

Interpretation of drug label instructions: a study among four immigrants groups in the Netherlands

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Abstract *Background:* Poor understanding of medical instructions or misinterpretations can be a cause for not using medication as prescribed. Previous studies reported misunderstanding of instructions and warnings on drug labels by up to 50 % of the adult population. *Objective:* The aim of this study was to assess interpretation of drug label instructions in different migrant populations living in the Netherlands. *Methods:* Interpretation of drug label instructions was examined in four populations of first-generation immigrants from the Antilles (n = 168), Iran (n = 180), Surinam (n = 155), and Turkey (n = 188). Participants were recruited at meeting places (e.g., mosques and educational or cultural centers) for the particular ethnic group. First-year pharmacy students (n = 153) born in the Netherlands were included as reference group. Correct interpretation of drug label instructions was assessed using a survey with questions about five instructions. *Results:* Only two out of five presented instructions were interpreted correctly by the majority of the respondents of all groups. Higher levels of education, longer duration of stay, and native ethnicity were positively associated with correct interpretation of drug labels ($p < 0.05$). *Conclusion:* Incorrect interpretation of certain drug label instructions occurred among the majority of both immigrants and natives.

Keywords Drug label · Ethnic background · Health literacy · Interpretation · Migrants · The Netherlands

Impact of findings on practice

- Many commonly used drug label instructions are unclear, and misunderstanding of these instructions occurs both in (highly educated) natives and immigrants.
- To improve comprehension of drug-use instructions, all medicine users would benefit from a clearer formulation of instructions, preferably in their own language.
- Healthcare providers should explain drug instructions to patients in an explicit language and then check if the instructions have been understood, especially in low-educated patients with a different language background.

Introduction

Patients do not always take their medicines as instructed, which may result in suboptimal quality of the outcome of the prescribed drug therapy and drug-related problems [1]. It has been reported that up to 50 % of adults may have misunderstand dosage instructions and warnings provided on drug labels [2, 3], which can be a cause of not using medication as prescribed. The assumption of healthcare providers that their patients can read, understand, and respond adequately to instructions presented on medication labels may therefore be unfounded. Problems regarding understanding of medical information seem to be more prevalent in certain patient groups, such as the elderly or people with another cultural or ethnic background [4–6]. Previous research has shown low health literacy—the

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ability to obtain, understand, and apply healthcare information to make appropriate health-related decisions—to be associated with poor adherence and health outcomes [7]. Patients with low health literacy skills perceive difficulties in understanding (written) drug information, such as drug labels and patient packages inserts. In Europe, relatively little is known about the understanding of drug label instructions by immigrant populations, and most previous work in this field has been performed in the USA [8–10]. However, it has been shown that ethnicity is associated with quality of medication use (e.g., adherence, medication errors) [11, 12].

Aim of the study

The aim of this study was to assess interpretation of drug label instructions in different migrant populations living in the Netherlands.

Methods

The study was designed as a cross-sectional study in which correct interpretation of drug labels was examined in first-generation migrants living in the Netherlands: people born in the Antilles, Persians (Iran), Surinamese, and Turks. Participants were recruited by pharmacy students with the same ethnic background at meeting places, such as cultural and educational centers or mosques, for the particular ethnic group. Respondents were excluded from participation if they were born in the Netherlands, had no sufficient comprehension of written Dutch language (tested with general reading ability questions), or were aged <18 years. First-year pharmacy students born in the Netherlands were included as reference group.

Participants individually completed a survey containing multiple-choice questions about five frequently used standard drug label instructions within Dutch pharmacies (Appendix). Before start of the study, experts of the university (staff members, practicing pharmacists) and the Royal Dutch Pharmacist Association were consulted for correct interpretations of the instructions and correct answers on the survey questions. In order to study characteristics influencing interpretation of instructions, we used correct interpretation, correct answering of all survey questions related to the specific instruction, as outcome measure for the regression model.

Educational level was categorized as low (no formal education), medium (lower/intermediate vocational, intermediate/higher secondary), or high (higher vocational/university). Chi-square testing was used to study differences in correct interpretation of instructions between

groups. Logistic regression analysis was used to study determinants of label interpretation. Age, gender, education, ethnicity, and duration of stay in the Netherlands were included as potential confounding factors in the multivariate model. Factors with p values less than 0.10 were included in the multivariate model. Data were analyzed using IBM SPSS version 20.0.

Results

Response rate was very high; 100 % of the invited Surinamese, 98.4 % of the Persians (183 approached, 183 consented, 3 excluded due to language barriers), 96.4 % of the Turks (195 approached, 194 consented, 6 excluded (3 excluded due to language barriers)), and 85.7 % of the invited Antilleans [196 approached, 176 consented, 8 excluded (2 excluded due to language barriers)] were included. By design of the study, participants in the native group were younger and more highly educated (Table 1). There were some differences between the four immigrant groups: Surinamese migrants and Turks had already lived for a longer period in the Netherlands, the Persian and Surinamese migrants were more highly educated compared to the other migrants, and respondents from Antillean and Persian origin were slightly younger ($p < 0.05$).

Table 2 presents the percentages of respondents of each ethnic group and the reference group, who interpreted the instructions correctly. Two instructions (“1 tablet as needed, maximum 6 tablets a day” and “complete the prescribed course”) were interpreted correctly by most participants. Three instructions were misinterpreted by the majority of respondents. The instruction “Take with water, not with milk” was correctly interpreted by less than 25 % of all respondents. The misinterpretation was especially due to the fact that participants did not associate cheese with milk products and/or had difficulties with the time period of milk abstinence. Also, *avoiding sunlight exposure* was often misinterpreted (<8 % correct). Subjects did understand the need to avoid a sunbath or sunbed; however, they tended to be too strict, by avoiding any sunlight exposure, e.g., no outside walks or indirect sunlight exposure indoors behind the glass. The instruction “Do NOT drink grapefruit juice along with this drug” was correctly interpreted by approximately half of the participants, while the Turkish (20 %) and Persian respondents (34 %) scored even lower.

Education seems consistently associated with the interpretation of instructions: Participants who were medium- or high-level educated were more likely to correctly interpret instructions compared to participants with a low educational level ($p < 0.05$) (Table 3). Furthermore, Turkish immigrants were more likely to misunderstand

Table 1 Characteristics of study population stratified by ethnicity

	Surinamese (n = 155), %	Antillean (n = 168), %	Turkish (n = 188), %	Persian (n = 180), %	Dutch (n = 153), %	p value*
Female gender	60.6	70.8	59.0	50.6	63.4	0.003
<i>Age group</i>						
18–34 years	14.2	36.4	43.2	55.6	100	<0.001
35–55 years	51.6	32.8	56.9	41.1	–	
55+ years	34.2	30.9	–	3.4	–	
<i>Educational level</i>						<0.001
Low	4.3	13.7	42.0	3.5	–	
Medium	75.1	55.3	45.2	69.8	–	
High	20.6	31.0	12.8	26.7	100	
<i>Duration of stay in the Netherlands</i>						<0.001
<5 years	5.8	31.5	5.9	18.3	–	
5–15 years	8.4	30.4	31.9	66.1	–	
15+ years	85.8	38.1	62.2	15.6	100	

* Difference between the ethnic groups (χ^2 test was performed)

instructions (instruction 1 and 5), whereas female gender and longer duration of stay were associated with the correct interpretation.

Discussion

This study shows misinterpretation of commonly used drug label instructions. Misunderstanding of instructions leads to suboptimal drug therapy resulting from taking less than instructed, attaining inadequate drug concentrations, or increased risk of adverse effects by overdosing and drug concentration increasing interactions [1]. Furthermore, misunderstanding instructions can cause unnecessary discomfort too by strictly following rules, such as no sun exposure at all (e.g., avoiding outside walks after the instruction “Avoid exposure to direct sunlight”) and the abstention of milk consumption during a long period, which might eventually lead to patients’ noncompliance with a drug.

We showed differences in correct interpretation between drug label instructions: For 3 of the 5 instructions, we showed lower comprehension, which might indicate these instructions are less clear or explicit formulated and should be adapted. In general, we believe it is important to formulate instructions in clear language and as specific and complete as possible. Furthermore, healthcare providers should explain backgrounds of instructions orally during patient counseling or additional written information to ensure that correct medication use should be provided. The instruction *Take with water, not with milk* could, for example, should be

reformulated by indicating also the avoidance of milk products (more complete) and adding a specific time frame for the avoidance of milk (products) as the majority of the study participants did not associate cheese with milk consumption or had difficulties with the period of milk abstention. Another example of an unclearly formulated instruction was the instruction “Do NOT drink grapefruit juice along with this drug.” This instruction could be more specifically formulated, by, for example, saying do not use grapefruit(juice) while taking this medicine and informing patients about underlying reasons why they should not use grapefruit juice during the use of this medicine (drug concentration increasing interactions). Reformulating instructions could improve patient understanding of instructions. Also, other studies showed that patient-centered instructions, instructions with specific timing, or additional graphic aid improved understanding [13, 14].

Turkish migrants most often experienced problems with comprehension of the tested instructions. Language barriers can be an explanation for this finding. One of the first steps in understanding health information is to speak and understand the language. It has been shown before that immigrants often experience difficulties with the language, as well as cultural barriers and socioeconomic differences, which may lead to health literacy problems [15]. We did not observe lower understanding of drug labels for Surinamese and Antillean migrants compared to the reference group. Linguistic problems may be less likely in these groups as both in Surinam and the Antilles, Dutch is also an official language. This might be supported by the fact that respondents who had lived for a longer period of time had better

Table 2 Interpretation of drug label instructions stratified by ethnicity

Instructions and survey questions	Correct answers	Surinamese (n = 155), %	Antillean (n = 168), %	Turkish (n = 188), %	Persian (n = 180), %	Dutch (n = 153), %	p value*
<i>Instruction 1^a: 1 tablet as needed, maximum 6 tablets a day</i>		72.9	65.5	48.4	70.0	86.9	<0.001
When do you take a tablet?	When necessary	74.2	74.3	52.1	71.7	88.2	<0.001
How many tablets do you take per day?	Maximum of 6 tablets	94.8	84.9	88.3	95.6	98.0	0.001
<i>Instruction 2^a: Complete the prescribed course</i>		91.6	81.0	88.3	79.9	95.4	<0.001
How long do you need to use the antibiotic capsules?	1 week	91.6	81.0	88.3	79.9	95.4	<0.001
<i>Instruction 3^a: Take with water, not with milk</i>		23.2	19.0	21.3	23.3	24.2	0.802
Are you allowed to take the drug with yoghurt?	No	96.1	97.6	88.8	84.4	84.3	<0.001
Are you allowed to eat cheese directly after intake of the drug?	No	52.3	59.9	56.9	48.3	35.3	<0.001
How many hours before and after intake are you not allowed to drink milk?	1 h before and 1 h after	38.1	27.5	30.9	40.6	41.8	<0.001
<i>Instruction 4^a: Avoid exposure to direct and/or artificial sunlight on your skin</i>		7.1	5.4	1.6	4.4	4.6	0.171
Can you sunbathe while using these drugs?	No	92.3	92.2	71.8	88.1	84.3	<0.001
Can you use a sunbed while using these drugs?	No	91.6	86.3	69.1	84.4	98.0	<0.001
Can you go for a walk outside during a sunny day, while using these drugs?	Yes, when covered up	49.0	37.3	41.5	49.4	60.1	<0.001
Is it allowed to sit in the sun behind glass?	Yes, for a short period of time	14.2	16.1	14.3	16.8	7.8	0.185
<i>Instruction 5^a: Do not drink grapefruit juice along with this drug</i>		45.2	44.0	19.7	33.9	49.7	<0.001
What does “Do not drink grape fruit juice mean”?	Do not eat or drink grapefruit (juice)	85.8	84.0	71.4	83.2	73.2	0.004
When can you drink grapefruit juice?	Not during this drug course	76.8	80.1	45.7	53.3	73.9	<0.001
Is it allowed to drink orange juice?	Yes	66.5	68.1	56.4	71.1	90.8	<0.001

* Difference between the ethnic groups (χ^2 test was performed)^a Based on correct answering of all individual survey questions for the indicating drug label instruction

Table 3 Patient characteristics associated with correct interpretation of drug label instructions

Variable	Instruction 1: 1 tablet as needed, maximum 6 tablets a day		Instruction 2: Complete the prescribed course		Instruction 3: Take with water, not with milk		Instruction 4: Avoid exposure to direct and/or artificial sunlight on your skin		Instruction 5: Do not drink grapefruit juice along with this drug	
	Cru OR (95 % CI)	Adj OR# (95 % CI)	Cru OR (95 % CI)	Adj OR# (95 % CI)	Cru OR (95 % CI)	Adj OR# (95 % CI)	Cru OR (95 % CI)	Adj OR# (95 % CI)	Cru OR (95 % CI)	Adj OR# (95 % CI)
Female gender	1.0 (0.7–1.3)	1.0 (0.8–1.4)	1.8 (1.2–2.7)*	2.1 (1.3–3.2)*	1.3 (0.9–1.8)	1.4 (1.0–1.9)	1.4 (0.7–2.9)	1.3 (0.6–2.9)	1.5 (1.2–2.1)*	1.5 (1.1–2.0)*
<i>Age group</i>										
18–34	1	1	1	1	1	1	1	1	1	1
35–55	0.6 (0.5–0.8)*	0.9 (0.6–1.2)	0.7 (0.4–1.0)	0.8 (0.5–1.2)	0.8 (0.5–1.1)	0.8 (0.5–1.2)	1.0 (0.4–2.1)	1.1 (0.5–2.7)	1.0 (0.7–1.3)	1.4 (1.0–2.0)*
55+	0.6 (0.4–1.0)	0.8 (0.5–1.3)	0.6 (0.3–1.0)	0.6 (0.3–1.2)	0.8 (0.5–1.3)	0.8 (0.5–1.5)	2.1 (0.9–5.0)	1.6 (0.6–4.7)	0.9 (0.6–1.4)	1.2 (0.8–2.0)
<i>Ethnicity</i>										
Dutch	1	1	1	1	1	1	1	1	1	1
Surinamese	0.4 (0.2–0.7)*	1.0 (0.5–2.0)	0.5 (0.2–1.4)	2.6 (0.8–8.5)	0.9 (0.6–1.6)	1.4 (0.7–2.8)	1.9 (0.7–5.2)	1.7 (0.4–6.9)	0.8 (0.5–1.3)	1.2 (0.6–2.1)
Antillean	0.3 (0.2–0.5)*	0.7 (0.3–1.5)	0.2 (0.1–0.5)	0.8 (0.3–2.6)	0.7 (0.4–1.3)	1.0 (0.5–2.2)	1.4 (0.5–4.0)	1.6 (0.4–7.2)	0.8 (0.5–1.2)	0.9 (0.5–1.8)
Turkish	0.1 (0.1–0.2)*	0.4 (0.2–0.8)*	0.4 (0.2–0.9)	2.2 (0.7–6.8)	0.8 (0.5–1.4)	1.3 (0.6–2.6)	0.4 (0.1–1.6)	0.4 (0.1–2.2)	0.2 (0.2–0.4)*	0.3 (0.2–0.6)*
Persian	0.4 (0.2–0.6)*	0.8 (0.4–1.6)	0.2 (0.1–0.4)	0.8 (0.3–2.3)	1.0 (0.6–1.6)	1.3 (0.6–1.2)	0.7 (0.2–2.3)	0.9 (0.2–4.2)	0.5 (0.3–0.8)*	0.7 (0.4–1.2)
<i>Education</i>										
Low	1	1	1	1	1	1	1	1	1	1
Median	3.3 (2.1–5.1)*	3.3 (2.1–5.1)*	1.8 (1.1–3.0)*	2.2 (1.3–3.8)*	1.2 (0.7–2.0)	1.2 (0.7–2.1)	1.1 (0.4–3.5)	1.1 (0.4–3.3)	1.3 (0.8–2.0)	1.2 (0.8–2.0)
High	7.2 (4.4–11.5)*	5.5 (3.2–9.3)*	4.9 (2.6–9.4)*	4.6 (2.3–9.3)*	1.4 (0.8–2.4)	1.5 (0.8–2.7)	1.1 (0.4–3.6)	0.9 (0.3–3.7)	2.2 (1.4–3.5)*	1.9 (1.1–3.2)*
<i>Duration of stay</i>										
<5	1	1	1	1	1	1	1	1	1	1
5–15	0.8 (0.5–1.3)	0.9 (0.6–1.5)	3.0 (1.7–5.4)*	3.8 (2.0–6.9)*	1.9 (1.1–3.5)*	1.9 (1.0–3.5)*	1.3 (0.4–4.9)	1.5 (0.4–5.7)	0.7 (0.4–1.0)	0.7 (0.4–1.2)
15+	1.2 (0.8–1.9)	1.0 (0.6–1.7)	3.4 (2.0–5.6)*	3.2 (1.8–5.7)*	1.4 (0.8–2.5)	1.3 (0.7–2.5)	1.6 (0.5–5.4)	1.0 (0.3–3.8)	0.9 (0.6–1.4)	0.7 (0.4–1.1)

Adjusted for gender, age, ethnicity, education and duration of stay, * $p < 0.05$

comprehension of the instructions. Fulton [16] described not being able to understand a language as important cause for medication errors. In line with previous research, we showed a higher level of education to be associated with the better understanding of instructions [17].

Strength of this study was the recruitment of participants by students with the same ethnic background resulting in a high response, making selective response less likely. Participants were recruited at meeting places for a specific cultural/ethnic group; therefore, not all respondents might have been regular medication users and familiar with presented instructions. Thus, comprehension of instructions might have been greater if participants reported on their own medication use. However, as we included standard medication instructions, we believe our results underline the problem of misunderstanding drug-related health information in daily practice. Furthermore, information on participants' prior or current medication use was lacking. Experiences with medicines may have influenced the study outcomes. Independent of medication use, this study underlines the problem of misinterpretation of drug instructions. Unfortunately, by design of the study, participants in the reference group were younger and higher educated, which hampers generalizability of results to the general population. However, our main objective was to assess general understanding of drug label instructions in different immigrant populations and not to explore differences in understanding between natives and immigrants. A reason for relatively poor understanding of drug instructions in the reference group might be the fact that younger people have less experience with the medication use. Non-natives in this study had to be capable of understanding written Dutch; therefore, our results are based upon a population which could understand, at least partly, the language, so there may be a low literate population which is even less likely to understand medication instruction because of language problems. Combined with the fact that even highly educated young people had difficulties with interpreting

instructions, this study underlines the importance of attention to the formulation of these labels.

Conclusion

Many standardly used drug label instructions are unclear, and misinterpretation of these instructions occurs both in highly educated natives and immigrants. Our results indicate that it is important to investigate patients' experience with label instructions and to pretest information among patients with different backgrounds (language, education). Drug labels—together with patient package inserts—are often the only written source of (dosage) instructions received by patients. Information presented on these labels is very limited, and these labels are only effective if patients are able to understand instructions, interpreted the information correctly, and can follow the advice provided on them.

We conclude that all patients would benefit from more clear and explicit formulation of instructions, preferably in their own language, to improve comprehension of drug instructions and ensure correct use. For healthcare providers, it is important to explain drug instructions to patients using explicit language and ask patients' feedback, especially in case of low-educated patients with a different language background.

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Conflicts of interest No conflict of interest to declare.

Appendix: Key section survey

The key section of the questionnaire contained 5 drug label instructions with questions about these instructions.

Instruction 1:

The doctor prescribes you acetaminophen for your headache. The following text is printed on the drug label: **1 tablet as needed, maximum 6 tablets a day**

1. When do you take a tablet?
 - Every day, even when I have no pain
 - When I have mild pain
 - When I cannot stand the pain anymore
 - When I think it is necessary (Correct answer)**
 - I don't know
 - Other, namely

2. How many tablets do you take per day?
- I can take more than 6 tablets a day
 - I cannot take more than 6 tables a day (Correct answer)**
 - I can use the tablets more than 6 days
 - I cannot use the tables for more than 6 days
 - I don't know
 - Other, namely

Instruction 2:

Imagine you will get antibiotic capsules for your sore throat for seven days. The following text is printed on the drug label: **Complete the prescribed course**

1. How long do you need to use the antibiotic capsules?
- 1 week (Correct answer)**
 - The number of days is not important
 - Until my sore throat is over
 - I don't know
 - Other, namely

Instruction 3:

The following text is printed on the drug label of an antibiotic: **Take with water, not with milk**

1. Are you allowed to take the drug with yoghurt?
- Yes
 - No (Correct answer)**
 - I don't know
 - Other, namely
2. Are you allowed to eat cheese directly after intake of the drug?
- Yes
 - No (Correct answer)**
 - I don't know
 - Other, namely
3. How many hours before and after intake are you not allowed to drink milk?
- 1 hour before and 1 hour after intake no milk consumption (Correct answer)**
 - I can take milk whenever I want
 - I cannot have milk at all
 - I don't know
 - Other, namely

Instruction 4:

Imagine you will get an antibiotic for one 1 week. The following text is printed on the drug label: **Avoid exposure to direct and/or artificial sunlight on your skin**

1. Can you sunbathe whilst using these drugs?
- Yes, without limitations
 - Yes, but no longer than 30 minutes
 - Yes, but not longer than 5-10 minutes
 - No, that's not allowed (Correct answer)**
 - I don't know
 - Other, namely
2. Can you use a sunbed whilst using these drugs?
- Yes, that is allowed
 - Yes, but no longer than 30 minutes
 - Yes, but not longer than 5-10 minutes
 - No, that's not allowed (Correct answer)**
 - I don't know
 - Other, namely
3. Can you go for a walk outside during a sunny day, whilst using these drugs?
- Yes, that is allowed
 - Yes, only when I cover up (wearing a head and long sleeves) (Correct answer)**
 - No, that's not allowed
 - I don't know
 - Other, namely
4. Is it allowed to sit in the sun behind glass?
- Yes, that is allowed for the whole day
 - Yes, but only for a short period of time (Correct answer)**
 - No, that's not allowed
 - I don't know
 - Other, namely

Instruction 5:

Imagine you use a medicine for allergies. The following text is printed on the drug label: **Do NOT drink grapefruit juice along with this drug**

1. What does “Do not drink grape fruit juice mean”?
 - Do not drink grapefruit juice or eat grapefruit (Correct answer)**
 - Do not drink grapefruit juice, but you can eat grapefruit
 - I don't know
 - Other, namely
2. When can you drink grapefruit juice?
 - Always
 - Just 2 hours before and after intake of the drug
 - No grapefruit juice at all (Correct answer)**
 - Only if I do not get symptoms from it
 - I don't know
 - Other, namely
3. Is it allowed to drink orange juice?
 - Yes (Correct answer)**
 - No
 - I don't know
 - Other, namely

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