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# Psychometric Properties of a German Version of the "Satisfaction with Information about Medicines Scale" (SIMS-D)

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#### ABSTRACT

Objective: The aim of this study was to translate the Satisfaction with Information about Medicines Scale (SIMS) into German and test its psychometric properties in a German primary care setting. The SIMS was developed to assess the extent to which patients feel they have received enough information about their medicines.

Methods: Three hundred seventy chronically ill patients were included in the study. The SIMS was translated to SIMS-D (German version) and evaluated in terms of acceptability, internal consistency, test–retest reliability, discriminant, and criterion-related validity.

**Results:** The SIMS-D showed good internal consistency (Cronbach's  $\alpha$  0.92) and adequate test–retest reliability (Pearson's r > 0.7). Relationships

to external criteria regarding medication management were acceptable (Spearman's  $\rho > 0.4$ ). The SIMS-D was reasonably well accepted (return rate of 71%); however, older people produced more missing values when filling in the questionnaire.

Conclusions: Preliminary evidence was given that the SIMS-D is a suitable instrument for measuring patient satisfaction with information about medicines in German primary care settings.

Keywords: medicines information, patient satisfaction, psychometric properties, questionnaire.

## Introduction

Information on medication plays an important role in the reliable and correct usage of prescribed medications and thus in the successful treatment of diseases [1], but low adherence is a ubiquitous problem with adherence rates of only about 50% for chronic medications [2]. Patient satisfaction is a multifaceted construct [3] that, among many other factors, directly influences adherence [4]. It appears to be important that the information given meets the patient's individual needs to improve patient satisfaction [1]. Nevertheless, essential issues from a physician's point of view do not necessarily correspond to what an individual patient requires to make an informed choice about the treatment and to be able to use the medication to best effect. Because information needs and preference vary between individuals, the final arbiter on the quality of information is the individual patient [5].

The "Satisfaction with Information about Medicines Scale" (SIMS) is a questionnaire developed to measure the patients' satisfaction with information provided by caregivers (SIMS and SIMS-D [German version], copyright of Robert Horne, University of London). It is a method of eliciting patients' views on medication information rather than defining the absolute quantity or quality of the information obtained. The SIMS therefore identifies unmet medicine information needs from the perspective of the individual patient [5]. The SIMS has been used in several studies with chronically ill patients to assess patient satisfaction

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with information on medicines [6–9]. So far, a German version of the SIMS has not been available. The aim of our study is to examine psychometric properties of a translated and culturally adapted version of the SIMS-D.

#### **Methods**

# Subjects

The questionnaire was sent to 370 chronically ill patients participating in a project aiming to harmonize medication communication between different health-care sectors. Inclusion criteria for patients were long-term medication for a chronic disease, participation in a disease management program, and expected hospitalization in the medium-term. On enrollment in the project, patients agreed on participating in a patient survey that had been approved by the Ethics Committee of the Medical Faculty of the University of Heidelberg. The questionnaire was sent to patients once their medication had undergone a quality check, consisting of an Internet-based knowledge database (AiD-*Praxis* http://www.aidpraxis.de) checking medication interactions, and a medication consultation with their GP (general practitioner).

#### Measures

The following measures were used and filled in by the patient: the SIMS-D and the "Medication Adherence Report Scale" (MARS-D, German version). The MARS is an instrument that showed good internal consistency in the original UK sample (Cronbach's  $\alpha$  0.67–0.90) in asthma, diabetes, and hypertension patient groups, and good test–retest reliability (Pearson's r=0.97) [10]. Three questions regarding medication management in the

patient's general practice were added because organizational factors are often related to patient satisfaction [4] as well as data on the patient's sociodemographic data: age, sex, education, self-reported diseases, and self-reported number of medicines.

SIMS. The SIMS is composed of 17 items derived from the recommendations of the Association of the British Pharmaceutical Industry. These specify the type of information that patients need for safe and accurate self-management of medication. Patients are asked to rate the medicine information they have received on a 5-point scale: "too much," "about right," "too little," "none received," and "none needed." The SIMS was translated into German (SIMS-D) according to the guidelines for translation and cultural adaptation of patient-reported outcome measures [10,11], which has been published elsewhere [12]. Shuman's random mode method was used to ensure that items and response choices were well understood and were equivalent to the original [13].

Responses of the items of the SIMS-D were coded analog to the English version: "too much," "too little," and "none received" were coded 0; "about right" and "none needed" were coded 1. A total score of all items was calculated ranging from 0 to 17 for overall satisfaction with information received; higher scores indicated a higher degree of total satisfaction. Summing items 1 to 9 (subscale 1) identified satisfaction with information about "action and usage of medication" (scores ranging from 0 to 9); items 10 to 17 (subscale 2) identified satisfaction with information about "potential problems of medication" (scores ranging from 0 to 8).

MARS-D. Self-report of adherence to medication was assessed using five questions with response alternatives that captured various dimensions of nonadherence ranging from "always" (scored 1) to "never" (scored 5). Scores ranging from 5 to 25 were calculated; higher scores indicated higher adherence.

Medication management. Medication management was assessed by asking if the patient had received a prescription medication plan from his or her physician (yes/no), if the physician usually inquired about further medication being taken, and if he or she asked whether the medication prescribed was being tolerated, using five response alternatives ranging from "always" to" never."

# Statistical Analysis

The software SPSS (version 15.0) (SPSS Inc., Chicago, IL) was used for statistical analyses. Because of skewed data distribution, nonparametric tests were performed for all correlations except for test–retest reliability to allow comparison with the original data.

Item descriptive. Descriptive analyses were performed to assess the frequencies for each item; mean, median, and standard deviation were calculated for the scores; ceiling and floor effects were explored. Acceptability and handling of the instrument were judged by the response rate and by evaluating questionnaires with missing items. Significant differences in sociodemographic data between patients sending back complete and incomplete questionnaires as well as differences in responders and nonresponders were analyzed using chi-square test and Mann–Whitney U test.

*Reliability.* Cronbach's α was used to estimate internal consistency at baseline to allow comparison with original data (results

of the original data set are demonstrated in Table 2). Interitem correlation was assessed by computing bivariate correlations using Spearman's p.

Test-retest reliability was assessed using a prospective follow-up sample computing Pearson's correlation coefficient r. The SIMS-D was sent to the first 50 patients to send back their questionnaire. This occurred 4 weeks after the initial round, requesting help for quality assurance of the instrument. One question was added at the end of the questionnaire asking if medication counseling by a physician or physician assistant had taken place since completing the last questionnaire. This procedure produced two groups. Group A was composed of patients who had not experienced counseling. These were included for test-retest. Group B was composed of patients who had a counseling session in between the first and the second measurement. Assuming that medication counseling has an impact on patient satisfaction with information on medicines and thus on the stability of the instrument, group B was excluded for test-retest but used in a second step to demonstrate discriminant validity. Discriminant validity was assessed by describing the difference in mean scores ( $\Delta$ ) between the first and the second measurement in patients with and without counseling. Because of the small sample size, no significance testing was performed.

*Validity.* Spearman's correlation coefficient  $\rho$  between subscale 2 ("potential problems of medication") and two questions regarding medication management in the practice was computed for criterion-related validity. Analog to the English validation process, correlation between MARS-D, and SIMS-D scores were computed to investigate the relationship between satisfaction with information and self-reported adherence using Spearman's  $\rho$  (original study  $\rho = 0.31$ , P < 0.05).

#### Results

In total, 264 of the 370 administered questionnaires were returned (71%). Excluding questionnaires with missing data, 212 questionnaires with complete SIMS-D (57%) could be analyzed. Table 1 displays characteristics of the study sample. Demonstration of item frequencies can be found at http://www.ispor.org/Publications/value/ViHsupplementary/ViH12i8\_Mahler.asp.

# Acceptability and Handling of the Instrument

There was no difference between responders and nonresponders regarding age (Mann–Whitney U test: Z = -0.22; P = 0.83) and sex (chi-square(1) = 0.52; P = 0.47). Patients who left out items (n = 52) were significantly older than patients who completed the whole questionnaire (n = 212) (mean = 72.7 years vs. mean = 68.3 years; Z = -2.42; P = 0.01). No significant difference was detected among other sociodemographic factors: sex (chi-square(1) = 0.46; P = 0.50), mother tongue (chi-square(1) = 2.31; P = 0.13), number of diseases (Z = -1.80; P = 0.07), or number of medicines (Z = -0.56; Z = -0.58).

The descriptive values of the scores obtained are displayed in Table 2. Substantial ceiling effects are demonstrated in all scores showing highest satisfaction in nearly 40% on the "action and usage" subscale. Considerable floor effects occurred on the subscale "potential problems of medication" (13.2%).

# Internal Consistency and Test-Retest Reliability

At baseline, the internal consistency for the whole SIMS-D and subscales 1 and 2 showed values of 0.92, 0.87 and 0.90, respectively. Interitem correlations were acceptable (Table 2).

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**Table I** Baseline characteristics of patients (n = 264)

Age (in years)	
Mean	69.1
Median	70
Minimum	19
Maximum	98
Sex (%)	
Male	52.1
Female	47.9
Mother tongue (%)	
German	81.4
Other languages	18.6
Educational level (%)	
9 years	77.0
10 years	1.3
Number of diseases (patient self-report)	
Mean	3.6
Median	3
Minimum	1
Maximum	8
Hypertension (%)	70.3
Musculoskeletal diseases (%)	62.5
Diabetes type 2 (%)	54.1
Cardiac insufficiency (%)	31.7
Number of medicines (patient self-report) (%)	
I-3	24
4–7	45
8–10	18
> 10	12

Forty questionnaires (80%) were returned in the retest sample, of which 30 (60%) were complete (including information about medication counseling in the meantime). Test–retest reliability of the SIMS-D in group A was adequate (Pearson's r > 0.7).

#### Assessing Criterion-Related Validity

The analysis of correlations between SIMS-D and additional questions regarding medication management revealed  $\rho\text{-values} > 0.43$  for subscale 2. These can be found in Table 2 at http://www.ispor.org/Publications/value/ViHsupplementary/ViH12i8\_Mahler.asp. The correlation between the MARS-D score and the SIMS-D total score showed a low value ( $\rho=0.26$ ) with statistical significance (P<0.01).

#### Discriminant Validity

For describing disciminant validity, the results of the two groups in the test–retest sample are shown: group A for test–retest patients who had not experienced counseling (n = 15) and group B for patients who had counseling (n = 15). Preliminary evidence can be assumed for discriminant validity because SIMS-D scores in group B improved after medication counseling. Supporting information can be found in Table 1 at http://www.ispor.org/Publications/value/ViHsupplementary/ViH12i8\_Mahler.asp. It

would be interesting to see whether the total score and subscales are sensitive to the training of GPs in medication counseling.

#### **Conclusions**

In general, the German version of the SIMS shows a reasonably high return rate, demonstrating the relevance of the issue; however, older people produce more missing values when filling in the questionnaire, which might have an impact on the results (nonresponder bias). The number of questionnaires without missing values in Horne's validation sample is notably higher [5]. The reasons may be patients' age—patients in our sample were older—and the fact that our questionnaire was a postal survey, so patients were not able to have their queries answered. In Horne's sample, the patients completed the questionnaire while waiting on the ward or outpatient clinic; understanding of the questionnaire and approval for participation were verified on the spot. An analysis of missing data in the SIMS-D should now be performed for further development of the instrument.

The psychometric properties of the German version are comparable with the original English version [5]. Our results suggest high internal consistency of the scale and give preliminary evidence for adequate test-retest reliability and discriminate validity (the test-retest sample was not large enough for a definitive conclusion). The overall high values in subscale 1 give evidence of the face validity of the SIMS-D because GPs mostly communicate information on usage of medication when counseling patients [14]. The correlation with questions regarding medication management in general practice also showed acceptable values [15]. These items may not appear to contribute significantly to the evaluation of criterion validity; however, they showed if physicians structure medication counseling, drawing attention to medication-related issues and information. The positive correlation between the SIMS-D and the MARS-D is marginal though statistically significant. A strong relationship between satisfaction with information about medicines and medication adherence, as Horne demonstrated, can therefore not be explained with our data. Cultural differences in reporting adherence may be responsible for these differences. We found substantial ceiling effects that are common in questionnaires assessing patient satisfaction with their physician [16] and have also been found in other studies applying the SIMS [8,9].

Our sample represents a typical population of chronically ill patients in Germany [17,18], although the generalizability of results may be somewhat limited because of the fact that a notable proportion of the sample was lost to nonresponse and incomplete questionnaires. Furthermore, the results may be biased by motivated physicians voluntarily taking part in the described project. Nevertheless, preliminary evidence is given that the SIMS-D measures patient satisfaction with information about medicines in this group of primary care patients.

Table 2 Descriptive statistics, score distributions (mean, range, median, SD, percentage of ceiling and floor effects), internal consistency, and interitem correlation of the SIMS-D (n = 212)

Satisfaction with	Mean (range)	Median	SD	Ceiling (%)	Floor (%)	Cronbach's $\alpha$ (original study)	Interitem correlation (Spearman's ρ)
information on "action and usage of medication" (subscale 1)	6.8 (0-9)	8	2.63	39.6	3.8	0.87 (0.67–0.87)	0.22-0.63
information on "potential problems of medication" (subscale 2)	4.5 (0–8)	5	3.01	28.8	13.2	0.90 (0.6–0.89)	0.42-0.76
total information received	11.3 (0–17)	12	5.14	25.0	2.8	0.92 (0.85-0.91)	0.13-0.76

Thus, within quality assurance, the SIMS-D could help target areas in need of improvement in routine care. These areas could be reaudited at a later point to verify refinement. In research settings, the SIMS-D could measure the impact of interventions to improve medication counseling. In clinical practice and all health-care settings where medication-related information is essential, the SIMS-D may help plan medication consultation, and identify and target individual information deficits of patients. It is hereby important to verify older patients' understanding of the questionnaire and willingness to participate.

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