

## Outpatient and Caregiver Understanding of Auxiliary Instructions on Medication Labels at Ongkharak Hospital, Nakhon Nayok

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### Abstract:

**Objective:** To investigate the understanding of common auxiliary instructions among outpatients and caregivers at Ongkharak Hospital, Nakhon Nayok, Thailand.

**Material and Methods:** This cross-sectional descriptive study was conducted from March to April 2017 at Ongkharak Hospital. The convenience sampling subjects were directly interviewed in order to assess their understanding of auxiliary instructions on five medication labels: Ibuprofen, Amoxicillin, Cetirizine, Ferrous fumarate and Insulin.

**Results:** Three hundred and eighty-five subjects participated in this study (212 patients and 173 caregivers). Most were female (66.0%) with an average age of 48.95±17.02 years, secondary school graduates (44.7%), and employees (29.6%). Concerning their experience, most of them (>90.0%) had seen and read the auxiliary instructions. All of the instructions were explicit. Pharmacists explained the instructions to them. Most of them received the auxiliary instructions of Ibuprofen, Amoxicillin and Cetirizine. Concerning their understanding of auxiliary instructions, they correctly understood the indication of Ibuprofen (62.3%), Cetirizine (58.4%), Ferrous fumarate (19.2%) and Amoxicillin (12.5%). They could comprehend how to administer Insulin (78.2%), Ibuprofen (74.8%) and Amoxicillin (61.3%). A few of them truly interpreted the side effects of Cetirizine (9.4%), Ferrous fumarate (8.8%) and Insulin storage (4.9%).

**Conclusion:** Some of the auxiliary instructions used at Ongkharak Hospital should be revised in order to be more concise and pertinent. Moreover, pharmacists should explain auxiliary labels every time to enhance outpatient and caregiver understanding of medication uses.

**Keywords:** auxiliary instruction, Ibuprofen, medication label, Ongkharak Hospital, understanding

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## Introduction

Medication labels are important sources of information which support appropriate medical use. Sometimes pharmacists lose opportunities to provide patients with sufficient medication information. Therefore, medication labels appear as a necessary literacy to communicate with patients.<sup>1</sup> The medication label principally consists of complete medication information, including name, strength, and administration instructions, as well as auxiliary instructions. The auxiliary instructions provide some specific information involving indication, administration instructions, side effects and storage.<sup>2</sup> The small size of the standard medication label limits the contents on labels, and therefore the phrases on auxiliary instructions and medication labels appear short and concise. It probably leads patients to a poor understanding of medication labels, which is associated with unintentional medication misuses and adverse effects.<sup>3,4</sup>

Ongkharak Hospital is a 60-bed community hospital located in Nakhon Nayok. Approximately 30 types of auxiliary instructions on medication labels are currently available to provide important medication information which assists patients for appropriate medication uses. At present, there is no established research to assess patient understanding of auxiliary instructions. In addition, pharmacists working in the Pharmacy Department plan to improve the auxiliary instructions on medication labels. As mentioned above, this study was conducted in order to investigate outpatient and caregiver understanding of common auxiliary instructions at Ongkharak Hospital, Nakhon Nayok.

## Material and Methods

This cross-sectional descriptive study was conducted from March to April 2017 at Ongkharak Hospital. The data were collected using structured interviews to assess the participants' understanding of current auxiliary

instructions on medication labels. Five Thai-language common medication labels were selected: Ibuprofen, Amoxicillin, Cetirizine, Ferrous fumarate and Insulin.

Using a convenience sampling technique, participants were eligible to be recruited if they were outpatients or caregivers who attended the Department of Pharmacy during the interview period, aged  $\geq 18$  years and able to communicate well in the Thai language both reading and writing. Participants were excluded if they were unwilling to participate or unable to completely finish the interviewing process. Based on the population of 9,000 persons who attended the Department of Pharmacy, Ongkharak Hospital during the 2 months, the sample size was calculated using the Taro Yamane formulation with 95% confidence interval for 383 participants. Participants voluntarily consented to participate in this research via a written informed consent form. The study protocol was approved by the Ethics Committee of the Faculty of Pharmacy, Srinakharinwirot University.

We developed tests of content validity and reliability, and a structured interview form comprising 4 parts: part 1, demographic characteristics; part 2, participants' experiences of medication uses; part 3, participants' understanding of auxiliary instructions on the labels of 5 medicines, and part 4, participants' opinion of auxiliary instructions. According to the interview process, trained research assistants administered structured interviews lasting approximately 15–20 minutes. First, trained research assistants asked participants to complete their demographic characteristics (gender, age, religion, marital status, educational level, occupation, monthly incomes, underlying disease and present medications) and their experiences of medical uses (Have you ever seen or read auxiliary instructions? In your opinion, are auxiliary instructions clear? And, have you ever received a pharmacist's medical instructions?). Then, five common auxiliary labels were presented to each participant:

Label 1: Ibuprofen “For pain (anti-inflammatory), take after meal immediately.”

Label 2: Amoxicillin “Antibiotic, take until finished.”

Label 3: Cetirizine “Anti-allergy, cause drowsiness.”

Label 4: Ferrous fumarate “Iron supplement, cause black stools.”

Label 5: Insulin “Keep in the refrigerator (2–8 °C). It will be expired 30 days after opened.”

Each of the five auxiliary instructions covered different aspects of indications, medication administration, side effects and storage. Next, in order to assess participant understanding of each auxiliary instruction, trained research assistants asked the interviewee questions including, “Have you ever received this auxiliary instruction?” “What does it mean?” “What is it used for?” “How do you take it?” “How do you keep it?” Finally, trained research assistants asked the participants’ their opinions on how they prefer the auxiliary instruction characteristics, such as “Should letters on the auxiliary instruction be increased in size or thickness?” “Should letters on auxiliary instruction be emphasized by underlined context or colorful labeling?” and “Do they prefer the pharmacist to advise or emphasize the auxiliary instructions every time before dispensing?” Trained research assistants recorded the answers of each question on the individual’s interview document.

The demographic characteristic of participants, their medication use experiences and understanding were presented as a percentage. The association between demographic characteristics, medication use experiences and their understanding were tested using chi-square with statistical significance defined at the alpha level of 0.05.

## Results

### Part 1 Demographic characteristics

A total of 385 participants were interviewed. They were divided into outpatients (55.1%) and caregivers (44.9%). Almost half of the participants were female (66.0%)

with an average age of 48.95 years (S.D.=17.02). A high percentage of them were Buddhist (87.0%). Their marital status was married (77.7%). Almost half of them (44.7%) had an education level of secondary school and some (39.5%) had an education level of primary school. Only 2.3% of them were uneducated. The socioeconomic status of participants varied according to their occupations and monthly incomes. Some of them were employees (29.6%) and no-occupation (21.8%). Half of them (57.7%) had a monthly income of less than 15,000 baht, whereas some (26.2%) had no monthly income. Concerning their health status, 46.8% of them had no underlying disease, while other 40.8% had 1–2 underlying diseases. Some of them had no daily medication use (38.7%) and 1–4 items of daily medication use was 36.4%, as shown in Table 1.

**Table 1** Demographic characteristics of participants (n=385)

Demographic characteristics	Number (person)	Percentage
Character of participants		
Outpatients	212	55.1
Caregivers	173	44.9
Gender		
Female	254	66.0
Male	131	34.0
Religion		
Buddhism	335	87.0
Islam	42	10.9
Christian	8	2.1
Marital status		
Married	299	77.7
Single	68	17.6
Divorce	10	2.6
Widow	8	2.1
Educational level		
None	9	2.3
Primary school	152	39.5
Secondary school	172	44.7
Graduate degree	48	12.5
Postgraduate degree	4	1.0

Table 1 (continued)

Demographic characteristics	Number (person)	Percentage
Occupation		
Employee	114	29.6
None	84	21.8
Agriculturist	66	17.1
Merchant	52	13.5
Government officer	26	6.8
Others*	25	6.5
Student	18	4.7
Monthly income (baht)		
None	101	26.2
Less than 15,000	222	57.7
15,000–30,000	50	13.0
More than 30,000	12	3.1
Underlying disease		
None	180	46.8
1–2 diseases	157	40.8
3–4 diseases	47	12.2
More than 4 diseases	1	0.3
The number of daily used medications		
None	149	38.7
1–4 items	140	36.4
5–8 items	87	22.6
More than 8 items	9	2.3

\*Others included private–business, drivers

**Part 2 Experiences of medication uses**

From their experiences, almost all 385 participants (99.5%) informed us that they had seen auxiliary instruction on medication labels, and 96.9% of them had read auxiliary instructions. In most of their opinions (99.5%), the auxiliary instructions were explicit and 99.2% of them had received pharmacists’ advice with auxiliary instruction.

**Part 3 Participants’ understanding of five auxiliary instructions**

Concerning receiving five Thai–language auxiliary instructions in this study, 98.2% of all participants had received the auxiliary instructions of Ibuprofen as “For pain (anti–inflammatory), take after meal immediately.”

Most of them (95.1%) had obtained the auxiliary instruction of Amoxicillin as “Antibiotic, take until finished”, whereas 90.6% of them had got the auxiliary instruction of Cetirizine as “Anti–allergy, cause drowsiness”; 61.6% and 40.8% of them had received the auxiliary instruction of Ferrous fumarate and Insulin, respectively as “Iron supplement, cause black stools” and “Keep in refrigerator (2–8 °C). It will be expired 30 days after opened.”

The five Thai–language auxiliary instructions on medication labels consisted of medication information, including indication, administration, side effects and storage. Participant understanding of these auxiliary instructions is represented in Table 2. Of all the 385 participants, 63.3% correctly interpreted the indication of Ibuprofen, 58.4% for Cetirizine, 19.2% for Ferrous fumarate, and 12.5% for Amoxicillin. They correctly interpreted the medication administration of Insulin (78.2%), Ibuprofen (74.8%), and Amoxicillin (61.3%). A few of them correctly interpreted the side effects of Cetirizine (9.4%), Ferrous fumarate (8.8%) and storage of Insulin (4.9%).

Consideration of the details for Label 1: Ibuprofen “For pain (anti–inflammatory), take after meal immediately”; 62.3% of participants correctly understood indication as “use Ibuprofen to relieve pain and swelling”, while 36.9% incorrectly understood it, thinking it meant “use Ibuprofen when you have an infection.” Some of the participants (74.8%) correctly interpreted administration as “take Ibuprofen immediately after the last spoon of food.” Only 12.2% of them incorrectly interpreted it as “take Ibuprofen within 30 minutes after meal.” Most of them (89.4%) also knew the reason why they had to take Ibuprofen immediately after a meal as “Ibuprofen irritates the stomach.”

In regard to Label 2, Amoxicillin: “Antibiotic, take until finished”, only 12.5% of all the participants understood that “Amoxicillin was used to kill bacteria.” Most of them misunderstood it as “Amoxicillin was used to kill other microorganisms such as virus, fungi or parasites.”

For medication administration, 38.4% of all participants misunderstood it as “Continue taking amoxicillin every day until you get better, then stop taking the medicine.” Some of them (71.9%) also knew the reason why they had to continue taking amoxicillin until completing the full course of the medicine so as to prevent drug resistance.

Concerning Label 3, Cetirizine: “Anti-allergy, cause drowsiness”, only 13.0% of all participants incorrectly comprehended that cetirizine was used to treat the side effects of other medicine. Only 9.4% of them correctly comprehended that cetirizine caused drowsiness, whereas others misunderstood, thinking that taking cetirizine before sleep or taking cetirizine as sleep aid. Most participants (85.5%) realized that after taking cetirizine, they should be careful driving or using machinery. On the other hand, 14.0% of them didn’t know that while taking cetirizine they should be careful of taking other medicines or alcoholic beverages together.

Consideration of the details for Label 4, Ferrous fumarate: “Iron supplement, cause black stools”, 19.2% of all participants understood that ferrous fumarate was used as an iron supplement or to treat anemia and not used only when pregnant. For side effects, only 8.8% of all participants correctly understood that this drug caused black or more intense color stools.

Lastly, for Label 5, Insulin: “Keep in refrigerator. It will be expired 30 days after opened”, 78.2% of all participants correctly interpreted that insulin must be thrown away 30 days after opening; 15.3% misinterpreted, thinking that insulin could be used longer than 30 days after opening, if kept in the refrigerator. For medication storage, only 5.7% of all participants truly understood that insulin should be kept in the refrigerator at a temperature of 2–8 °C, not frozen. Others (79.0%) misunderstood and believed that insulin could be kept in the refrigerator door.

**Table 2** Participant understanding of five auxiliary instructions (n=385)

Topics on auxiliary instruction	Number of participants correctly interpreted the auxiliary instructions (%)
Medical indications	
Label 1: Ibuprofen “For pain (anti-inflammatory) take after meal immediately.”	240 (62.3)
Label 2: Amoxicillin “Antibiotic, take until finished.”	48 (12.5)
Label 3: Cetirizine “Anti-allergy, cause drowsiness.”	225 (58.4)
Label 4: Ferrous fumarate “Iron supplement, cause black stools.”	74 (19.2)
Medical administration	
Label 1: Ibuprofen “For pain (anti-inflammatory), take after meal immediately.”	288 (74.8)
Label 2: Amoxicillin “Antibiotic, take until finished.”	236 (61.3)
Label 5: Insulin “Keep in refrigerator (2–8 °C). It will be expired 30 day after opened.”	301 (78.2)
Side effects	
Label 3: Cetirizine “Anti-allergy, cause drowsiness.”	36 (9.4)
Label 4: Ferrous fumarate “Iron supplement, cause black stools.”	34 (8.8)
Storage	
Label 5: Insulin “Keep in refrigerator (2–8 °C). It will be expired 30 days after opened.”	19 (4.9)

#### Part 4 Participants' opinion of auxiliary instructions

All 385 participants suggested that pharmacists should advise and emphasize the auxiliary instructions every time while dispensing. In addition, some of them (27.0 and 25.2%) thought that the letters on the auxiliary instructions should be increased in size and boldness.

#### Part 5 The associations between demographic characteristics, medication use experiences and participant understanding

Regarding the relationships among the demographic characteristics, medication use experiences and participant understanding, we revealed the relationships of only 3 factors: participant educational levels, clarification of auxiliary labels, and pharmacist instructions. First, participant educational levels affected their understanding of the indication and administration of Amoxicillin ( $p$ -value=0.004 and 0.040, respectively), including the side effects of Cetirizine and Ferrous fumarate ( $p$ -value<0.001 and 0.01, respectively). It also affected the misunderstanding of insulin storage ( $p$ -value<0.001). Secondly, clarification of auxiliary labels was related to the understanding of insulin-administration and the side effects of cetirizine ( $p$ -value=0.040 and 0.009, respectively). Lastly, pharmacist instructions significantly affected participant understanding of the indication of Amoxicillin ( $p$ -value=0.040).

## Discussion

The present study investigated the participants' understanding of the auxiliary instructions on five medication labels available at Ongkharak Hospital from March to April 2017. Our results revealed that some of the 385 participants misunderstood some aspects of indication, administration, side effects and storage. Regarding their understanding of the auxiliary instructions of Amoxicillin, a few of the participants (12.5) correctly understood the

indications of amoxicillin, although most of them (95.1%) had received amoxicillin labels. Our finding was different from the study by Mongkolchaipak et al.<sup>5</sup> which reported that customers at the pharmacy store located in Pathum-thanee had a moderate understanding of antibiotics. It was probably due to different educational levels, as most of their subjects were graduate level, whereas most of our participants were secondary school level. Educational level was tied to health literacy as the better educated were more likely to understand prescription instructions. In our study, we also reported the association of educational level and interpretation of indication and administration of amoxicillin. In addition, Davis et al. investigated patients' ability to understand the drug labels of common prescription medications. They indicated that literacy was significantly associated with misunderstanding.<sup>6</sup> As mentioned above, we propose that better educated participants could search for information to answer their doubts unlike participants with a lower education.

Regarding their understanding of the auxiliary instructions of Cetirizine and Ferrous fumarate, a few participants (9.4 and 8.8%, respectively) correctly understood the side effects on the medication labels. For Cetirizine, most of the participants (90.6%) had received medication labels which were usually written as "Take medicine before sleeping." This administrative instruction of cetirizine resulted from its drowsiness side effect. However, some participants were probably confused and thought that Cetirizine was used as a sleep aid. Angsuwattanakul et al.<sup>7,8</sup> studied the development of pictorial labels for illiterate patients at Pak Panang Hospital, Nakhon Si Thammarat. They revealed that pictorial labels improved illiterate patients' comprehension. Of all 290 participants, most of them understood the pictorial labels of "drowsiness", "take until finished" and "take immediately after meal" as 93.2, 91.6 and 88.6%, respectively.

Therefore, we suggest that pictorial labels have a high potential to improve patients' understanding.

In the aspect of their understanding of the auxiliary instructions of insulin, only 4.9% of all participants understood how to store insulin. It correlated with the study conducted by Jittsue et al.<sup>9</sup> which reported that only 34.9% of diabetic patients correctly understood how to store insulin. Of all the participants, 79.5% misunderstood about keeping insulin in the door of the refrigerator, which correlated with the study conducted by Karakes et al.<sup>10</sup> They found that 53.3% of patients inappropriately kept insulin in the door of the refrigerator. It was probably due to the many areas in a refrigerator, leading to patient confusion. In addition, Jittsue et al.<sup>9</sup> revealed that patient understanding of insulin administration, including its storage, was improved after receiving pharmacists' advice. As mentioned above, pharmacists' advice, including using pictures, could provide patients with easier understanding of the appropriate storage of insulin.

Concerning the limitations of this study, firstly the interview form consisted of a lot of questions in order to gather complete participant information. Participants had to spend a long period of time (15–20 minutes) being interviewed and some of them could not complete the interviewing process. Secondly, participants often preferred closed-ended questions to opened-ended questions, which probably indicates that their answers didn't represent their virtual reality. Lastly, the limited number of auxiliary instructions, only 5, studied doesn't reflect the current situation of all auxiliary instructions available in Ongkharak Hospital.

Finally, we offer some suggestions as follows: the interview form should be adjusted to be more concise in order to facilitate the interview process within a shorter period of time with complete information. For further study, we suggest that the scope of this study be expanded for other auxiliary instructions used in Ongkharak Hospital. In addition, the development of auxiliary patterns on

medication labels, such as pictorial labels, should be investigated.

## Conclusion

Our results indicate that some participants misunderstood some aspects of the auxiliary instruction on medication labels, especially in aspects of medication side effects and storage. The researchers suggest that some of the auxiliary instructions used at Ongkharak Hospital should be improved in order to be more concise and pertinent. Moreover, the pharmacist attendants' explanations of medication labels have been important for enhancing outpatient understanding of medications uses.

## Conflict of interest

There is no conflict of interest in this study.

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