Improvement of Consumer's Understanding of Drug Leaflet Content

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ABSTRACT

In many countries, drug leaflets are usually provided along with drug products in order that consumers can read, understand and follow the instructions for effective and safe medication. However, there are inadequacies regarding consumer's understanding of leaflet content and these may lead to inappropriate medication. The objective of this study is to identify factors that can improve consumer understanding of leaflet content. Content format and behavior in reading drug leaflets are proposed to affect such understanding. A two-group experimental design was conducted by using two content formats. Format A is an actual content format of a drug, while format D is a developed format based on the derived principle: use simple and clear words, emphasize important words, separate sentences into items if possible and order content. Subjects recruited from university students are randomly divided into two equivalent groups. Each group is assigned to read format A or format D and then asked to answer a questionnaire, measuring content understanding and reading behavior. Results reveal that the format D group has a significantly higher mean score of understanding than the other, Both content format and reading behavior significantly affect consumer understanding, and the former has a larger effect than the latter. Therefore, in order to improve consumer's understanding, an important factor is to develop a more understandable leaflet content based on the derived principle used. An additional factor is to promote consumers to read drug leaflets.

Key words: Consumer's understanding, Drug leaflet content

INTRODUCTION

Background

In a health care system, drugs are usually employed as a means of curing people's diseases. Drugs taken by consumers could possibly produce both positive and negative effects in their bodies (Edwards and Aronson, 2000). Due to the two-sided effects of any drug, the main purpose of drug therapy is to obtain maximum effectiveness from positive effect and maximum safety from negative effect. To achieve this purpose, consumers must necessarily know and use drugs properly. Written drug information is a source that can give such knowledge and usage. Drug leaflet is a medium of written drug information that can provide necessary drug information to consumers. WHO recognizes the importance of drug leaflet/label and recommends guidelines concerning content (WHO, 2000). Similarly, many

countries including Thailand are concerned with this important matter and mandate drug producers to provide drug leaflets and labels with drug products in order that consumers or related persons can get optimal usefulness (Stichele et al., 1996). Beside governments, consumers themselves are also aware that drug leaflets are helpful, and need them for safe medication (Mazis et al., 1978; Johnson et al., 1986; Culberston et al., 1988; Kucukarslaan, 1998). Consumers find that it is useful for them to properly comply with drug regimen from drug leaflet (Fleckenstein et al., 1976; Morris and Halperin, 1979; Gotsch and Liguori, 1982; Levy et al., 2000). These reports demonstrate the importance of drug leaflets to consumers.

Though a drug leaflet is officially provided with the drug product, its presence is not adequate to ensure that consumers medicate with the drug effectively and safely. Before taking a drug, consumers should read, understand and follow drug instruction according to drug information present on the drug leaflet. Thus, understanding the drug information written on drug leaflet is also an important step to achieve drug therapy (Holt et al., 1990). Understanding the leaflet content could result in fully complying with the drug direction (Ciociola et al., 2001). Leaflet content should be simple, easy and understandable to lay consumers so that they can correctly follow the instruction (Farley, 1997; Nordenberg, 1999). Food and Drug Administrations (FDA) of many developed countries require that drug leaflet must pass understanding test on consumers (Dickinson et al., 2001; Greenberg, 2001) while in some countries, this test is not officially required. There are several studies which are concerned with consumer's understanding. It was shown that patients had difficulty in understanding drug information on drug leaflets and needed clearer and easier instructions (Hermann et al., 1978; Miselli and Tognoni, 1990; Stichele et al., 1991; Bandesha et al., 1996; Baker, 1997). Furthermore, some patients misunderstood and misinterpreted drug instruction about dosage regimen (Holt et al., 1992). These reports indicated an inadequacy of understanding among consumers. Additionally, consumer-oriented approach is acceptable because the outcome of drug therapy depends to a large extent on consumer (Chewning and Sleath, 1996). If consumers do not understand leaflet content, it is hardly possible to achieve drug therapy. Therefore it is necessary to improve understanding of consumers.

Theoretical Framework

An important purpose of drug leaflet is to communicate written drug information with consumers in order that they can read, understand and follow it properly. This purpose corresponds to that of Communication Theory. Basic constructs of the theory are sender, message (content), channel, receiver and effect (Finnegan and Viswanath, 1997). The aim of communication is that a sender wants to produce a desirable effect on a receiver by a message via channel. In this case, drug producers under regulation of FDA (as sender) have to send written drug information (as message) via drug leaflet (as channel) to consumers (as receiver) in order to make them medicate drug appropriately (as effect). In this study, variables to be investigated that derive from these constructs are: leaflet content, consumer character and effect. Effect on a person can be described in different ways depending on our viewpoints. A viewpoint is that a person may have these aspects: behavior, cognition and affect (Pervin, 1984). The aspects of interest are the understanding, a kind of cognition and behavior. As a result, the theoretical framework is concerned with leaflet content, consumer behavior as independent variables, and consumer understanding on leaflet content as a dependent variable.

It has been shown that easy and clear messages of product label are associated with subject understanding and recall (Heaps and Henley, 1999; White and Parsons, 2001). Similarly, the message of written drug information on a drug leaflet, such as breadth of topics, depth of information, is related to consumer cognition (Schommer et al., 2001). Different illustration of drug information on drug labels was found to associate with subject comprehension (Friedman et al., 1997). These findings suggest that message attributes on a drug leaflet could possibly influence consumer's understanding. This leads to the development of a leaflet content expected to be more understandable. To develop a leaflet content, WHO guideline of content for drug leaflet is employed. Several studies also give recommendations for making drug leaflet more understandable to consumers. Included in these recommendations are notice easily (Kalsher et al., 1996), use bullet and bold type (Krass et al., 2002), use short sentences or paragraphs (Payne et al., 2000), order information (Dickinson et al., 2001), and use plain language (Miquel et al., 2000). Based on the guideline and recommendations, a derived principle is formulated (Table 1). It consists of using simple and clear words, emphasizing critical words, separating sentences into items if possible, and ordering content. According to this principle, a leaflet content called format D is developed from an actual leaflet content named format A. Thus the study hypothesizes that

H 1 Subjects who read content format D would have higher understanding score than those who read content format A.

Beside content attributes, subject's behavior in reading a content was found to associate with his understanding (Zinar, 2000). More use of product label would result in more understanding (Mangleburg et al., 1997). Drug overdose in young people could occur since they did not read drug label and this led them to misunderstanding of label instructions (Ellen et al., 1998). Additionally, consumer who engaged in purchasing drugs tended to have more understanding of drug information from the drug label (Sansgiry et al., 2001). According to these findings, it is indicated that subject's behavior in reading drug leaflet could relate to their understanding of it, i.e., the better their reading behavior, the greater their understanding. Thus the study hypothesizes that

H 2 Reading behavior score would have positive relation to understanding score.

Table 1. A derived principle for development of leaflet content

Principle	**Example**	
	Format A	**Format D**
Use simple and clear words	mg	milligramme add property topic
Emphasize critical words	to treat	**to treat**
	to prevent	**to prevent Treatment, Prevention**
Separate sentences into items	property sentences indication sentences	property items indications items
Order content	properties not ordered	properties ordered

MATERIALS AND METHODS

Study Design

A two-group experimental design was used to determine the influence of content format (format A and format D) and reading behavior on consumer's understanding. Subjects were randomly divided into two equivalent groups, format A group and format D group. Each subject was assigned to read a content format corresponding to his group, and to administer a questionnaire measuring understanding score on content and reading behavior score.

Content Format

A previous study on drug label/leaflet by the same authors collected a number of drug leaflets from community pharmacies (Burapadaja et al., 2002). From these drug leaflets, a set of them with one page content containing necessary drug information, i.e., composition, property, indication, dosage, side effect, contraindication, caution and storage, was chosen. An actual drug leaflet of roxithromycin was randomly selected from the set. Romycin was the fictitious trade name for this drug in this study. The drug leaflet of Romycin was reprinted on A4 paper with the same context and form of its original. This Romycin leaflet was referred to as actual format or format A. To be more understandable than format A, another Romycin leaflet was developed based on the derived principle. This Romycin leaflet was also printed on A4 paper with the same font and size of format A, and referred to as developed format or format D. Both content formats are shown in Appendix 1

Subject

Subjects were freshman students of a university. They were randomly selected according to their student codes from the student list. Four hundred and fifteen freshmen (about 10% of the total) participated in this study.

Measures

Dependent variable:

A 24-item question was formulated from the leaflet content to measure subject understanding (see Appendix 2). All items included all content topics described on the drug leaflet. Each item had three possible choices. A correct choice of each item was given a score. A summated score from all items was the understanding score for a subject. High score indicated high level of subject understanding and vice versa.

Independent variables:

Reading behavior was determined by subject responses to these four items.

"Normally, I read the drug leaflet content in this amount" Responses were on a five-place scale ranging from least content (1) to entire content (5).

"Normally, I read the drug leaflet content in this manner". Responses were on a five-place scale ranging from unintentional (1) to intentional (5).

"Previously every time when I purchased drugs, I score my reading leaflet content as follow. Responses were on a ten-place scale ranging from never (1) to every time (10).

"Previously every time when I took drugs, I score my reading leaflet content as follow". Responses were on a ten-place scale ranging from never (1) to every time (10).

A summated score from these items was the reading behavior score for each subject. Higher score reflected better reading behavior. This measure was reliable (Cronbach alpha was 0.84) and unidimensional (factor loadings were .798, .773, .861 and .859 respectively).

Demographic Data:

Gender, age, student year status and faculty affiliation were also included in the questionnaire.

Data Collection

The study was carried out during the second semester of the academic year 2002 in a university located in the Northern part of Thailand. Almost all freshman resided in the university dormitories. Subjects were randomly divided into two equivalent groups. One group would receive format A while the other would obtain format D. Each subject was delivered a cover letter, a content format (format A or format D, corresponding to his group) and a questionnaire at his room. Each one was asked to read the format and answer the questionnaire based on his own understanding of content and reading behavior. A week later, the questionnaires were collected from their rooms. Four hundred and twenty-three questionnaires were returned (91.95%). The completed questionnaires from 415 respondents (90.22%) were used for data analysis.

Data Analysis

Descriptive statistics was used to determine demographic data. Chi square and t-test were employed to compare group characteristics. Multiple regression was used to analyze the influence of content format and reading behavior on subject's understanding. Pearson correlation coefficient was also calculated. All analyses used the level of statistical significance of 0.05. The analysis was carried out on a personal computer, using SPSS version 7.5 for Windows.

RESULTS

Demographic data in Table 2 indicates that the two groups were equivalent. Table 3 demonstrates the average item scores of the two groups. The average item scores of 18 items in format D group were significantly higher than those in format A group. In both groups, the average item scores of the other 5 items were not significantly different. There was one item for which the average score of format D group is significantly lower than that of the other. Overall, the mean score of all items in format D group was 18.366 and that of the other was 13.812.

Table 2. Characteristics of subjects

	Group		p value
	Format A	**Format D**	
Age (years)	18.64±.66	18.59±.61	>.05
Faculty affiliated (f)			
Humanity and Social science	84	89	>.05
Science and Technology	88	77	>.05
Medical Science	35	42	>.05
Gender (f)			
Male	104	105	>.05
Female	103	103	>.05

f = frequency

Table 3. Average item scores of the two content formats

Topic	**Item no.**	**Format A**	**Format D**	**p value**
Composition	1	.42±.49	.43±.56	>.05
	2	.60±.88	.86±.35	.000
	3	.47±.50	.93±.26	.000
	4	.89±.32	.95±.21	.018
Property	5	.16±.37	.91±.28	.000
	6	.47±.50	.87±.34	.000
	7	.70±.46	.68±.47	>.05
	8	.24±.43	.40±.49	.000
Indication	9	.18±.38	.47±.50	.000
	10	.71±.45	.71±.45	>.05
	11	.49±.50	.60±.49	.027
	12	.53±.50	.83±.38	.000
Dosage	13	.89±.31	.96±.19	.008
	14	.76±.43	.51±.50	>.05
	15	.85±.36	.88±.33	>.05
	16	.23±.42	.88±.33	.000
	17	.84±.37	.95±.22	.000
	18	.58±.49	.89±.31	.000
Side effect	19	.78±.42	.89±.31	.002
Contraindication	20	.81±.40	.92±.27	.000
	21	.31±.47	.28±.45	>.05
Caution	22	.35±.48	.77±.42	.000
	23	.80±.40	.95±.22	.000
Storage	24	.75±.43	.85±.36	.009

From multiple analysis, two models are presented in Table 4. The first model demonstrated that content format significantly affected understanding score and it explained 37.7% of variance of understanding score. The intercept and regression coefficient were 13.812 and 4.554 respectively. Since format A was coded as 0 and format D as 1, therefore the mean score of all items for both formats were 13.812 and 18.366 respectively. The two means were significantly different. This result supported the first hypothesis. In the second model with adjusted R^2 = .384, both content format and reading behavior were significantly related to the understanding score. Small but significant effect of reading behavior on understanding score was present. Though reading behavior added a small amount to the proportion of variance of understanding score, its effect on such score was more obvious in format D group (Table 5).

Table 4. Regression equation of understanding score

Model		Coefficient	p value	R^2
1	(constant)	13.812	.000	.377
	Content format	4.554	.000	
2	(constant)	12.237	.000	.384
	Content format	4.528	.000	
	Reading behavior	0.0667	.023	

Table 5. Regression equation of understanding score according to group

Group		Coefficient	p value	R^2
Format A	(constant)	13.274	.000	.000
	Reading behavior	.022	.596	
Format D	(constant)	15.857	.000	.028
	Reading behavior	.105	.009	

Table 6 shows the mean scores of understanding and reading behavior, and the correlation coefficient of both variables. The correlation coefficients of both scores were significant in format D group. Though the relation was shown only in format D group, this result could support the second hypothesis.

Table 6. Subject scores and correlation

	Group		p value
	Format A	Format D	
Understanding score			
Range	5-22	9-23	
Mean	13.81±2.91	18.37±2.94	.000
Reading behavior score			
Range	7-30	5-23	
Mean	23.61±4.73	24.00±5.08	
Correlation coefficient (r)	.037	.181	>.05, .009

DISCUSSION

It is recognized that age is associated with consumers' processing about content on the product label (Heroux et al., 1988). Younger has more tendencies to understand content than older. Education level is also related to understanding. Persons with higher education level (college or university) tend to have more understanding on product label than those with lower level (White and Parsons, 2001). Hence this study recruits young subjects whose age and education levels are similar.

Though there is no standard of passing rate for understanding test, an acceptable one used is a minimum rate of correct answers from all answers is 80%, or a rate of subjects who correctly respond all the answers they expose is 80% (Morris et al., 1998; Dickinson et al., 2001; Raymond et al., 2002). Based on previous findings, subjects in this study are expected to understand leaflet content adequately. But the mean understanding score in format A group is 13.812 or 57.55% of the total answers. This value is lower than the acceptable one. This suggests that consumer's understanding level is inadequate to medicate drug effectively and safely. In this case, although the subjects are undergoing university education, they are deficient in understanding leaflet content. For those who have very low education level or other lay consumers, understanding level should be much lower. Therefore, it is very necessary to improve such understanding.

In this study, two factors are proposed to affect consumer's understanding: content format and reading behavior. Content format can explain 37.7% of variance of understanding score. Therefore, content format is the important factor affecting the consumer's understanding score. Format D, developed from the derived principle, can increase the understanding score from 13.81 to 18.37. This indicates that to improve consumer's understanding, it is necessary to develop a content format based on the principle: use simple and clear words, emphasize important words, separate sentences into items if possible and order content. However, the format D has not increased the understanding level (18.37/24 = 76.54%) to an acceptable one. Additional principles may be needed.

Beside content format, reading behavior also affects consumer's understanding score. It can significantly increase the proportion of variance of consumer's understanding score from 37.7% to 38.4%. Though this effect seems to be small, its effect in format D group is more obvious. For this group it can explain 2.8% of variance of consumer's understanding score. Its correlation coefficient ($r = .181$, $p = .009$) demonstrates that an increase in reading behavior can lead to an increase in the understanding. Thus, it is reasonable to stimulate or promote subjects to intentionally read the entire drug leaflet content every time they purchase and take drugs.

It is essential to recognize consumer understanding of leaflet content, since to understand is an important step leading to proper medication (Coulter, 1998). Effectiveness of a drug is always proved before the drug is used in human beings. This requirement should be applied to leaflet content too. A test to prove the effectiveness of leaflet content should be a consumer's understanding test. To take care of consumer medication, FDA should consider this test to be a part of drug regulation.

Suggestion

To measure understanding, this study directly sent the drug leaflets and questionnaires to subjects at their residences in order that they could read and understand them in the way they actually or usually did. Time spent on reading and understanding might vary among subjects, and this might affect understanding score. For future study concerning such time variation, this customary condition of reading and understanding leaflet content could be changed to other conditions. Subjects might be invited to a study room and assigned to read the leaflet content and then administered the questionnaire within a certain time.

CONCLUSIONS

It is necessary to improve consumer understanding on leaflet content. This finding demonstrates that there are two factors affecting consumer understanding, i. e., content format and behavior in reading drug leaflet. It suggests that an important method to improve such understanding is to develop drug leaflets more understandable to consumers. A principle used for development includes use simple and clear words, emphasize important words, separate sentences into items if possible and order content. Promoting consumers to intentionally read the entire drug leaflet content every time when purchasing or taking drugs is also a suggestion from this study to increase their understanding.

Appendix 1. Content formats (Translation from Thai version)

Format A
Drug leaflet
Romycin

Composition

Each tablet contains

Roxithromycin	150 mg

Romycin is a semi-synthetic antibiotic belonging to the macrolide group that is stable to gastric acid and destroys microbes by inhibiting protein synthesis.

Romycin is well absorbed to the body resulting to high drug peak. It can distribute well to various tissues and body fluid of the body and exist for a long time. In addition, it can penetrate well into phagocytic cells that make it advantageous to treat infection in the cells.

Indication

Use to treat infectious diseases sensitive to this drug, especially for respiratory tract, ear, throat, nose, skin, soft tissue, urinary tract and genital organ (except gonorrheal infection), Use to prevent the infection meningococcal meningitis (brain inflammation) for persons who have to closely stay with the patients.

Dosage

Dose recommended for adult

Each time take 1 tablet morning-evening and should take it before meal at least 15 minutes

Adverse effect

Side effects frequently found are gastrointestinal symptoms such as nausea, abdominal pain and diarrhea.

Contraindication

1 Persons who are allergic to this drug
2 It is prohibited to co-administer this drug with ergotamine and its derivatives since it will stimulate vasoconstriction of red blood vessel and lead to lack of blood.

Caution

Be cautious in using this drug among pregnant women, women who are breast-feeding and persons who have liver disorder and when using this drug with other drugs.

Storage

Keep at room temperature
Keep from light

Format D
Drug leaflet
Romycin

Composition

Each tablet contains Roxithromycin as active ingredient 150 milligramme and other components

Property

- A semi-synthetic drug belonging to Macrolide group
- Destroy bacteria by stopping protein synthesis of bacteria
- Stable to gastric acid
- Good absorption into blood circulation
- Distribute to various organ and body fluid
- Penetrate to phagocytic cell making it advantageous to treat infection in the cells

Indication

Treatment Romycin is used **to treat** bacterial infection at various organs

- Respiratory tract such as sinusitis, tonsilitis, sore throat
- Skin and soft tissue
- Urinary tract and genital organ such as urethritis (excluding gonorrheal infection at urethra)

Prevention Romycin is used to prevent bacterial infection called meningococcal meningitis for persons closely staying with patients who have such infection.

Dosage

Dose for adult

Orally take 1 tablet two times a day every 12 hours. Regularly take the drug every day. The drug can be taken in empty stomach.

Side effect

Someone who have taken Romycin may have side effect after taking it. Common side effects are gastrointestinal symptoms, such as nausea, abdominal pain and diarrhea.

Contraindication

- Persons who are allergic to roxithromycin or drugs in the macrolide group
- Persons who are taking migraine drug containing ergotamine and its derivative. This is because Romycin can increase vasoconstriction effect of ergotamine and its derivative on blood vessel, and leads to lack of blood supply. This may endanger the body.

Caution

- Romycin may be transferred to fetus and infant. Pregnants and females who are breast-feeding must be cautious in drug use
- Romycin is bad to liver. Persons who have liver disorder and those having to take it usually must be cautious in drug use.

Storage

Keep the drug at room between 15-30 degree celsius and protect it from sunlight.

Appendix 2. Questionnaire (Translation from Thai version)

After reading the drug leaflet provided, please answer these questions according to your own understanding (Acceptable answers were in parentheses)

1 What is Romycin?. (c)
- a A trade name of a drug
- b A trade name of roxithromycin
- c A trade name of a drug containing roxithromycin

2 What is roxithromycin?. (b)
- a A drug name
- b An active ingredient name
- c A component name

3 Is roxithromycin a single component in the tablet?. (b)
- a Yes
- b No
- c Not sure

4 How many roxithromycin are there in a tablet?. (b)
- a 150 microgramme
- b 150 milligramme
- c Not sure

5 What is the use of Romycin?. (c)
- a Antifungal drug
- b Antimicrobial drug

c Antibacterial drug

6 How does Romycin act on microbes (b)
- a Destroy protein
- b Prevent protein synthesis
- c Reduce protein synthesis

7 Romycin can be orally taken because (a)
- a It is stable to gastric acid
- b It is a macrolide agent
- c It is a semi-synthetic agent

8 What is the property of Romycin that make it use for various organs?. (b)
- a Absorption
- b Distribution
- c Penetration

9 If your skin has a fungal infection, will you treat it with Romycin?. (b)
- a Yes
- b No
- c Not sure

10 If you have bronchitis, Will you treat it with Romycin?. (a)
- a Yes
- b No
- c Not sure

11 If you have meningitis, Will you treat it with Romycin?. (b)
- a Yes
- b No
- c Not sure

12 What is meningococcal meningitis?. (b)
- a A name of microbe
- b A name of disease
- c A name of symptom

13 How many tablets of Romycin will you take for a day?. (b)
- a 1 tablet
- b 2 tablets
- c 3 tablets

14 The time for taking Romycin is during morning to evening, Is it true?. (b)
- a Yes
- b No
- c Not sure

15 The number of dose should (a)
- a Be constant
- b Depend on the meals
- c Not sure

16 On day 1, if you start to take the first tablet at 9 a.m. At what time should you take the following tablet?. (c)
- a 3 p.m.
- b 6 p.m.
- c 9 p.m.

17 On day 2, At what time will you take Romycin?. (b)
- a 7 a.m.
- b 9 a.m.
- c 11 a.m.

18 How do you take Romycin?. (a)
- a Take it according to time
- b Take it according to symptom
- c Take it according to meals

19 Does side effect of Romycin occur in everyone who takes it?. (b)
- a Yes
- b No
- c Not sure

20 If you are allergic to a drug belonging to macrolide group, should you use Romycin?.(b)
- a Yes
- b No
- c Not sure

21 If you take Romycin with ergotamine, the danger to body may occur due to (b)
- a Romycin
- b Ergotamine
- c Derivative of ergotamine

22 Taking Romycin during pregnancy may be dangerous to (a)
- a Fetus
- b Mother
- c Fetus and mother

23 If it is necessary to take Romycin for a long time, what should you do?. (a)
- a Check liver function
- b Check intestine function
- c Check gastric function

24 Where will you keep Romycin?. (c)
- a Refrigerator
- b Room with ambient temperature
- c Room with specified temperature

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