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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 ( $\sim$ 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.

#### 1. 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-

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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. 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). 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. 5,13

#### 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.

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