that an education on the product quality is urgently needed than ever.

In terms of the incomplete labels, only 55.11% of all 9 questions were determined correctly. This percentage was even lower than that in the defective products described previously. This findings was more worrisome since the incomplete labels were not brand-specific. The low performance level could be attributable to the fact that finding a missing information was more difficult than determining an unusual appearance. Like defective products, retailer participants correctly identified 79.00% of the 4 questions of damaged packages. Again this suggested that to identify the unusual physical appearances was easier than the missing information.

As we found that the retailers were able to determine a relatively small portion of incomplete labels (55.11%), their performance and behavior might not be different from the consumers. A study of Burapadeja¹³ showed that the consumers were less likely to read the labels.¹⁰ We postulated that such a low performance could be attributable to small letters and overwhelming information on the labels, poor layout designs of the labels, and simply a weak reading culture. In addition, some information could be difficult to understand. We proposed that necessary and crucial information such as caution and warning should be seen easily.

Our study had some limitations. First, since the number of participants was small, with a response rate of 42.69%, representativeness to the retailers was limited. A larger sample size is recommended for future studies. This low response rate could be in part due to the fear of inspection by the government officers. Strategies to alleviate such fear should be utilized for this kind of study in the future. In addition, some stores were closed at the surveying time, therefore business hours of the stores should be pre-determined. A small number of questions on damaged packages could have made the findings less reliable. We

recommend a larger set of questions in the future studies. Bias in our study was in part subject to brand-specific characteristics. For example, the plastic cap-seals on the bottle differ from brand to brand, therefore the answers of the seal breaching possibly depended on the retailer's experience. Not only more brands, but also the most popular brands, should be tested in the future. Lastly, the internal consistency reliability of the questions on damaged packages was low. The Cronbach's alpha coefficient was 0.316 which was much lower than the acceptance cut-off of 0.7. Since this reliability was partly a function of the number of questions, more questions should be considered in the future.

Based on our findings, practical points could be recommended as follows. With a relatively low performance level of the retailers in determining defective products, incomplete labels and damaged packages, continuing education and training of the Thai traditional non-prescription medicine products are urgently needed. All relating parties are deemed crucial for cooperation. These parties include the Food and Drug Administration, the provincial health service office, pharmacy schools, the associations of pharmacists and drugstores, as well as the associations of other retailers.

In conclusion, the retailers had a relatively low performance in determining quality of the Thai traditional non-prescription medicine products. Continuing education and training on the issue should be encouraged.

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Editorial note

*Manuscript received in original form on November 2, 2016;
accepted in final form on December 4, 2016*