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## Recognizing pharmaceutical illiteracy in community pharmacy: Agreement between a practice-based interview guide and questionnaire based assessment

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### ABSTRACT

**Background:** Patients with limited pharmaceutical literacy are at increased risk of drug-related problems. Recognizing these patients in daily practice is difficult. The Recognition and Addressing of Limited Pharmaceutical Literacy (RALPH) interview guide was developed as practical set of questions to recognize patients

with limited pharmaceutical literacy in daily pharmacy practice.

**Objective:** To compare agreement between pharmaceutical literacy measured with the RALPH guide and a validated general health literacy questionnaire. In addition, we provide insight into patients' pharmaceutical literacy using the RALPH interview guide.

**Methods:** Structured face-to-face interviews with patients who visited a community pharmacy to fill a prescription for themselves were conducted. The interview included the RALPH guide as well as the Functional Communicative Critical Health Literacy (FCCHL) questionnaire to measure general health literacy. Functional, communicative and critical skills were measured and agreement between two methods was calculated.

**Results:** Data were collected from 508 patients. Patients with limited pharmaceutical literacy, indicated by the RALPH questions, also had a lower general health literacy level according to FCCHL scores. Agreement between

the RALPH guide and FCCHL questionnaire was moderate (~60%) for the three health literacy domains. Most patients (> 90%) had correct understanding of frequency and timing of medication use, but 25% did not understand warnings or precautions correctly. Finding understandable information (39%), assessing information applicability (50%) and reliability (64%) were mentioned as difficult by patients.

Conclusion: Patients experienced difficulties with more complex skills, e.g. interpretation of warnings or precautions when using a medicine, finding and analyzing medication information. Whereas the FCCHL questionnaire is useful to assess general health literacy, the RALPH interview guide provides insight in the level of skills needed for good medication use and is more suitable for use in a medication specific context such as community pharmacy. Context specific assessment of skills is important to provide tailored pharmaceutical care.

## INTRODUCTION

Good health literacy is crucial for patients to be able to understand the information and instructions given to them about their medical treatment.<sup>1,2</sup> The Dutch medical treatment act requires pharmacists to inform patients about the aim and (adverse) effects of the proposed treatment strategy. Pharmacists label medication packages with instructions and warnings concerning appropriate use of the product and provide patients with oral and written information about beneficial and adverse effects or precautions when using the medication.<sup>3</sup> Previous studies showed that a considerable proportion of patients have limited health literacy.<sup>4-6</sup> These patients experience difficulties in understanding medication information, which may result in suboptimal use and drug-related problems.<sup>4,7,8</sup> Leendertse et al.<sup>9</sup> showed that drug related problems lead to a large number of preventable hospitalizations each year. It thus is important to identify patients with limited health literacy skills related to medication use, in this manuscript referred to as pharmaceutical illiteracy, as these patients might be at increased risk of drug-related problems. Measurement of pharmaceutical literacy requires assessment of specific skills required for (correct) medication use. There are however no specific tools or instruments for assessment of skills in this specific context.

Previous research showed that pharmacy staff mainly use their intuition (“gut feeling”) or certain patient characteristics to identify patients with limited health literacy skills.<sup>10</sup> We developed the Recognition and Addressing of Limited Pharmaceutical Literacy (RALPH) interview guide as practical tool to support pharmacy staff in recognizing patients with limited pharmaceutical literacy. Details of development of the RALPH interview guide are described elsewhere in this issue.<sup>11</sup> Briefly, the RALPH interview guide comprises 10 questions, all directly linked to the patient's own medication, to be used during patient counseling. Besides instructions on how to use the interview guide, tips and tools are provided to support pharmacists in recognizing and supporting patients with limited pharmaceutical literacy.

The aim of this study was to measure agreement between the RALPH interview guide and a validated general health literacy questionnaire, to verify that the (pharmaceutical) health literacy domains are adequately assessed by the RALPH guide. In addition, we provide insight into patients' pharmaceutical literacy using the newly developed practice-based RALPH interview guide.

## 2. METHODS

### 2.1. Setting and population

We conducted a cross-sectional interview study in community pharmacies affiliated with the Utrecht Pharmacy Practice network for Education and Research (UPPER), a network consisting of pharmacies that regularly participate in research and internships for pharmacy students.<sup>12</sup> Community pharmacies participating in internships for students of the Utrecht School of Pharmacy and pharmacies employing a pharmacist for the advanced community pharmacist education program (to become a specialist community pharmacist) in the time period January–July 2017 participated in the study. The study protocol was approved by the Institutional Review Board of the Division of Pharmacoepidemiology & Clinical Pharmacology, Utrecht University.

Structured face-to-face interviews were performed by 109 master students or the specialist community pharmacist trainees. They randomly invited 3–5 patients to participate in an interview. All adult patients (aged 18 years or older), who filled at least one prescription for themselves and had sufficient understanding of verbal Dutch language were eligible for participation. Before the start of the interview, the purpose of the study was explained, and consent was obtained.

### 2.2. Data collection

Interviews were guided by a structured interview questionnaire consisting of three elements: (1) the Recognition and Addressing of Limited Pharmaceutical Literacy (RALPH) interview guide, (2) the Functional Communicative Critical Health Literacy (FCCHL) instrument and (3) sociodemographic questions (age, gender, educational level, country of origin).

The RALPH interview guide, described elsewhere in this issue,<sup>11</sup> comprises 10 questions directly linked to the patient's own medication: three in the functional domain (understanding instructions for correct use), three in the communicative domain (finding and understanding information) and four in the critical domain (critically analysing information).

The topics of the interview guide are presented in Table 1.

Questions in the functional domain were scored as correct, incorrect or patient does not know. For analysis, answers were dichotomized as correct or incorrect. The option “patient does not know” was included as incorrect. Questionnaire items in the communicative domain were scored on a four-point Likert scale ranging from very easy to very difficult, later on for analysis, the responses were dichotomized as easy or difficult. The option “not searching for information” was also classified as perceiving difficulties with this skills. The same scoring method was applied for the items in the critical domain, except for one question about using reliable sources which was also scored as correct or incorrect.

The Dutch version of the FCCHL was used to measure three generic aspects of health literacy: (1) functional (5 questions), communicative (5 questions) and critical

skills (4 questions).<sup>13</sup> All questions were scored on a four point Likert-scale ranging from never perceiving difficulties (score 1) to often perceiving difficulties (score 4). A proportion of patients mentioned that the questionnaire items in the critical or communicative domain were not applicable to them. These items were treated as missing data. Mean total FCCHL scores and mean subscale scores were calculated by summing item scores divided by the total number of items in the subscale, resulting in a score ranging from 1 to 4. Patients with mean scores <3 on the FCCHL subscale were defined as having adequate health literacy.<sup>5,13</sup>

### **2.3. Data analysis**

Descriptive statistics were used to calculate pharmaceutical and health literacy scores for the three domains. The percentage of overall agreement between items in the RALPH and FCCHL subdomains was calculated as follows: the number of patients having a correct score on the RALPH domain as well as adequate health literacy on the FCCHL domain + the number of patients having an incorrect score on the RALPH domain as well as limited health literacy on the FCCHL domain, divided by the total number of patients, multiplied by 100. A percentage of  $\geq 60\%$  was considered moderate. T-testing was used to assess differences in FCCHL scores for patient with correct vs, incorrect answers using the RALPH interview guide. Data were analyzed using IBM SPSS version 23.0 (IBM Corp., Armonk, NY, USA) for Windows.

## **3. RESULTS**

### **3.1. Study population**

Data were collected from 508 patients by 109 community pharmacist( s) (trainees). The characteristics of the study population are shown in Table 2. The majority of patients were women, mean age was 67 years and most patients were of native Dutch origin.

### **3.2. Functional skills**

Most patients (> 90%) had correct understanding on how to use their medication (frequency and timing of intake). A quarter of patients had difficulties understanding specific instructions or warnings. These patients also had higher sum scores on the FCCHL functional domain, which indicates lower health literacy (Table 3A). Table 3B shows agreement between pharmaceutical literacy measured with the RALPH interview guide and health literacy skills measured with the FCCHL for the functional domain. Agreement between the two measures was approximately 60%. A considerable proportion of patients had a correct understanding of how to use their own medication based on RALPH, but were classified as having limited functional health literacy based on FCCHL scoring. For example, 39.4% of the patients (171/434) who mentioned the correct indication for use of their own medicine were classified as having limited functional health literacy skills based on the FCCHL.

[TABLE 1] [TABLE 2] [TABLE 3A] [TABLE 3B] [TABLE 4]

### **3.3. Communicative skills**

In total, 39.3% of the patients experienced difficulties with finding understandable information about their medicines (Table 4A). Asking questions about medication or

expressing concerns was less difficult for patients. Agreement between the RALPH communicative domain items and the FCCHL sum scores in this domain varied between 57.5% and 69.1% for the different RALPH items. Many patients reported no difficulties with asking questions (n=462) or addressing concerns (n=446) measured with the RALPH guide, but a considerable proportion of them was classified as having limited health literacy in this domain according to the FCCHL (Table 4B).

### 3.4. Critical skills

Table 5A shows that a considerable proportion of patients experienced difficulties in this domain; 64.0% had troubles with assessing reliability of medication information. Agreement between the RALPH interview guide and FCCHL questionnaire varied between 49.3% and 79.1% for the different items in this domain. Many patients reported difficulties with assessing information applicability (n=254) or assessing reliability of medication information (n=325) (Table 5B).

## [TABLE 5]

## 4. DISCUSSION

Our results show that most patients have sufficient understanding about how often and when to take their medication, but that they are more likely to experience difficulties with more complex tasks such as interpretation of warnings or precautions and critically analyzing of medication information. This is in line with other studies on health literacy showing that patients often experience more difficulties with skills in the communicative and critical domain, which may negatively influence self-management.<sup>5,6,14</sup> There are many different tools to measure (general) health literacy,<sup>15</sup> including both objective and subjective methods of assessing skills. Previous research has shown that different methods may lead to different results.<sup>16</sup> In this study we used a practice-based interview guide to assess pharmaceutical literacy and compared these results with a questionnaire-based assessment of general health literacy. Our results show that patients with limited pharmaceutical literacy indicated by the RALPH interview guide also had lower FCCHL scores, indicating a lower general health literacy level. However agreement between the methods was only moderate. Patients reported a higher level of pharmaceutical literacy compared to their general health literacy level. For the functional skills, a large proportion of patients with adequate pharmaceutical literacy (e.g. correct understanding of how to use their own medication) were classified as having limited health literacy based on the FCCHL scoring. For the RALPH functional domain, the questions are objective measures about the patient's own medication which results in a correct or incorrect answer. In contrast, the FCCHL questions are more subjective and ask for difficulties with reading and writing in a more general manner. The RALPH interview guide was developed to gain insight in patients' pharmaceutical literacy with respect to their own medication use. When patients have been using a specific medicine for some time, it is reasonable to expect that most of them know how to use it, explaining the higher RALPH scores.

Also for the communicative and critical domain, a large proportion of patients with adequate pharmaceutical literacy were classified with limited general health literacy. Many patients mentioned not to experience difficulties with addressing their concerns

about medication or asking a question, whilst the same patients scored lower in this domain using the FCCHL. The questions about communicative and critical pharmaceutical literacy skills are related to the context of medication use in which the community pharmacy often is the clinical setting. It may be easier for patients to ask information about medicines there than in a more general medical situation. This may also be because community pharmacies are widely recognised as accessible locations from which people seek advice about treatment of their (chronic) conditions and medication use.<sup>17,18</sup> To our knowledge this is one of the first studies using a practicebased guide to recognize pharmaceutical illiteracy in daily clinical practice. Duell et al. al.<sup>19</sup> assessed suitability of 43 health literacy instruments for use in routine clinical practice and found that the Newest Vital Sign (NVS) instrument was the most practical.<sup>20</sup> They concluded there is urgent need for health literacy instruments applicable in specific clinical settings. In our previous work we also used the NVS to assess health literacy among pharmacy visitors.<sup>4</sup> The NVS consists of nutrition label from an ice-cream container with six questions about the information on the label. We found that the NVS was suitable to assess reading and numeracy skills (basic functional health literacy), but other skills, communicative and critical skills, also important for correct medication use were not measured. Also, the patients in our study were confused about the questions about a food label in the context of the pharmacy setting. Therefore, we concluded that for the context of medication use and to gain insight in all necessary skills, it is relevant to also gain insight in other skills such as asking questions and addressing concerns. Thus an instrument that assessed pharmaceutical literacy, such as the RALPH interview guide was needed. The information about the patient's pharmaceutical literacy level can be used to provide tailored care and improve comprehension of medication information and use.<sup>21,22</sup> There are different implications for use of the RALPH interview guide in daily pharmacy practice. The interview guide can, for example, be used at the pharmacy counter during refill encounters to assess if patients have understood information about a new medicine or the provided instructions, especially for medicines with a difficult application method (e.g. an inhaler). In addition, pharmacy staff can use the

RALPH guide, the total questionnaire or subsets of questions, to assess pharmaceutical literacy in patients for whom they expect limited pharmaceutical literacy.<sup>10</sup> As described in the paper of Vervloet et al.,<sup>11</sup> during the development phase of the RALPH interview guide we also assessed patients' experience and they were in general positive about the RALPH interview and did not mention to feel "tested". This is in line with a study of Ryan et al.<sup>23</sup> in which 98% of the patients agreed with health literacy assessment in clinical practice. Also pharmacists were positive about use of the RALPH guide during patient encounters. An advantage of the RALPH interview guide is the nature of the questions which can be easily incorporated in patient counseling as they relate to the patient's own medication use, in contrast to general health literacy instruments such as the NVS or TOFHLA.<sup>24</sup>

#### **4.1. Strengths and limitations**

The large sample size and inclusion of patients in different pharmacies across the Netherlands is a major strength of the study as it increases generalizability of the findings. Different students and pharmacist trainees conducted the interviews in these pharmacies. Before start of the data collection period, we provided them with clear instructions and we used a structured (including both RALPH and FCCHL) interview

guide during data collection, thus we believe this has not influenced the quality of the collected data. All questionnaires were verbally administered which also enabled inclusion of patients with limited reading and writing skills (low level of functional skills). This decreased the risk of selection bias.

The RALPH interview guide was developed as a practice-based tool for pharmacists and will in future use, also be used by many different pharmacists. The questions are phrased in such a way that they can also be used by other health care professionals, e.g. general practitioners or nurses, to assess pharmaceutical literacy.

## 5. CONCLUSION

In the pharmacy setting, patients experienced mainly difficulties with more complex skills, such as interpretation of warnings or precautions when using a specific medicine, finding and assessing medication information. Whereas the FCCHL questionnaire is useful to assess general health literacy, the practice-based RALPH interview guide provides insight in the specific level of pharmaceutical literacy and is therefore likely to be more suitable for use in a medication specific context such as community pharmacy. This information can be used to tailor the information strategy about medicines, by providing patients with question prompt sheets or using teach back methods.

### Conflicts of interest

This study was financed by a research grant from the Royal Dutch Pharmacists Association (KNMP).

The authors report no conflicts of interest related to this study.

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### Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.sapharm.2018.01.009>.

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## TABLES

Table 1  
Questionnaire topics RALPH interview guide.

Health literacy domain	Description of question
Functional 3 questions on patients' understanding of use instructions of their own medication	- indication for use - instruction for use - understanding of precaution or warning (if applicable)
Communicative 3 questions about communication about medication (information)	- asking questions - expressing concerns - finding understandable information
Critical 4 questions about analyzing medication information	- judging reliability of (medication) information encountered in the media or elsewhere - judging applicability of this information - engagement in shared decision making - handling contradictory information

Table 2  
Study population characteristics.

	Total population (N = 508)
Male gender, % (n)	43.9 (223)
Age, mean (SD)	67.6 (15.2)
Educational level <sup>a</sup>	
No formal education/low	40.6 (206)
Middle	34.8 (177)
High	20.1 (102)
Other	4.5 (23)
Native origin, n (%)	91.0 (435)

<sup>a</sup> No or low educational level was defined as no secondary education (only primary school) or lower vocational. Middle was defined as intermediate vocational or higher secondary education, and high educational level was defined as higher vocational or university.

**Table 3A**  
Mean FCCHL functional domain scores for RALPH functional domain questions.

RALPH question		% (n)	FCCHL score, mean (SD)	P-value
Indication for use	Correct	85.4 (434)	2.0 (0.8)	< .001
	Incorrect	14.6 (74)	2.4 (0.8)	
Frequency of medication use <sup>a</sup>	Correct	95.9 (487)	2.1 (0.8)	< .001
	Incorrect	4.1 (21)	2.9 (0.9)	
Timing of medication use <sup>a</sup>	Correct	91.3 (464)	2.0 (0.8)	.001
	Incorrect	8.6 (44)	2.5 (0.9)	
Understanding of warning or specific instruction for use	Correct	74.7 (242)	2.0 (0.8)	.002
	Incorrect	25.3 (82)	2.3 (0.8)	

<sup>a</sup> In the final RALPH interview guide question 2 and 3 are combined [Vervloet, 2017].

**Table 3B**  
Health literacy based on FCCHL classification for RALPH functional domain questions.

RALPH question		FCCHL – functional skills	
		Adequate health literacy	Limited health literacy
Indication for use	Correct	263	171
	Incorrect	25	49
	% agreement		61.4
Frequency of medication use	Correct	284	203
	Incorrect	4	17
	% agreement		59.3
Timing of medication use	Correct	273	191
	Incorrect	15	29
	% agreement		59.4
Understanding of warning or specific instruction for use <sup>a</sup>	Correct	153	89
	Incorrect	32	50
	% agreement		62.7

<sup>a</sup> Not applicable for all patients (n = 324).

**Table 4**  
Mean FCCHL communicative domain scores for RALPH communicative domain questions.

RALPH question		% (n)	FCCHL score, mean (SD)	P-value
Asking questions	Easy	90.9 (462)	2.2 (0.8)	< .001
	Difficult	9.0 (46)	2.9 (0.7)	
Addressing concerns	Easy	87.8 (446)	2.2 (0.8)	< .001
	Difficult	12.2 (62)	2.8 (0.8)	
Finding information	Easy	60.6 (308)	2.0 (0.7)	< .001
	Difficult	39.3 (200)	2.8 (0.6)	

RALPH question	FCCHL – communicative skills		
		Adequate health literacy	Limited health literacy
Asking questions	Easy	199	160
	Difficult	8	28
	<b>% agreement</b>		<b>57.5</b>
Addressing concerns	Easy	196	149
	Difficult	11	39
	<b>% agreement</b>		<b>59.5</b>
Finding information	Easy	175	90
	Difficult	30	98
	<b>% agreement</b>		<b>69.1</b>

**Table 5**  
Mean FCCHL critical domain scores for RALPH critical domain questions.

RALPH question		% (n)	FCCHL score, mean (SD)	P-value
Contradicting information	Searching information in reliable source	70.1 (356)	2.4 (0.9)	.87
	Searching in non-reliable source	29.9 (152)	2.4 (0.9)	
Assessing information applicability	Easy	50.0 (254)	2.1 (0.8)	< .001
	Difficult	50.0 (254)	2.9 (0.8)	
Assessing information reliability	Easy	36.0 (183)	2.1 (0.8)	< .001
	Difficult	64.0 (325)	2.9 (0.8)	
Shared decision making	Easy	64.7 (329)	1.8 (0.6)	< .001
	Difficult	35.3 (179)	2.9 (0.7)	

  

RALPH question	FCCHL – critical skills		
		Adequate health literacy	Limited health literacy
Contradicting information	Searching for information in reliable source	138	163
	Searching in non-reliable source	41	60
	<b>% agreement</b>		<b>49.3</b>
Assessing information applicability	Easy	139	88
	Difficult	18	96
	<b>% agreement</b>		<b>68.9</b>
Assessing information reliability	Easy	124	40
	Difficult	33	152
	<b>% agreement</b>		<b>79.1</b>
Shared decision making	Easy	149	128
	Difficult	14	58
	<b>% agreement</b>		<b>59.2</b>