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# A brief report of the status of self-medication with over-the-counter drugs: a pilot cross-sectional survey

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## Abstract

**Objective** The extent of perceived knowledge and usage status regarding over-the-counter (OTC) drugs among Japanese citizens remains unclear. This study aims to assess OTC drug use through a pilot cross-sectional survey.

**Results** Conducted on April 30, 2023, at the Graduate School of Pharmaceutical Sciences, Osaka University, the survey garnered 180 valid responses. Among these, 76.1% were female and 56.1% aged 16–19 years. Over the past year, 70.6% used OTC drugs, and price (60.0%), effectiveness (50.0%), and ingredients (43.3%) were the top three factors focused on during OTC drug selection. Most respondents (97.2%) were aware of Package Inserts (PI), with 51.7% reading them before purchasing or using new OTC drugs. 10% reported online purchases. However, 17.2% were unaware of expiration dates, and only 43.3% read storage and handling instructions from PI. This study indicates moderate proper use of OTC drugs but highlights risks due to low awareness of storage precautions and expiration dates. Results are preliminary; further research is needed for generalization.

**Keywords** Over-the-counter drug, Self medication, Pilot paper survey, Proper use

## Introduction

Self-medication using over-the-counter (OTC) drugs is a convenient way to treat minor diseases and maintain health [1]. Proper use of OTC drugs is promoted in Japan to solve the problem of high national medical care costs. However, despite these drugs being relatively safe, misuse or abuse may sometimes cause delayed treatment or adverse events [2–6]. Governing the use of OTC drugs and providing appropriate medical care is becoming a critical social issue.

This study mainly aimed to examine (1) OTC drug use experiences, (2) the factors focused on when choosing OTC drugs, (3) perspective awareness of knowledge on OTC drugs (e.g., package insert (PI) and expiration date), (4) the extent of safe use of OTC drugs, (5) other related information including the opinion on the outer boxes by a paper survey. Moreover, online sales of OTC drugs have become possible with the enforcement of the revised Pharmaceutical Affairs Law in 2014 [7]. The extent of online purchasing experience was also evaluated.

## Methods

### Questionnaire design

The cross-sectional survey questionnaire was originally designed and utilized in Japanese, with an English translation available in supplemental materials (Table S1a-S1b). The translation was conducted by YS Tian and

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**Table 1** The demographic information of participants (n = 180)

| | *n* (%) |
|---|---|
| **Gender** | |
| Female | 137 (76.1) |
| Male | 40 (22.2) |
| No Answer | 3 (1.7) |
| **Age** | |
| 16–19 years | 101 (56.1) |
| 20–29 years | 4 (2.2) |
| 30–39 years | 2 (1.1) |
| 40–49 years | 57 (31.7) |
| 50- years | 16 (8.9) |
| **Education Level** | |
| Below High School Graduation | 89 (49.4) |
| Bachelor or above | 51 (28.3) |
| No Answer | 16 (8.9) |
| Master or above | 12 (6.7) |
| High School Graduation | 12 (6.7) |
| **Occupation** | |
| Student | 95 (52.8) |
| Employee | 45 (25.0) |
| Housewife or Househusband | 13 (7.2) |
| Employer | 12 (6.7) |
| No Answer | 12 (6.7) |
| Others | 3 (1.7) |
| **Used OTC Drugs Over The Past Year** | |
| Yes | 127 (70.6) |
| No | 41 (22.8) |
| No Answer | 12 (6.7) |
| **Knowing Expiration Date** | |
| Yes | 149 (82.8) |
| No | 31 (17.2) |
| **Online Purchasing** | |
| No | 162 (90) |
| Yes | 18 (10) |

verified by H Hatabu. Due to its descriptive nature and not requiring factor analysis confirmation, the questionnaire underwent validation for understandability and completion ease (H Asano).

### *Participants*

Visitors to the Graduate School of Pharmaceutical Sciences at Osaka University during the *Icho Festival* on April 30, 2023.

### *Inclusion criteria*

1. Agreement to informed consent and ability to complete the questionnaire.
2. Japanese nationality or proficiency in reading/writing Japanese.
3. Over 16 years old.

Participants not meeting all criteria were excluded.

**Table 2a** Focusing factors when choosing OTC drugs (multiple answer question)

| Factors | *n* (%) |
|---|---|
| Price | 108 (60.0) |
| Effectiveness | 90 (50.0) |
| Ingredients | 78 (43.3) |
| Ease of Use | 76 (42.2) |
| Publicity | 55 (30.6) |
| Recommendation from Family and Friends | 30 (16.7) |
| Introduction from Staff | 29 (16.1) |
| Brand Name | 29 (16.1) |
| Dosage Form | 19 (10.6) |
| Internet Info | 18 (10.0) |
| Sales Ranking | 10 (5.6) |
| TV Commercial | 5 (2.8) |
| Impact of Package | 5 (2.8) |

### *Sample size*

Although no pre-calculations were made, a sample size of 180 yielded *post hoc* powers of 63% and 76% for detecting odds ratios (ORs) of 2.15 and 3.38 using a two-group z-test with $p < 0.05$ significance using G*Power 3.1.9.7 [8].

The study assumed participants would have higher OTC drug comprehension than the general Japanese population, serving as a useful pilot survey. Convenience sampling was chosen to facilitate university-citizen communication and provide social value.

### *Analysis*

Descriptive statistics and logistic regression were performed using R ('glm' package). Statistical significance was set at $p < 0.05$.

## Results

### Basic information on respondents

A total of 273 questionnaires were collected. After excluding 29 incomplete responses, as well as 64 instances with missing, unreadable, or unreported ages (including those aged under 16 years), we included 180 valid responses in the analysis (Fig. S1 and Table 1). Most respondents were female (76.1%) and fell into the age groups of 16–19 years old (56.1%) or 40–49 years old (31.7%). This indicates that the majority of festival visitors were high school students and their parents. The education levels were also in line with the attributes of the visitors, who were mostly in the category of high school graduation below (49.4%) and followed by bachelor or above (28.3%). For the occupations of subjects, besides 95 students (52.8%), 25.0% were employees, 7.2% were housewives, 6.7% were employers, and remained no answer (6.7%) or others (1.7%) (Table 1).

### The OTC drug use experience

127 (70.6%) subjects responded that they had used OTC drug(s) over the past year. For the awareness of the expiration date of OTC drugs, 17.2% answered "No." Thus, Using expired drugs may be a potential risk. Out of our expectations, only 10.0% of responders exhibited online purchasing experiences when checking the purchasing places (Table 1).

### The factors influencing the OTC drug selection

The top three factors are price, effectiveness, and ingredients (Table 2a). Besides price, effectiveness and ingredients are also chosen in high proportion, suggesting that people are likely to choose OTC drugs that fit their diseases rather than the values of name and others. Notably, 30 subjects (16.7%) responded that they consider recommendations from family members and friends important, an approximate level of those who consider recommendations from staff important (16.1%).

### Information collection and the use of package inserts (PIs)

The correct information collection regarding the proper use of OTC drugs is needed. Understanding the information sources can help to design interventional schemes to promote safe self-medication practices. The information on OTC drugs was most frequently obtained out of the box (88.3%), on bottles or inside bags (55.6%), and from PI (54.4%). More than 50% of people read precautions, dosages, and efficacy before they use an OTC drug. Only 43.3% read the precautions for storing and handling (Table 2b).

Next, we examined the awareness of the PI and the frequency of reading PI (Table 3). 175 subjects (97.2%) were aware of the PI. Of them, 94.3% agreed that PI is necessary for an OTC drug. However, when asked about the frequency of reading PI before using OTC drugs, only 33.7% answered "Always," and 42.9% answered "Sometimes." Therefore, over 20% of people were aware of PI seldom or never read PI before using an OTC drug. We further examined the frequency of reading PI when the OTC drug purchasing or using differs from the usually used one. At this time, "Always" increased to 51.4%, and "Sometimes" decreased to 29.1%, suggesting people do not always read PI due to the perceived comprehension of the drug. Subsequently, we asked those who always or sometimes read PI about PI's comprehension and use experience. 2.1% and 57.2% answered that PI is very difficult and difficult. However, 36.6% responded that it is not difficult to find important information in PI (Table S2). The most frequently answered reasons from those who seldom or never read PI were "PI is too long" (48.6%), "PI is too difficult" (18.9%), and "Can use an OTC drug without reading PI" (13.5%) (Table S2). Only five subjects responded as unaware of PI. However, two of them answered that they always read the descriptions out of the box or on bottles or bags of OTC drugs before using them (Table 3).

**Table 2b** Routes and contexts of information before using an OTC drug

| **Routes of Information** | ***n* (%)** |
|---|---|
| Out of Box | 159 (88.3) |
| On Bottle or Inside Bag | 100 (55.6) |
| Package Insert | 98 (54.4) |
| From Family and Friends | 26 (14.4) |
| Internet* | 18 (10.0) |
| Others | 1 (0.6) |
| **Contexts of Information** | **n (%)** |
| Precaution | 151 (83.9) |
| Dosage | 143 (79.4) |
| Efficacy | 135 (75.0) |
| Volume | 84 (46.7) |
| Precautions for Store and Handling | 78 (43.3) |
| Ingredients | 60 (33.3) |
| Others | 3 (1.7) |

* One response as the OTC company's homepage was included.

### The factor related to the safe use of OTC drugs

We defined the safe use of OTC drugs as "always read PI for those aware of PI or always read descriptions out of the box or on the bottle or bag for those unaware of PI, at least before using a different OTC drug." After recounting, 93 subjects belonged to the "Safe Use" group and 87 to the "Not Safe Use" group (Table 3). We constructed two multiple variate logistic regressions to analyze how focusing on "ingredients" (Fig. S2a) or "dosage form" (Fig. S2b) during OTC drug selection influences safe use behavior. These models revealed that age and focusing on ingredients or dosage form were positively contributing to safe use. However, when using both focusing factors, the statistical significance was lost (Fig. S2c). The low sample size may cause this. Age category and Occupation were also detected as significant factors, suggesting higher-aged people were less likely to be safe use, and occupation (housewives) showed higher possibility to be safe use (Fig. S2).

### Opinions toward the outer boxes

90.6% of subjects have no opinion, followed by "Suggest using QR (Quick Response) code" (14.4%), "Can not find the necessary information" (13.9%), and others (Table S2). In Japan, the use of electronic PIs for prescription drugs has become the norm, commencing on August 1, 2021. In contrast, paper PIs will continue to be included with products purchased directly by consumers, such as OTC drugs [9]. In this study, 13.9% of respondents recommended using QR codes for OTC drug PIs. This was a lower percentage than the number of respondents who

**Table 3** Awareness of package insert and frequency of reading information before using OTC drugs

| | ***n*** **(%)** |
|---|---|
| **Awareness of Package Insert of OTC drugs** | 175 (97.2) |
| *PI is Necessary (n = 175)* | |
| Agree | 165 (94.3*) |
| No Answer | 7 (4.0*) |
| Not Agree | 3 (1.7*) |
| *How Frequent Reading PI Before Using OTC Drugs (n = 175)* | |
| Always | 59 (33.7*) |
| Sometimes | 75 (42.9*) |
| Seldom | 31 (17.7*) |
| Never | 5 (2.9*) |
| No Answer | 5 (2.9*) |
| *Before Using NEW OTC Drugs (n = 175)* | |
| Always | 90 (51.4*) |
| Sometimes | 51 (29.1*) |
| Seldom | 25 (14.3*) |
| No Answer | 7 (4.0*) |
| Never | 2 (1.1*) |
| **Unawareness of Package Insert of OTC drugs** | 5 (2.8) |
| *How Frequently do You Read the Description Out of the Box or on the Bottles or inside Bags Before Using OTC Drugs (n = 5)* | |
| Always | 2 (40.0*) |
| Sometimes | 2 (40.0*) |
| Seldom | 1 (20.0*) |
| *Before Using NEW OTC Drugs (n = 5)* | |
| Always | 2 (40.0*) |
| Sometimes | 1 (20.0*) |
| No Answer | 1 (20.0*) |
| Seldom | 1 (20.0*) |
| **Safe Use** | |
| Yes | 93 (51.7) |
| No | 87 (48.3) |

* The percentage for questions in each category is calculated by dividing the number of respondents to each question by the total number within the category

indicated that a PI was necessary (97.2%). These results suggest that the participants in this study generally agree with the current inclusion of paper PIs. However, 48.6% felt the PI was too long. Therefore, using QR codes to provide useful information for understanding PIs may help to promote the use of OTC drugs.

## Discussion

### Key findings

This survey revealed that Japanese citizens generally manage OTC drug use well, focusing on price, effectiveness, and ingredients rather than other factors. However, a high proportion of receiving recommendations from family or friends may pose risks due to their lack of professional knowledge compared to pharmacists or registered sellers.

In Japan, all OTC drugs accompany PIs, crucial for guiding safe use. A previous study on OTC PIs for cold and antipyretic analgesics in Japan has reported that most PIs complied with the notice [10]. Another previous questionnaire survey of participants in an OTC promotion education event also has shown that reading OTC PI is one of the important factors associated with self-medication [11]. The utilization of PI was detected to be high in this study. However, precautions for storage and handling, as well as expiration dates, are less focused.

When attempting to determine the important factors for safe use, focusing on ingredients or dosage forms proved significant. This suggested that people who have higher literacy on drugs are more likely to engage in safer behaviors. Overdose and misuse of OTC drugs have been associated with various adverse events [12–19]. For instance, excessive intake of dextromethorphan—an ingredient common in cough medicines—can lead to severe side effects like tachycardia, agitation, hyperthermia, acidosis, and, in rare instances, death [12–14]. Similarly, while loperamide is generally safe for treating diarrhea at standard doses, overdosing can result in serious cardiac issues such as unexplained syncope and significant electrocardiographic abnormalities, including QT-interval prolongation [15, 16]. Additionally, case reports from Japan and other countries indicate that abuse of antitussive medications containing codeine and diphenhydramine can cause convulsions and acidosis [17, 18]. Japanese authorities have reported adverse events associated with OTC use irrespective of dosage levels [20]. Emphasizing the importance of ingredients or dosage forms is thus recognized as a significant factor in promoting good practice in Japan. Moreover, age category and occupation (housewives) were also significant. Higher age showed lower safety behavior, indicating a higher risk when people become familiar with OTC drugs and have a perceived understanding of the drugs. Familiarity may reduce the perceived need to follow instructions carefully or consider potential side effects, interactions, or dosage limits. For sex differences, in a retrospective study conducted at a city hospital in Japan, focusing on hospitalized patients' prior use of OTC drugs, it was discovered that women used these medications significantly more than men [21]. In a survey of primary care patients in Germany, 42% of women reported frequent purchases of OTC drugs [22]. Although in this study, sex differences were not detected as significant, housewives showed a higher proportion regarding "safe use."

When interpreting our study results and considering their applicability to other countries, it is crucial to account for cross-cultural aspects such as differences in

healthcare systems, regulatory environments, and cultural norms. Previous research has shown that cultural backgrounds play a significant role in influencing medication adherence and effectiveness [23]. Japan's regulatory framework for nonprescription medicines employs risk-based classification systems similar to those used in the UK, which mandate pharmacist oversight for specific drugs [24]. This approach contrasts with countries where regulations may be less stringent, potentially leading to different patterns of safe use. Additionally, Japan's collectivist culture often encourages individuals to seek health advice from family and community members rather than relying solely on personal decision-making. This cultural tendency differs markedly from the more individualistic cultures found in other countries, where personal autonomy in health-related decisions is emphasized. These cross-cultural differences must be considered when extending our findings beyond Japan.

### Further research

Further research, including psychological factors related to human behaviors, is being conducted.

## Conclusion

This pilot study revealed that 51.7% of the responders practice proper use of OTC drugs. Not always reading drug information, low focus on precautions for storing and handling, and unawareness of the expiration date were the potential problems when people use OTC drugs.

### Limitations

Major limitations are the following: (1) Population bias: Participants were university festival visitors, limiting generalizability. Despite this, they are considered to have higher drug literacy than the average Japanese population, effectively highlighting potential risks. (2) Sample Size: The limited sample size restricts statistical significance testing power. This study acts as a pilot, with plans for further insights and research.

#### Abbreviations

| | |
|---|---|
| OTC | Over-the-counter |
| PI | Package Insert |
| QR | Quick Response |

## Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13104-025-07114-5.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Supplementary Material 4

Supplementary Material 5

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#### Author contributions

YST and AH organized and coordinated the study, AH, HA, and KI collected the data, and YST and AH performed analyses. KF and KI rechecked the results. All authors contributed to writing the final manuscript and managing or administering the study.

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#### Data availability

The dataset is available from the corresponding author upon reasonable request.

## Declarations

#### Ethics approval and consent to participate

The study protocol complied with the "Ethical Guidelines for Medical Research Involving Human Subjects" and was approved by the ethics review committee of the Graduate School of Pharmaceutical Science, Osaka University (Approval number: Yakuhito2023-1). Informed consent to participate in the study was obtained from all participants as follows: Participants were informed that submitting their responses indicated consent to the study. The survey was anonymous, and results were aggregated to ensure confidentiality. Additionally, the study's purpose, question details, time required, and confidentiality were clearly explained before consent was given.

#### Consent for publication

Not applicable.

#### Competing interests

The authors declare no competing interests.

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## Publisher's note