Misunderstanding of medication labels: results of a national survey in Taiwan

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Objectives: To investigate, in a national sample of Taiwanese adults, the extent to which adults misunderstand medication labels and the relationships between misunderstanding and functional and communicative health literacy. **Methods:** We partnered with the Taiwan Social Change Survey in 2011 to collect data for this study. Misunderstanding of the medication label was measured by survey respondents' inability to correctly answer 8 questions regarding the route of administration, dosing time, next dosing schedule, individual dosage instructions, indications, warnings, side effects, and physical features of the drug. Respondents' health literacy levels were measured with four screening questions. **Results:** Of the 2,003 respondents, 1,127 (56.3%) misunderstood one or more elements of the medication label. Logistic regression models showed that among the four health literacy skills, only reading was significantly associated with misunderstanding of the medication label. Age, educational level, occupation, and urbanization of the residential area were significantly associated with misunderstanding of the medication label. **Conclusions:** This study demonstrates that misunderstanding of medication labels is a problem in the general population of adults in Taiwan. Clear medication labels may be insufficient to ensure the public's safe use of prescription drugs. Additional efforts may be needed to improve the design of medication labels, such as using pictorial presentations to convey the key information of medications. (*Taiwan J Public Health. 2014;***33(3):***238-250*)

Key words: medication label, functional health literacy, communicative health literacy

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INTRODUCTIONS

Misuse of prescribed medications could results in adverse drug events, such as unfavorable side effects, overdose, ineffective treatment, or dangerous drug interactions [1,2]. The vast majority of studies on medication safety have focused on preventing errors in hospital settings [1,3,4]. Yet, the majority of medication problems occur when medications are taken at patients' homes [5] and may be prevented if patients are better educated and

informed of medications and their proper use.

The benefits of clear labeling in preventing medication errors are well documented in a number of studies [6-9]. In 2002, to improve the safety of medication use, the Taiwan Healthcare Reform Foundation took initiative to advocate for clear labeling of prescriptions and to improve the format and content of labels [10-12]. The Foundation recommended hospitals and clinics to replace the traditional labels that indicated only the patient's name, drug name, and administration instructions with new labels that contained the following information: patient name and gender, drug name, strength, total quantity in the package, route of administration, individual dosage instructions, name of the prescriber, date of dispensing, name of the pharmacy/dispensing agency, address of the pharmacy/dispensing agency, telephone of the pharmacy/dispensing agency, warning, and side effects. Following the recommendation, in 2011, the Ministry of Health and Welfare issued a new regulation that mandated 13 required items and 3 optional items to be shown on the labels of medications dispensed by hospitals, clinics, and pharmacies [13].

Clear medication labels facilitate the communication of critical prescription information from clinicians to patients. The effectiveness of communication may be limited, however, if the prescription information is incomprehensible to patients. In this study, we extend the literature by using a nationally representative sample to investigate the extent to which the general adult population misunderstands the information provided on a medication label that uses a recommended format and factors that are related to misunderstanding.

Misunderstanding of medication labels, a leading cause of medication errors and adverse events, appears to be a function of an individual's health literacy level [14]. Health literacy is an individual's ability to access, process, and comprehend health information in making basic health decisions [15]. Previous studies showed that low health literacy was significantly associated with difficulty in understanding medication names, indications, and instructions and poor adherence to treatment regimens [9,16-18]. Those studies were conducted primarily in clinical settings. Evidence regarding the degree of misunderstanding medication labels at the population level is scant. Moreover, health literacy includes functional and communicative literacy in the health encounters. Current evidence relates solely to how functional health literacy, specifically reading skills, affects understanding of medication labels [16-18]. Little information is available about the association between communicative health literacy and misunderstanding of medication labels.

MATERIALS AND METHODS

Sample and data collection

We partnered with the research team of the Taiwan Social Change Survey (TSCS) to collect data for this study. The TSCS was conducted between July and November, 2011 [19]. The sampling frame was Taiwan's household registration system. The survey employed a three-stage stratified probability-proportional-to-size random sampling method to select 3,878 non-institutionalized civilians aged 18 years or older. A total of 2,005 respondents completed a face-to-face interview. The response rate (51.7%) was similar to those of other recent national surveys [20]. The sociodemographic characteristics of respondents in terms of age, gender, and education were similar to those of the national population. To ensure accurate representation of the population, the sample

was weighted in accordance to the Census data in the analysis.

Of all the respondents, 87 were unable to answer the questions regarding their understanding of the medication label employed in the survey, of whom 56 (2.8%) were unable to read and 31 (1.5%) had severely impaired vision or other conditions. We coded those respondents as having incorrect answers to questions regarding the medication label and included them in the analysis, because those respondents were at risk for improper medication use. The valid sample was 2,003 after excluding two respondents who refused to answer the medication label questions.

Measurement

The analysis included misunderstanding of a medication label, health literacy assessment, and selected sociodemographic characteristics.

Misunderstanding of a medication label: The questions were designed on the basis of a common diabetes prescription, Euglucon. It was adapted from medication label questions that appeared on the Mandarin Health Literacy Scale (MHLS), a validated health literacy scale for Mandarin Chinese speakers [21]. We consulted with a panel of clinicians, pharmacists, and health literacy experts in designing the medication label to be used in the survey interview. On the basis of the panel's recommendation, we decided to incorporate information about the physical features of the drug on the label. The label was formatted in accordance to the recommendations by International Pharmaceutical Federation (FIP) [22], and FDA [13].

During the survey interview, respondents were asked to read a copy of the medication label and answer 8 multiple-choice questions regarding the route of administration, dosing time, next dosing schedule, individual dosage instructions, indications, warnings, side effects, and physical features of the drug (e.g., shape and color). Incorrect answer was coded 1, and correct answer 0. We used the sum of the answers, ranging from 0 to 8, to measure "the degree of misunderstanding of prescription medication labels". A higher score indicated a greater degree of misunderstanding. In an exploratory factor analysis of the eight items using principal axis factoring, one factor was identified, which explained 71.3% of the total variance. We used the Kuder-Richardson Formula 20 (KR-20) to estimate the internal consistency of the 8 items. The KR-20 coefficient was 0.96, suggesting those 8 items were a homogeneous test.

Health literacy assessment: The survey included two questions to assess functional health literacy: "How confident are you in filling out medical forms by yourself (i.e. personal profile, health history, consent form)?" (1=extremely, 2=quite a bit, 3=somewhat, 4=a little bit, or 5=not at all) and "How often do you have problems learning about your health condition because of difficulty understanding medication labels or self-care instructions?" (1=all of the time, 2=most of the time, 3=some of the time, 4=a little of the time, or 5=none of the time). These two questions have been shown to effectively identify individuals with limited functional health literacy skills [23-26]. The survey also included two questions to assess communicative health literacy: "How often do you have problems learning about your health condition because of difficulty understanding health providers' explanations?" and "How often do you have problems learning about your health condition because of difficulty asking health providers questions?" Answers to these two questions were also assessed on a five-point Likert scale. As a set, these 4 questions assessed, respectively, a respondent's writing, reading, speaking, and listening competences in a health care encounter. Following previous

studies [24], we coded the responses of ever having problems (1-4) as "limited health literacy," and the response of never having problems (5) as "adequate health literacy." The correlations among reading, writing, speaking, and listening health literacy ranged from 0.25 to 0.70, which were statistically significant but not too high to cause concern of multicollinearity in the multivariate analysis.

Sociodemographic characteristics: Previous studies indicated that sociodemographic characteristics were associated with health literacy and medication errors. Therefore, we included the following sociodemographic variables as controls in the analysis: age, gender, level of education, occupation, and residential locations [8,9,16-18]. Occupations were categorized based on the ISCO 88 codes [19]. Levels of urbanization were categorized based on the TSCS codes [19]. Metropolitans and industrial cities were coded as high urbanization, newly developed cities and cities whose economy relied on traditional industries were coded as moderate urbanization; low developed citied and remote areas were coded as low urbanization.

Statistical analysis

Descriptive statistics were calculated for each variable. Because several variables were not normally distributed, we performed non-parametric, bivariate analyses – specifically, Kruskal-Wallis test and Wilcoxon-Mann-Whitney test – to examine the relations between the degree of misunderstanding of the medication label and health literacy and sociodemographic characteristics. Logistic regression analysis was performed to identify factors that were associated with misunderstanding of the medication label. Weights were used in all the analyses following the procedures described in a previous report [20]. We tried several cut-off points to dichotomize the degree of misunderstanding (at least one incorrect answer vs. 8 correct answers; 2 or more incorrect answers vs. 7 correct answers; 3 or more incorrect answers vs. 6 correct answers; 4 incorrect answers vs. 4 correct answers) in the logistic regression analysis. Although there were differences in the estimated coefficients, the differences were small and did not affect the substantive interpretation of the findings.

In the following, we report logistic regression results obtained from using the most stringent criterion — i.e., at least one incorrect answer vs. 8 correct answers — because all the medication label questions were deemed crucial for ensuring medication safety. All statistical analyses were performed with SPSS software, version 19.0.

RESULTS

The characteristics of the study sample are summarized in Table 1. Approximately half of the respondents were women; 30.5% reported less than junior high school education; the majority had a skilled job (45.0%). Close to half of the respondents (44.0%) reported not confident in filling out medical forms by themselves, 21.9% had problem learning about their health condition because of difficulty understanding written information, 28.8% had problem learning about their health condition because of difficulty understanding health providers' explanations, and 29.4% had problem learning about their health condition because of difficulty asking health providers questions.

Overall, 56.3% of respondents misunderstood one or more elements of the medication label. Table 2 shows the percentage of incorrect response to each medication label question. The three questions with the highest incorrect response

Table 1 Descriptive Statistics of the Sample Characteristics

Variable	N (%)
Age	
18-29	451 (22.5)
30-39	412 (20.6)
40-49	409 (20.4)
50-59	358 (17.9)
60 and above	373 (18.6)
Gender	
Male	998 (49.9)
Female	1,004 (50.1)
Education	
Junior high and below	610 (30.5)
Senior High school	597 (29.8)
College	252 (12.6)
University	439 (21.9)
Graduate school	102 (5.1)
Occupation	
Professional	266 (13.3)
Semi-Professional	322 (16.1)
Clerk/service worker	244 (12.2)
Skilled worker	901 (45.0)
Unskilled/labor worker	152 (7.6)
Urbanization of residential area	
High	973 (48.6)
Moderate	707 (35.3)
Low	324 (16.2)
Filling out medical forms	
Confidence	1,113 (55.5)
No full confidence	882 (44.0)
Having problem reading written information	
Never	1,560 (77.9)
More or less	439 (21.9)
Having problem understanding health providers' explanations	
Never	1,420 (70.9)
More or less	577 (28.8)
Having problem asking questions to health providers	
Never	1,409 (70.3)
More or less	589 (29.4)

Total sample size N=2,003

were related to the medicine's physical features (45.3%), side effects (22.1%) and warnings (9.4%). There was a substantial variation among respondents in terms of the degree of misunderstanding; 876 (43.7%) respondents answered correctly all the medication label questions whereas 91 (4.5%) respondents either unable to read or misunderstood completely information on the medication label (Table 3).

Table 4 reports the bivariate associations of health literacy and sociodemographic characteristics with the degree of misunderstanding of the medication label (measured as the sum of incorrect answers). Respondents who

Table 2 Percentage of Incorrect Answers to the Items Shown on the Medication Label

Elements of the Label	N (%)
Route of administration	122 (6.1)
Dosing time	151 (7.5)
Next dosing schedule	152 (7.6)
The number of pills per dose	119 (5.9)
Indications	134 (6.7)
Warnings	189 (9.4)
Side effects	443 (22.1)
Physical features of the drug	908 (45.3)
Missed at one of the above items	1,127 (56.3)

Table 3 Frequencies of Incorrect Answers to Medication Label Questions

Numbers of Incorrect Answers	n	%
8	91	4.5
7	3	.1
6	11	.5
5	6	.3
4	25	1.2
3	41	2.0
2	202	10.1
1	748	37.3
0	876	43.7
total	2,003	100.0

were older, female, with a lower education level, having a lower-status job, and residing in less urbanized areas were more likely to misunderstand information on the medication label. The degree of misunderstanding was significantly and negatively associated with writing, reading, listening, and speaking health literacy—that is, respondents who were less confident in filling out medical forms and who had difficulties understanding written information, speaking with and following the explanations of the health care provider were more likely to misunderstand the medication label.

Table 5 displays the logistic regression results. Four sociodemographic characteristics—i.e., age, education level, occupation, and urbanization of the residential area—were significantly associated with misunderstanding of the medication label. Compared with those aged 18-29, respondents who were 50-59 (adjusted OR=1.70, 95% CI=1.18 - 2.45) and 60 and older (adjusted OR= 2.36, 95% CI=1.59 - 3.49) were more likely to misunderstand the label. Respondents who did not complete junior high school education were most likely to misunderstand the label (adjusted OR=0.72 [95% CI=0.53 - 0.96] for high school, adjusted OR=0.51 [95% CI=0.35 - 0.74] for college, adjusted OR=0.36 [95% CI=0.25 - 0.54] for university, adjusted OR=0.35 [95% CI=0.20 - 0.62] for graduate school). Compared to professionals, respondents who were in the clerk/service (adjusted OR=1.75, 95% CI=1.19 – 2.57), skilled worker (adjusted OR=1.45, 95% CI=1.03 - 2.04), and unskilled worker/labor forces (adjusted OR=1.92, 95% CI=1.17 - 3.15) had a greater likelihood of misunderstanding. Respondents who resided in less urbanized areas had a significantly higher chance (adjusted OR=1.60, 95% CI=1.19 - 2.14) than those living in highly urbanized areas to misunderstand the label.

Among the four health literacy skills, only reading was significantly associated with misunderstanding the label (OR=1.40, 95% CI=1.02 - 1.93); respondents with reading problems were more likely to misunderstand the medication label. The other three skills did not have an independent association with misunderstanding of the label, holding constant the other factors.

Table 4 Degree of Misunderstanding of the Medication Label by Sociodemographic Characteristics and Health Literacy

Variable	Mean score of misunderstanding	Non-parametric test
Age		<.001[a]
18-29	0.50±0.68	
30-39	0.69±1.17	
40-49	0.90±1.41	
50-59	1.21±1.59	
60 and above	2.44±2.83	
Gender		<.001[b]
Male	0.92±1.42	
Female	1.29±2.07	
Education		<.001[a]
Junior high and below	2.20±2.65	
High school	0.85±1.04	
College	0.57±0.66	
University	0.41±0.61	
Graduate school	0.37±0.60	
Occupation		<.001[a]
Professional	0.59±1.02	
Semi-Professional	0.68±1.10	
Clerk/service worker	0.72±0.96	
Skilled worker	1.27±1.88	
Unskilled/labor worker	2.24±2.80	
Urbanization of residential area		.001[a]
High	1.01±1.67	
Moderate	1.10±1.83	
Low	1.43±1.99	
Filling out medical forms		<.001[b]
Confidence	0.71±0.95	
no full confidence	1.59±2.35	
Having problem reading written information		<.001[b]
Never	0.84±1.21	
More or less	1.59±2.35	
Having problem understanding health providers' explanations		<.001[b]
Never	0.95±1.47	
More or less	1.45±2.31	
Having problem asking questions to health providers		<.001[b]
Never	0.96±1.48	
More or less	1.43±2.30	

[a]Kruskal-Wallis test
[b]Wilcoxon-Mann-Whitney test

DISCUSSIONS

In the present analysis of national, population-based data in Taiwan, approximately 3 out of 5 adults (56%) misunderstood one or more aspects of a medication label that contained information recommended by FIP and FDA [13,22] and information that was

Table 5 Factors Associated with Misunderstanding of the Medication Label

Variable	Odds Ratio (95% CI)	Adjusted Odds Ratio (95% CI)[a]
Age		
18-29	1.00	1.00
30-39	1.17 (0.90-1.54)	0.97 (0.72-1.31)
40-49	1.79 (1.37-2.35)	1.18 (0.86-1.63)
50-59	2.89 (2.16-3.86)	1.70 (1.18-2.45)
60 and above	4.52 (3.34-6.12)	2.36 (1.59-3.49)
Gender		
Male	1.00	1.00
Female	1.23 (1.03-1.47)	1.04 (0.85-1.28)
Education		
Junior high and below	1.00	1.00
High school	0.46 (0.36-0.58)	0.72 (0.53-0.96)
College	0.29 (0.21-0.40)	0.51 (0.35-0.74)
University	0.18 (0.14-0.23)	0.36 (0.25-0.54)
Graduate school	0.16 (0.10-0.25)	0.35 (0.20-0.62)
Occupation		
Professional	1.00	1.00
Semi-Professional	1.23 (0.89-1.71)	1.30 (0.92-1.86)
Clerk/service worker	1.75 (1.23-2.49)	1.75 (1.19-2.57)
Skilled worker	2.34 (1.77-3.09)	1.45 (1.03-2.04)
Unskilled/labor worker	3.93 (2.54-6.07)	1.92 (1.17-3.15)
Urbanization of residential area		
High	1.00	1.00
Moderate	1.06 (0.87-1.29)	0.97 (0.78-1.20)
Low	1.83 (1.40-2.38)	1.60 (1.19-2.14)
Filling out medical forms		
Confidence	1.00	1.00
no full confidence	1.53 (1.28-1.83)	1.05 (0.85-1.31)
Having problem reading written information		
Never	1.00	1.00
More or less	1.45 (1.17-1.81)	1.40 (1.02-1.93)
Having problem understanding health providers' explanations		
Never	1.00	1.00
More or less	1.13 (0.93-1.38)	1.21 (0.89-1.66)
Having problem asking questions to health providers		
Never	1.00	1.00
More or less	0.99 (0.82-1.20)	0.73 (0.53-1.01)

[a] adjusted odds ratio: adjusting for all variables shown

deemed important (e.g., physical features of the drug) by a panel of clinical and health literacy experts. The rate appeared to be higher than those found in previous research that used a clinical sample in the U.S [9]. Such widespread misunderstanding of the medication label is surprising in Taiwan where the illiteracy rate in the adult population is only 1.8% [27]. As education level is negatively associated with difficulty understanding the medication label, our results suggest that misunderstanding of medication information may be even more

severe in countries where the literacy level is lower.

Similar to previous research [9,28], our findings demonstrated that older adults had greater difficulty understanding medication labels. Because they often are on multiple medications, older adults may be in double jeopardy for medication errors. A sizeable body of literature has documented that communication of clinicians regarding safe and appropriate use of medications is inadequate, in part because of the medical jargon they use [1,6,29-31]. Therefore, efforts are needed to educate and encourage health care providers to effectively explain medications and their proper use in simple terms that are understandable to patients – particularly, older patients [1].

Our study also found that adults who had lower occupational status and who resided in the least urbanized areas had a greater risk of misunderstanding the medication label. The findings are consistent with previous studies that showed individuals with low health literacy tended to have unskilled jobs or live in less urbanized areas [32,33]. In our study, these associations were statistically significant even after controlling for individual demographic attributes, suggesting unexamined factors that were occupation- and environment-specific may differentiate individuals' ability to comprehend medication information. It is possible, for example, that people with a low occupational status and those living in rural areas may have limited access to up-to-date health information and that they may tend to use health services from local health providers that have yet to adopt a recommended format of medication labels. Whatever the explanations may be, our findings suggest that worksite education interventions and education campaigns in rural areas may be needed to increase the awareness of drug safety and improve individuals' ability to comprehend medication information.

Consistent with earlier studies [9,16,17], we found that low functional health literacy impaired comprehension of medication labels. Our analysis showed, in particular, that reading was an independent factor of misunderstanding medication information. Writing, listening and speaking, on the other hand, did not have an independent association with misunderstanding of the medication label. Two possibilities may explain the findings. First, self-reported health literacy screening questions may not be sensitive enough to accurately detect the different levels of writing, listening, and speaking health literacy skills among Taiwanese adults. Second, reading, in comparison to writing, listening and speaking, may be a more basic and fundamental skill that determines individuals' ability to function in today's health care system. Most health education, for example, is disseminated in writing. Thus, having a reading difficulty may constrain an individual's ability to comprehend health information in general and understand medication labels in specific. To the extent this explanation is valid, medication information (and health information in general) should be presented in simple terms, at a low enough reading level that is appropriate for the majority of adults. For adults who are unable to read, involvement of, and explanation of medication information to, their significant others or caregivers may help to circumvent the reading problem and therefore misuse of medications [34,35].

Our results pointed out that physical features and side effects of the medication were the most difficult aspects to comprehend. It is possible that health consumers may not recognize that all the information included on the medication label was equally important and they may be most familiar with the route of administration and dosage information. If so, proper patient education can empower

patients to identify and prevent medication errors [36]. It is also possible that the design of the medication label highlighted certain aspects of the medication than others. Current FDA regulations focus mainly on ensuring that all important information appears on the medication label. To increase clarity of the information, equal attention should be paid to the design and format of the label [6,37]. A research review suggested that use of pictorial aids may enhance patients' understanding of medications [38]. One study of a pill card showed that visual medication schedule improved patients' comprehension of prescription labels and reduced the risk for medication-related adverse events [39]. Therefore, rather than simply describing the appearance of the drug, it may be useful to use pictorial aids that display either a color image of the drug or a photo of the pill on the medication label.

Two limitations in our study should be noted. First, the measures of health literacy were based on self-report. Previous studies have demonstrated the usefulness of these measures for detecting inadequate health literacy [24,40-42]. However, the measures are subjective and less effective as health literacy tests in detecting low health literacy [23,24]. Therefore, our findings should be interpreted with caution. Second, actual medication use behaviors were not observed in this study. We did not investigate actual medication behavior. However, our purpose here is to describe the degree of misunderstanding and identify the risk factors. Further studies can investigate the effects of standardized medicine label instructions on drug safety and health outcomes and costs.

Conclusions

This study demonstrates that a substantial proportion of adults in Taiwan do not understand the information on a medication label. Efforts to improve the design of the label and continually monitoring and evaluating misunderstanding of medication labels are warranted. The lessons in Taiwan may also inform similar policies in other countries for improving safe use of prescription medicine.

Practice Implications

Clear medication labelling is a necessary step towards drug safety but is insufficient to achieve safe use of prescriptions. Additional efforts are needed. They may include: (1) involvement of patients to identify key aspects of information that contribute to safe use of medications, (2) continuing improvement in the design of medication labels, perhaps using pictorial presentations to convey key medication information to consumers, (3) encouraging health professionals such as pharmacists and nurses to use plain language to educate and counsel patients and families regarding correct use of medications, and (4) regular surveillance of medication errors to inform policy and intervention strategy.

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誤解藥袋標示：一項台灣全國性調查結果

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目標：本研究是以全國性樣本調查台灣成年民眾誤解藥袋標示及其功能性和溝通性健康識能之相關性。**方法：**本研究透過2011年台灣社會變遷調查收集研究資料，共有2,003位具全國代表性的樣本。誤解藥袋標示是測量受訪者是否能正確回答「用法」、「劑量」、「數量」、「作用」、「適應症」、「警語」、「副作用」、「藥物外觀」這八項藥袋上的標示。受訪者的健康識能程度則以四題篩檢問題測量。**結果：**研究結果發現有1,127 (56.3%)受訪者誤解一題或一題以上的藥袋標示，邏輯斯回歸分析結果顯示四種健康識能中，僅有閱讀能力與藥袋標示誤解有顯著關係。受訪者的年齡、教育程度、職業、居住地都市化程度都與誤解藥袋標示有顯著關係。**結論：**本研究顯示誤解藥袋標示對於台灣民眾仍是一個問題。藥袋明示化並不足以確保民眾使用處方藥物的安全，未來還需改善藥袋標示的設計及使用圖片輔助說明藥袋上重要的訊息。(台灣衛誌 2014；**33**(**3**)：238-250)

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