

Original Paper

Relationship between Health Literacy and the Use of Patient Information Leaflets for Older Adults Who Use Pharmacies

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Received, January 14, 2025; Accepted, June 2, 2025

Abstract

In this study, a self-administered anonymous questionnaire study of older adults (over 65 years old) was conducted to investigate the relationship between the constructs of older adults' awareness of the use of patient information leaflets (PILs) and their health literacy, as well as the relationship with patient background characteristics. On exploratory factor analysis, two factors were extracted: "Knowledge", which is the awareness of wanting to know specific information about PILs; and "Reliance", which is the awareness arising from trust in PILs. Multiple regression analysis of the awareness of using PILs showed that "Knowledge" was related to "Critical Health Literacy" and "Communicative Health Literacy", whereas "Reliance" was related to "Functional Health Literacy" and "Communicative Health Literacy". These relationships tended to be higher in late-older adults (age > 75 years) than in early-older adults (age 65-75 years), and in females than males. In addition to these two factors, "Anxiety" about using PILs was positively related to "Critical Health Literacy" and negatively related to "Functional Health Literacy". These findings suggest that pharmacists should provide support for the use of PILs to older adults with low levels of "Communicative Health Literacy" or "Critical Health Literacy", as well as accurate and easy-to-understand evidence-based information to older adults with high levels of "Critical Health Literacy" or low levels of "Functional Health Literacy" to help prevent excessive anxiety.

Key words: patient information leaflets, older adults, health literacy, pharmacy

Introduction

The use of patient information leaflets (PILs) in Japan has spread rapidly since the 1996 revision of the Medical Fee Payment System, which set an additional fee for the provision of leaflets. In addition, the 2006 revision of the Japanese Pharmaceutical Affairs Law made the provision of leaflets a legal obligation of pharmacy proprietors.

This law requires pharmacists to provide patients with face-to-face guidance based on the necessary information in writing and necessary pharmacological knowledge. For this purpose, PILs are required to include the name of the drug, indications, dosage, and administration, matters necessary to prevent the occurrence of health hazards, and matters deemed necessary for the proper use of the drug.

A previous study reported that 94% of patients who

received satisfactory explanations said that PILs were helpful¹. However, the general public acceptance of PILs remains unclear. Some studies have reported that PILs can generate adverse emotional reactions²⁻⁴, and that older adults with poor eyesight or hearing who cannot obtain appropriate information adjust their medication on their own, leading to worse drug compliance⁵. It has also been reported that older adults do not check the names of medicines, dosages, administration, side effects, etc., in PILs as thoroughly as young and middle-aged people⁶. These previous findings suggest that even when older adults receive pharmacotherapy guidance from pharmacists, they do not always make full use of PILs.

In addition, it has been reported that the main sources of medical information for older adults aged ≥ 60 years are passive sources, such as television (45%), friends and family (40%), and newspapers (36%), with only 14%

using the Internet⁷. This suggests that the media through which this age group actively gathers information are limited.

Against this background, when pharmacists provide pharmacotherapy guidance, it is necessary to be creative in how to use PILs so that each older adult can obtain and use accurate information about health and medical care, such as knowledge about the use of pharmaceuticals.

Therefore, this study focused on older adults visiting community pharmacies and examined the relationship between health literacy (HL), which is the ability to obtain, understand, and use knowledge about health and medical care, and the use of PILs. In addition, which patient background characteristics were related was examined, and which terminology and explanations in PILs would be most effective for pharmacists providing information to older adults at community pharmacies in the future were explored.

Methods

Target patients

Between 8 May 2023 and 10 August 2023, posters were displayed in four pharmacies of Shirakaba Pharmacy Co., Ltd. (Sapporo, Japan) for recruiting to participate in the study.

Next, a questionnaire study of older adults (age > 65 years) who offered to cooperate in the study with the pharmacists was conducted. This study was conducted by anonymizing the data collected. Target patients were informed of the purpose and methods of the study, and their written informed consent was obtained before the study began.

Research items

The questionnaire items were as follows: age, gender, number of drugs being taken at the time of the study, experiences with side effects, whether information was being searched online, whether the patient had someone to consult about drugs and illnesses, 14 questions on HL, and 10 questions on patient awareness of PILs. The PILs using in this study are generally those widely sold by vendors in pharmacies throughout Japan. Pharmacists provided the patients' age, gender, and number of drugs being taken at the time of the study, and the respondents checked the applicable options for the other questions (Table 1).

The questions on HL (Q1-Q3) were adapted from the 14-item Health Literacy Scale for Japanese Adults

(HLS-14)⁸, which was developed as an HL scale for Japanese adults. This scale is composed of five questions on "Functional Health Literacy (FHL)", five questions on "Communicative Health Literacy (COHL)", and four questions on "Critical Health Literacy (CHL)". Patient awareness of PILs was evaluated based on 10 items (Q4). These questions regarding patient awareness for the use of PILs were set with reference to previous research that examined hospital visits⁶ and were adjusted to suit the purpose of the present study. The answers were sought using a five-point scale ("strongly disagree", "somewhat disagree", "neither agree nor disagree", "somewhat agree", and "strongly agree").

All scores except for FHL were assigned in ascending order (FHL scores were assigned in descending order, from 5, "strongly disagree" to 1, "strongly agree", because each question on the FHL scale is a negative question).

In addition, original questions were set regarding the side effects experienced (Q5), searching for information online (Q6), and someone to consult (Q7).

Statistical analysis

After confirming that there were no ceiling or floor effects in the questions related to PILs, the constructs were extracted in advance through exploratory factor analysis. Using a factor loading of ≥ 0.4 as the criterion, the reliability of each factor was verified using Cronbach's α and composite reliability (CR). The standard values for Cronbach's α ($\alpha \geq 0.7$)⁹ and CR ($CR \geq 0.7$)¹⁰ were set. In addition, discriminant validity was verified using average variance extracted (AVE), and the standard for AVE ($AVE \geq 0.5$)¹¹ was set. In addition, the subscale scores for each factor related to PILs, as well as the subscale scores for FHL, COHL, and CHL, were calculated. To determine whether it would be possible to process the data using multivariate analysis, it was confirmed that there was no ceiling or floor effect.

Subsequently, multiple regression analysis was conducted with each factor related to PILs and the questions not included in each factor as the objective variables, and FHL, COHL, and CHL as the explanatory variables. In addition, explanatory variables as dummy variables included "females" (males as 0 and females as 1), "late-older adults" (early-older adults [age 65-75 years] as 0, and late-older adults [age > 75 years] as 1), "polypharmacy" (fewer than six types as 0 and six types or more as 1), "side effects experienced" (none as 0 and

Table 1 Question items, health literacy score, and abbreviations for non-HL questions.

| Question items | health literacy score |
|---|---|
| Q1. When you read instructions or leaflets from hospitals or pharmacies, how do you agree or disagree about the following? | |
| 5 point scale (5 strongly disagree, 4 somewhat disagree, 3 neither agree nor disagree, 2 somewhat agree, 1 strongly agree) | |
| a I find characters that I cannot read b The print is too small for me c The content is too difficult for me d It takes a long time to read them e I need someone to help me read them | Functional Health Literacy (FHL) score: subscale scores for a-e (5 items) |
| Q2. If you are diagnosed as having a disease and you have little information about the disease and its treatment, how do you agree or disagree about the following? | |
| 5 point scale (1 strongly disagree, 2 somewhat disagree, 3 neither agree nor disagree, 4 somewhat agree, 5 strongly agree) | |
| a I collect information from various sources b I extract the information I want c I understand the obtained information d I tell my opinion about my illness to my doctor, family, or friends e I apply the obtained information to my daily life | Communicative Health Literacy (COHL) score: subscale scores for a-e (5 items) |
| Q3. If you are diagnosed as having a disease and you can obtain information about the disease and its treatment, how do you agree or disagree about the following? | |
| 5 point scale (1 strongly disagree, 2 somewhat disagree, 3 neither agree nor disagree, 4 somewhat agree, 5 strongly agree) | |
| a I consider whether the information is applicable to me b I consider whether the information is credible c I check whether the information is valid and reliable d I collect information to make my healthcare decisions | Critical Health Literacy (CHL) score: subscale scores for a-d (4 items) |
| Q4. How do you agree or disagree about use of patient information leaflets? | abbreviations for non-HL questions |
| 5 point scale (1 strongly disagree, 2 somewhat disagree, 3 neither agree nor disagree, 4 somewhat agree, 5 strongly agree) | patient information leaflets (PILs) |
| a I usually read these over and over again b I think these are useful c I get anxious when I read these d I save these every time e I think that these are necessary every time f I use these to check the names of the medicines each time g I use these to check when to take my medicine and how many to take h I use these to check the efficacy and effectiveness of medicines i I use these to check for side effects of medication j I use these to check for drug interactions | PILs 1 : Careful reading PILs 2 : Usefulness PILs 3 : Anxiety PILs 4 : Storage PILs 5 : Dependence PILs 6 : Drug identification PILs 7 : Usage and dosage PILs 8 : Medicinal efficacy PILs 9 : Side effects PILs 10 : Drug interaction |
| Q5. Have you ever experienced side effects from taking medication? | side effects experienced |
| Q6. Do you often search online about drugs and illnesses? | searching for information online |
| Q7. Is there anyone you can easily talk to about drugs and illnesses? | someone to consult |
| Items for pharmacists to fill in | |
| Pharmacy ID : _____, Gender : <input type="checkbox"/> Male or <input type="checkbox"/> Female, Age : _____, | |
| Number of types of drugs taken : _____types | |

present as 1), “searching for information online” (none as 0 and present as 1), and “someone to consult” (none as 0 and present as 1). Polypharmacy was defined as the intake of six or more drugs, based on a previous study in Japan that found a high risk of adverse drug reactions (ADRs) in older adults taking six or more drugs¹²⁾.

In addition, multiple regression analysis models that satisfied a significance level of 5% for the test of variance ratio (F-value) and the effect size of $R^2 > 0.13$ were chosen¹³⁾. The correlations between quantitative and categorical variables were tested using the correlation ratio (η), at a significance level of 5%, and an effect size of $\eta^2 > 0.01^{13)}$ was taken to indicate a practically meaningful correlation. Furthermore, the correlations between categorical variables were tested using the association coefficient (ϕ) with a significance level of 5%, and the absolute value ϕ ($|\phi| > 0.1$)¹³⁾ as an effect size was taken to indicate a practically meaningful difference.

IBM SPSS Statistics for Windows Version 30.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis.

Ethical approval

This study was approved by the Ethics Committee of the Hokkaido University of Science (approval No.: 23-01).

Results

Of the 558 patients who responded to the study, 484 gave their consent to complete the paper survey (response rate: 86.7%). Of them, 406 were analyzed (valid response rate: 83.9%) after excluding respondents with incomplete answers, those who chose the same answer for all questions, those who gave multiple answers to the same question, and those who gave contradictory answers.

Exploratory factor analysis of questions about awareness of how to use PILs

Regarding the awareness of how to use PILs, the mean value and standard deviation of each question were calculated, and no ceiling effect or floor effect was found. Therefore, an exploratory factor analysis was conducted to search for constructs that met the criteria (Table 2).

The first factor (f1) had high factor loadings for “PILs 9 Side effects”, “PILs 8 Medicinal efficacy”, “PILs 10 Drug interactions”, and “PILs 7 Usage and dosage”. This was

Table 2 Exploratory factor analysis of questions about older adults’ awareness of how to use PILs ($n = 406$).

| | f1 | f2 |
|---------------------------|----------------|----------|
| | Knowledge | Reliance |
| Cronbach’s α | 0.811 | 0.700 |
| AVE | 0.525 | 0.547 |
| CR | 0.813 | 0.707 |
| | Factor loading | |
| PILs 9 Side effect | 0.835 | 0.019 |
| PILs 8 Medicinal efficacy | 0.756 | 0.074 |
| PILs 10 Drug interaction | 0.668 | -0.114 |
| PILs 7 Usage and dosage | 0.619 | 0.043 |
| PILs 2 Usefulness | -0.077 | 0.763 |
| PILs 1 Careful reading | 0.133 | 0.716 |

Note. Maximum Likelihood Method, Promax Method with Kaiser Normalization.

called “Knowledge (f1)”, because it indicated an awareness of wanting to know specific details about PILs. The second factor (f2) consisted of “PILs 2 Usefulness” and “PILs 1 Careful reading”. This was called “Reliance (f2)”, because it indicated an awareness resulting from trust in PILs in case using as an objective variable of regression models. To examine the reliability of each factor, Cronbach’s α and CR were calculated. “Knowledge (f1)” was $\alpha = 0.811$, CR = 0.813, and “Reliance (f2)” was $\alpha = 0.700$, CR = 0.707, which met the standard. Regarding convergent validity, “Knowledge (f1)” had an AVE = 0.525, and “Reliance (f2)” had an AVE = 0.547, which met the criteria. Therefore, it was shown that each mean value could be used as a variable representing the construct. Furthermore, “Anxiety (PILs 3)”, “Storage (PILs 4)”, “Dependence (PILs 5)”, and “Drug identification (PILs 6)” were not included, because the model including these did not meet the standard for reliability or validity. Therefore, these variables were used alone.

Comparison of patient background characteristics regarding awareness of the use of PILs

Next, the average values for each item on awareness of the use of PILs were compared by patient background characteristics (Table 3). The results showed that female older adults had significantly higher Reliance (f2) and Drug identification (PILs 6) than male older adults. In addition, Reliance (f2) was significantly higher in the late-older than in the early-older adults. In addition to Knowledge (f1) and Reliance (f2), Anxiety (PILs 3) was also higher in the older adults who had experienced side effects. Knowledge (f1), Reliance (f2), and Drug identification (PILs 6) were significantly higher in older

Table 3 Comparison of patient background characteristics regarding awareness of the use of PILs.

| | gender | | | | <i>P</i> ^{a)} | older adults category | | | | <i>P</i> ^{a)} |
|------------------------------|------------------------|------|--------------------------|------|------------------------|---|------|--|------|------------------------|
| | Male (<i>n</i> = 180) | | Female (<i>n</i> = 226) | | | early-older adults ^{b)} (<i>n</i> = 170) | | late-older adults ^{c)} (<i>n</i> = 236) | | |
| | mean | SD | mean | SD | | mean | SD | mean | SD | |
| Knowledge (f1) | 3.19 | 0.96 | 3.36 | 0.90 | 0.072 | 3.31 | 0.81 | 3.27 | 1.01 | 0.646 |
| Reliance (f2) | 3.57 | 0.91 | 3.79 | 0.78 | 0.007 | 3.58 | 0.83 | 3.78 | 0.85 | 0.016 |
| Anxiety (PILs 3) | 2.20 | 1.03 | 2.32 | 1.06 | 0.240 | 2.26 | 0.97 | 2.27 | 1.10 | 0.951 |
| Storage (PILs 4) | 3.28 | 1.26 | 3.48 | 1.22 | 0.106 | 3.34 | 1.16 | 3.43 | 1.29 | 0.457 |
| Dependence (PILs 5) | 2.99 | 1.19 | 3.07 | 1.17 | 0.487 | 3.04 | 1.12 | 3.03 | 1.22 | 0.923 |
| Drug identification (PILs 6) | 3.09 | 1.30 | 3.41 | 1.20 | 0.011 | 3.41 | 1.13 | 3.17 | 1.33 | 0.066 |

| | polypharmacy | | | | <i>P</i> ^{a)} | side effects experienced | | | | <i>P</i> ^{a)} |
|------------------------------|-----------------------------|------|-----------------------------|------|------------------------|--------------------------|------|----------------------|------|------------------------|
| | ≥ 6 types (<i>n</i> = 257) | | < 6 types (<i>n</i> = 149) | | | yes (<i>n</i> = 64) | | no (<i>n</i> = 342) | | |
| | mean | SD | mean | SD | | mean | SD | mean | SD | |
| Knowledge (f1) | 3.30 | 0.93 | 3.28 | 0.93 | 0.830 | 3.62 | 0.70 | 3.23 | 0.96 | < 0.001 |
| Reliance (f2) | 3.73 | 0.86 | 3.64 | 0.81 | 0.300 | 3.93 | 0.68 | 3.65 | 0.86 | 0.005 |
| Anxiety (PILs 3) | 2.27 | 1.06 | 2.26 | 1.04 | 0.922 | 2.55 | 1.07 | 2.22 | 1.04 | 0.025 |
| Storage (PILs 4) | 3.56 | 1.23 | 3.10 | 1.20 | < 0.001 | 3.53 | 1.22 | 3.36 | 1.24 | 0.314 |
| Dependence (PILs 5) | 3.11 | 1.20 | 2.90 | 1.14 | 0.078 | 3.31 | 1.26 | 2.98 | 1.16 | 0.055 |
| Drug identification (PILs 6) | 3.30 | 1.29 | 3.23 | 1.20 | 0.602 | 3.52 | 1.17 | 3.23 | 1.27 | 0.075 |

| | searching for information online | | | | <i>P</i> ^{a)} | someone to consult | | | | <i>P</i> ^{a)} |
|------------------------------|----------------------------------|------|----------------------|------|------------------------|-----------------------|------|----------------------|------|------------------------|
| | yes (<i>n</i> = 137) | | no (<i>n</i> = 269) | | | yes (<i>n</i> = 268) | | no (<i>n</i> = 138) | | |
| | mean | SD | mean | SD | | mean | SD | mean | SD | |
| Knowledge (f1) | 3.50 | 0.75 | 3.18 | 0.99 | < 0.001 | 3.33 | 0.95 | 3.21 | 0.88 | 0.225 |
| Reliance (f2) | 3.82 | 0.64 | 3.63 | 0.92 | 0.036 | 3.79 | 0.78 | 3.52 | 0.94 | 0.002 |
| Anxiety (PILs 3) | 2.30 | 1.01 | 2.25 | 1.07 | 0.673 | 2.26 | 1.05 | 2.29 | 1.04 | 0.768 |
| Storage (PILs 4) | 3.34 | 1.2 | 3.42 | 1.26 | 0.536 | 3.42 | 1.25 | 3.33 | 1.22 | 0.462 |
| Dependence (PILs 5) | 3.13 | 1.11 | 2.99 | 1.18 | 0.237 | 3.09 | 1.19 | 2.93 | 1.16 | 0.189 |
| Drug identification (PILs 6) | 3.49 | 1.07 | 3.16 | 1.33 | 0.012 | 3.37 | 1.25 | 3.08 | 1.24 | 0.027 |

Note. ^{a)} *t* test, significant level: *P* < 0.05, ^{b)} early-older adults: age 65–75 years, ^{c)} late-older adults: age > 75 years.

adults who frequently searched for information online. Similar to the female older adults, the older adults who answered that they had someone to consult had significantly higher Reliance (f2) and Drug identification (PILs 6) scores.

Multiple regression analysis related to awareness of how to use PILs

Multiple regression analysis of Knowledge (f1)

The results of multiple regression analysis with Knowledge (f1) as the objective variable are shown in Table 4A. CHL and COHL were significant at the 5% level. Older adults with higher CHL and COHL indicated that they checked the contents of PILs in detail. A comparison of partial regression coefficients (β) showed that CHL, which indicates the ability to analyze and act critically, was the largest. From this, CHL was considered to be the most strongly related to Knowledge (f1).

The comparison of patients with/without side effects

showed a difference in Knowledge (f1) in the univariate model (Table 3), but not in the multiple regression model (Table 4A). This was the same for “searching for information online”. To investigate the reason for this, the relationship with the explanatory variables related to f1 was examined.

“Side effects experienced” showed a significant correlation with CHL (Table 5A). This shows that many older adults who experienced side effects have high CHL.

“Searching for information online” showed a significant correlation with COHL or CHL (Table 5A). The reason for this was considered to be that many older adults who search for information online have high CHL and COHL.

Multiple regression analysis of Reliance (f2)

The results of the multiple regression analysis with Reliance (f2) as the objective variable are shown in Table 4B. FHL and COHL were significant at the 5%

Table 4A Multiple regression analysis associated with Knowledge (f1) (n = 406).

| dependent variables (including dummy variables) | β | SE | <i>P</i> | 95%CI | |
|---|---------|-------|-------------------|--------|-------|
| FHL ^{a)} | 0.035 | 0.048 | 0.472 | -0.060 | 0.130 |
| COHL ^{b)} | 0.139 | 0.067 | 0.038 | 0.008 | 0.270 |
| CHL ^{c)} | 0.277 | 0.063 | < 0.001 | 0.153 | 0.402 |
| female | 0.154 | 0.090 | 0.088 | -0.023 | 0.332 |
| late-older adults | 0.088 | 0.093 | 0.347 | -0.095 | 0.271 |
| polypharmacy | 0.034 | 0.090 | 0.708 | -0.144 | 0.211 |
| side effects experienced | 0.222 | 0.120 | 0.066 | -0.014 | 0.459 |
| searching for information online | 0.131 | 0.103 | 0.204 | -0.072 | 0.335 |
| someone to consult | -0.028 | 0.093 | 0.765 | -0.210 | 0.154 |

Note. $R = 0.411$, adjusted $R^2 = 0.150$, $P < 0.05$ (constant: 1.699, SE 0.297).

^{a)} Functional Health Literacy, ^{b)} Communicative Health Literacy, ^{c)} Critical Health Literacy.

Table 4B Multiple regression analysis associated with Reliance (f2) (n = 406).

| dependent variables (including dummy variables) | β | SE | <i>P</i> | 95%CI | |
|---|---------|-------|-------------------|--------|-------|
| FHL ^{a)} | 0.145 | 0.043 | < 0.001 | 0.060 | 0.230 |
| COHL ^{b)} | 0.289 | 0.060 | < 0.001 | 0.172 | 0.407 |
| CHL ^{c)} | 0.062 | 0.057 | 0.278 | -0.050 | 0.173 |
| female | 0.192 | 0.081 | 0.018 | 0.033 | 0.351 |
| late-older adults | 0.307 | 0.083 | < 0.001 | 0.143 | 0.471 |
| polypharmacy | 0.065 | 0.081 | 0.422 | -0.094 | 0.224 |
| side effects experienced | 0.120 | 0.108 | 0.268 | -0.092 | 0.332 |
| searching for information online | 0.081 | 0.093 | 0.383 | -0.101 | 0.263 |
| someone to consult | 0.127 | 0.083 | 0.126 | -0.036 | 0.290 |

Note. $R = 0.434$, adjusted $R^2 = 0.170$, $P < 0.05$ (constant: 1.579, SE 0.266).

^{a)} Functional Health Literacy, ^{b)} Communicative Health Literacy, ^{c)} Critical Health Literacy.

Table 4C Multiple regression analysis associated with Anxiety (PILs 3) (n = 406).

| dependent variables (including dummy variables) | β | SE | <i>P</i> | 95%CI | |
|---|---------|-------|-------------------|--------|--------|
| FHL ^{a)} | -0.230 | 0.053 | < 0.001 | -0.335 | -0.125 |
| COHL ^{b)} | -0.055 | 0.074 | 0.456 | -0.200 | 0.090 |
| CHL ^{c)} | 0.461 | 0.070 | < 0.001 | 0.323 | 0.599 |
| female | 0.061 | 0.100 | 0.543 | -0.136 | 0.257 |
| late-older adults | 0.046 | 0.103 | 0.656 | -0.157 | 0.249 |
| polypharmacy | -0.002 | 0.100 | 0.987 | -0.198 | 0.195 |
| side effects experienced | 0.208 | 0.133 | 0.119 | -0.054 | 0.471 |
| searching for information online | -0.098 | 0.115 | 0.394 | -0.323 | 0.127 |
| someone to consult | -0.114 | 0.103 | 0.266 | -0.316 | 0.087 |

Note. $R = 0.442$, adjusted $R^2 = 0.177$, $P < 0.05$ (constant: 2.057, SE 0.329).

^{a)} Functional Health Literacy, ^{b)} Communicative Health Literacy, ^{c)} Critical Health Literacy.

level, indicating that older adults with higher FHL and COHL were more conscious of using PILs. In these patients, COHL's β was larger than that of FHL, indicating that the ability to obtain information through various forms of communication was most strongly related to the awareness of how to use PILs. Further, "females" and "late-older adults" were significant at the 5% level. This shows that females and late-older adults are more aware of the importance of PILs than males and early-older adults, respectively.

Although the comparison between the two groups of patients with or without having experienced side effects, searching for information online, and having someone

to consult showed significant differences, they were not significant on multiple regression analysis (Table 4B). To investigate the reason for this, the relationships with the explanatory variables related to f2 were examined.

"Side effects experienced" showed a significant phi coefficient (ϕ) ($P < 0.001$) with "females" related to f2 (Table 5B). This shows that older adults who experience side effects tend to be more likely to be female.

"Searching for information online" was significantly correlated with FHL or COHL (Table 5A), which were both related to f2 in the multiple regression analysis. This shows that many older adults with high FHL and COHL use the Internet to search for information. In

contrast, significant negative correlations were found with “females” ($\phi = -0.150$) and “late-older adults” ($\phi = -0.345$) related to f2 (Table 5B). This shows that the numbers of older adults who reported searching for information online were low among females and late-older adults.

“Someone to consult” was found to be significantly correlated with COHL (Table 5A), which was related to f2 on multiple regression analysis. In addition, “someone to consult” was significantly related to “females” (Table 5B), which was related to f2. This shows that many older adults who have someone to talk to tend to have high COHL, and this is more prevalent among women.

Multiple regression analysis of Anxiety (PILs 3)

The results of the multiple regression analysis with

Anxiety (PILs 3) as the objective variable are shown in Table 4C. FHL and CHL were significant at the 5% level. Older adults with higher CHL and FHL were more and less anxious to use PILs, respectively.

Although the comparison between the two groups of patients with or without having experienced side effects showed a significant difference ($P = 0.025$), “side effects experienced” was not significant on multiple regression analysis (Table 4C). To investigate the reason for this, the relationships with the explanatory variables (FHL, CHL) related to PILs 3 were examined.

“Side effects experienced” was significantly correlated with CHL ($P = 0.018$), which was related to PILs 3 on multiple regression analysis (Table 5A). This shows that many older adults who have someone to talk to

Table 5A Correlation between FHL, COHL, CHL and patient background dummy variables (n = 406).

| | FHL ^{a)} | COHL ^{b)} | CHL ^{c)} | FHL ^{a)} | COHL ^{b)} | CHL ^{c)} |
|----------------------------------|------------------------------|--------------------|-------------------|--------------------------|--------------------|-------------------|
| | correlation ratio (η) | | | effect size (η^2) | | |
| female | 0.077 | 0.032 | 0 | 0.006 | 0.001 | 0 |
| late-older adults | 0.045 | 0.145 | 0.134 | 0.002 | 0.021 | 0.018 |
| polypharmacy | 0.032 | 0 | 0 | 0.001 | 0 | 0 |
| side effects experienced | 0.045 | 0.095 | 0.134 | 0.002 | 0.009 | 0.018 |
| searching for information online | 0.105 | 0.324 | 0.292 | 0.011 | 0.105 | 0.085 |
| someone to consult | 0.045 | 0.141 | 0.130 | 0.002 | 0.020 | 0.017 |
| <i>P</i> value | | | | | | |
| female | 0.107 | 0.500 | 0.909 | | | |
| late-older adults | 0.366 | 0.003 | 0.007 | | | |
| polypharmacy | 0.509 | 0.846 | 0.716 | | | |
| side effects experienced | 0.373 | 0.062 | 0.006 | | | |
| searching for information online | 0.031 | < 0.001 | < 0.001 | | | |
| someone to consult | 0.369 | 0.004 | 0.008 | | | |

Note. effect size $\eta^2 > 0.01$, significant level $P < 0.05$.

^{a)} Functional Health Literacy, ^{b)} Communicative Health Literacy, ^{c)} Critical Health Literacy.

Table 5B Correlation between patient background dummy variables (n = 406).

| | 1 | 2 | 3 | 4 | 5 | 6 |
|------------------------------------|----------------------------|----------------|--------|-------|-------|---|
| | phi coefficient (ϕ) | | | | | |
| 1 female | 1 | | | | | |
| 2 late-older adults | 0.067 | 1 | | | | |
| 3 polypharmacy | 0.073 | 0.162 | 1 | | | |
| 4 side effects experienced | 0.168 | 0.011 | 0.049 | 1 | | |
| 5 searching for information online | -0.150 | -0.345 | -0.073 | 0.049 | 1 | |
| 6 someone to consult | 0.145 | 0.008 | 0.047 | 0.011 | 0.094 | 1 |
| <i>P</i> value | | | | | | |
| 1 female | | | | | | |
| 2 late-older adults | 0.179 | | | | | |
| 3 polypharmacy | 0.143 | 0.001 | | | | |
| 4 side effects experienced | < 0.001 | 0.826 | 0.324 | | | |
| 5 searching for information online | 0.003 | < 0.001 | 0.143 | 0.327 | | |
| 6 someone to consult | 0.004 | 0.868 | 0.344 | 0.828 | 0.058 | |

Note. effect size $|\phi| > 0.10$, significant level $P < 0.05$.

tend to have high CHL.

Multiple regression analysis of Storage (PILs 4), Dependence (PILs 5), and Drug identification (PILs 6)

The effect sizes (R^2) of the multiple regression analysis model with Storage (PILs 4), Dependence (PILs 5), and Drug identification (PILs 6) were all < 0.13 (PILs 4: $R^2 = 0.031$, PILs 5: $R^2 = 0.017$, and PILs 6: $R^2 = 0.055$). The F-value of the multiple regression analysis model with Dependence (PILs 5) as the objective variable was not significant ($F(9, 396) = 1.76$, $P = 0.074$). Based on these results, these models were not adopted in the multiple regression analysis.

Discussion

In this study, the relations between the constructs of older adults' awareness of the use of PILs and their HL, as well as the relations with patient background characteristics, were clarified.

Based on the results, "Knowledge (f1)" and "Reliance (f2)" were extracted as constructs from awareness of the use of PILs. In contrast, many previous studies¹⁴⁻¹⁹ reported that knowledge and reliance are necessary for pharmacists to be valued by patients. Therefore, "Knowledge" and "Reliance" are also suggested to be important factors in pharmacists' pharmacotherapy guidance using PILs.

The model of multiple regression analysis with Knowledge (f1) as the response variable indicated that CHL, which is the ability to analyze and act critically, is the most relevant factor for the awareness of wanting to know specifics about PILs. This previously unreported fact supports a logical relationship. In addition, COHL was shown to be a factor related to Knowledge (f1). In the concept of COHL proposed by Nutbeam (2000)²⁰, COHL includes the ability to relate well with others, participate actively in daily activities, obtain information through various forms of communication, and increase motivation and confidence to act independently based on knowledge in a supportive environment. This suggests that older adults with high COHL tend to use PILs actively as an information source. In contrast, when considering the communication process with patients, it is thought that pharmacists need to provide accurate information in an easy-to-understand manner, especially to older adults with low CHL and COHL, after understanding their experiences, living conditions, and relationships. At that time, it is suggested that information on the experience of ADRs or Internet use can

also be used to gain a better understanding of patients' perceptions and behaviors because many older adults who have experienced ADRs or search for information online have high CHL and COHL.

The model of multiple regression analysis with Reliance (f2) as the response variable indicated that COHL was the most related to Reliance (f2). The ability to obtain information and use knowledge through various forms of communication was strongly related to the awareness of the reliability of PILs. Female older adults had higher Reliance (f2) than male older adults. It has been reported that females are more likely to use their "close social networks" such as family members and friends²¹, are more empathetic than males²², and are better at interpersonal communication²³. These suggest that "someone to consult" is a variable closely related to "females". On multiple regression analysis, it was speculated that "someone to consult" was not a significant variable because of a confounding relationship with "females". Therefore, it is thought that the reliability of pharmacotherapy guidance using PILs can be increased by empathetic communication, not only for females, but also males. Thus, empathic communication was suggested as a way to make more effective use of PILs.

The results also showed that Reliance (f2) was associated with FHL. FHL involves the ability to "understand what the doctor has explained to you", "understand the explanation of the drug given by the pharmacist", and "read and understand the instructions for the medicine". In general, due to the age-related deterioration of physical abilities such as eyesight and hearing, and of cognitive functions such as understanding and remembering things, older adults have more difficulty understanding the explanations given by doctors and pharmacists and reading and comprehending the contents of PILs. In other words, many older adults have decreased FHL. Some ideas for improving FHL include "using visual effects such as illustrations and pictograms"²⁴ and "printed text should not be smaller than 14 points"²⁵. Therefore, it is necessary to consider expressions other than letters and the size of letters when preparing PILs. In addition, it is necessary to provide PILs that are easy for older adults to understand.

In a multiple regression analysis model related to Anxiety (PILs 3), which is one of the items not included in the two factors, CHL resulted in increased anxiety to use PILs. This indicated that PILs may increase anxiety about taking medications in older adults, who

are more capable of seeking and acting on health information on their own. Anxiety (PILs 3) is thought to correspond to perceived barriers that cause major health problems related to medication use^{26,27}. It has been reported that these perceived barriers can also be a factor in reducing drug adherence²⁸. In addition, Kinjo et al.⁷ reported that patients have various concerns about obtaining medical and health information in general, and that the acquisition and interpretation of wrong information may affect their drug adherence. Therefore, when pharmacists provide pharmacotherapy guidance to older adults with high levels of CHL using PILs, they need to provide accurate information based on statistical evidence and explore the behavioral psychology of patients so as not to increase their anxiety unnecessarily. Furthermore, pharmacists need to work to reduce patient anxiety by communicating that the risk can be reduced through follow-up observations.

This study is significant as an explanatory model that examines the relationship between the awareness of the use of PILs and HL. However, the determination coefficient of the multiple regression analysis model was not high, because it was not intended to investigate the relationship with any other factors. To explore the factors related to the use of PILs, it is necessary to consider the relationship with highly correlated factors, such as the type and severity of the disease, support from family members, and self-efficacy. This is a topic for future research. In addition, since this study was conducted in a limited area, further research is required.

Conclusion

An exploratory factor analysis of awareness of the use of PILs identified two factors: “Knowledge (f1)”, which refers to the awareness of knowing the specific content of PILs; and “Reliance (f2)”, which refers to the awareness that arises from trust in PILs. In addition, multiple regression analysis of awareness of the use of PILs showed that Knowledge (f1) was related to CHL and COHL, and that Reliance (f2) was related to FHL and COHL, with late-older adults and females showing higher values than early-older adults and males, respectively. In addition to these two factors, “Anxiety” about using PILs was positively related to CHL and negatively related to FHL. Therefore, to avoid causing excessive anxiety, pharmacists should provide support for the use of PILs to older adults with low levels of COHL or

CHL and provide accurate, easy-to-understand, evidence-based information for older adults with high levels of CHL or low levels of FHL.

Conflict of Interest (COI)

The authors have no conflicts of interest to declare.

Acknowledgments

The authors would like to thank the pharmacists at Shirakaba Pharmacy Co., Ltd. (Ryuichirou Matsune, Masae Wada, Tomoki Ueda, Masaaki Kuroda, Haruko Kudou, Harunori Ueda, and Wakae Kagota) and the patients who cooperated with this research.

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