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## Development and Validation of a Primary Care Medication Experience Scale for Patients with Chronic Diseases: Post-print

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### Abstract

**Background** Improving patients' medication experience is a key factor in enhancing medication adherence and a necessary condition for improving patient outcomes and medical safety. Currently, there is a lack of measurement tools for medication experience among chronic disease patients at the primary care level in China, which severely hinders research and practice in pharmaceutical services and management in primary healthcare institutions.

**Objective** This study aims to develop a primary care medication experience scale for chronic disease patients suitable for chronic disease management practice in China, and to conduct reliability and validity testing, in order to provide tool support for research and practice in health management of chronic disease patients.

**Methods** This study adopted a combined qualitative and quantitative approach for scale development. A preliminary item pool was constructed through literature analysis, and an initial primary care medication experience scale for chronic disease patients was developed through semi-structured interviews guided by perceived value theory. The Delphi expert consultation method was used to consult and validate the preliminary scale, followed by revisions and improvements. In October 2023, a field survey was conducted among chronic disease patients seeking care at primary healthcare institutions in Shandong Province using random sampling methods. The scale underwent linguistic and cultural adaptation, and its reliability and validity were tested. Further optimization and adjustments were made to the scale, resulting in the final primary care medication experience scale for chronic disease patients.

**Results** Through literature analysis, 14 medication experience-related dimensions were extracted, and through semi-structured interviews, a preliminary item pool containing 8 dimensions and 40 items was constructed. The Delphi expert consultation method was used to revise and improve the scale. The response rates for the two rounds were 95% and 100%, respectively, and the average expert authority coefficients were 0.86 and 0.88. The experts provided scientifically authoritative revision suggestions and opinions, resulting in a scale containing 7 dimensions and 29 items. Field survey results showed good reliability and validity. Critical ratio analysis of scale items showed all P-values  $< 0.05$ . Cronbach's  $\alpha$  coefficients for the total scale and each dimension were  $> 0.8$ , split-half reliability was  $> 0.7$ , and intraclass correlation coefficients (ICC) were  $> 0.8$ . Factor loadings for all items after rotation were  $> 0.5$ . Confirmatory factor analysis model fit indices were: chi-square/degrees of freedom ratio (CMIN/DF) = 1.485, goodness-of-fit index (GFI) = 0.902, root mean square error of approximation (RMSEA) = 0.039, root mean square residual (RMR) = 0.03, comparative fit index (CFI) = 0.981, normed fit index (NFI) = 0.945, incremental fit index (IFI) = 0.981. Composite reliability (CR) values were  $> 0.7$ , and average variance extracted (AVE) values were  $> 0.5$ . The final primary care medication experience scale for chronic disease patients included three primary dimensions (functional value, emotional value, social value), 7 secondary dimensions, and 28 measurement items.

**Conclusion** The primary care medication experience scale for chronic disease patients developed in this study demonstrates good reliability and validity, with strong local appropriateness, and can be used for investigating medication experience among chronic disease patients at the primary care level.

## Full Text

### Development of a Primary Medication Experience Scale for Patients with Chronic Disease and Its Reliability and Validity Testing

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## Abstract

**Background:** Improving patient medication experience is a key factor in enhancing medication adherence and is essential for improving patient outcomes and medical safety. Currently, China lacks measurement tools for assessing primary care medication experiences among chronic disease patients, which severely constrains research and practice in pharmaceutical services and management at primary healthcare institutions.

**Objective:** This study aimed to develop a Primary Medication Experience Scale for chronic disease patients applicable to China' s chronic disease management context and to test its reliability and validity, thereby providing instrumental support for research and practice in chronic disease patient health management.

**Methods:** This study employed a mixed-methods approach combining qualitative and quantitative techniques. An initial item pool was constructed through literature analysis, and a preliminary Primary Medication Experience Scale was developed through semi-structured interviews guided by perceived value theory. The Delphi expert consultation method was used to evaluate and refine the preliminary scale. In October 2023, on-site surveys were conducted using random sampling among chronic disease patients seeking care at primary healthcare institutions in Shandong Province. The scale underwent linguistic and cultural adaptation, followed by reliability and validity testing, with further optimization and adjustments to finalize the Primary Medication Experience Scale for chronic disease patients.

**Results:** Literature analysis identified 14 dimensions related to medication experience, while semi-structured interviews initially produced an 8-dimension, 40-item scale. Through Delphi consultation, the scale was revised and improved. Expert participation rates were 95% and 100% across two rounds, with mean authority coefficients of 0.86 and 0.88, respectively. Experts provided scientifically authoritative revision suggestions, resulting in a 7-dimension, 29-item scale. Field testing demonstrated satisfactory reliability and validity. Critical ratio analysis showed  $P < 0.05$  for all items. Cronbach' s  $\alpha$  coefficients exceeded 0.8 for the total scale and all dimensions, split-half reliabilities exceeded 0.7, and intraclass correlation coefficients (ICC) exceeded 0.8. Factor loadings after rotation were all  $> 0.5$ . Confirmatory factor analysis yielded the following fit indices:  $\chi^2/df$  (CMIN/DF)=1.485, goodness-of-fit index (GFI)=0.902,

root mean square error of approximation (RMSEA)=0.039, root mean square residual (RMR)=0.03, comparative fit index (CFI)=0.981, normed fit index (NFI)=0.945, and incremental fit index (IFI)=0.981. Construct reliability (CR) values exceeded 0.7, and average variance extracted (AVE) values exceeded 0.5. The final scale comprised three first-order dimensions (functional value, emotional value, social value), seven second-order dimensions, and 28 items.

**Conclusion:** The developed Primary Medication Experience Scale for chronic disease patients demonstrates good reliability and validity with strong local applicability, making it suitable for investigating primary care medication experiences among chronic disease patients in China.

**Keywords:** chronic disease; medication experience; patient experience; scale development

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## Background

Data show that in 2019, approximately 390 million Chinese residents aged 15 and above suffered from chronic diseases, including about 270 million with hypertension and 97 million with diabetes. In 2020, chronic diseases accounted for 88.5% of total deaths and nearly 70% of the total disease burden [1-3]. Chronic diseases impose heavy economic and psychological burdens on patients and families while representing a major public health issue affecting national socio-economic development [3]. Since the new healthcare reform, primary healthcare institutions have shouldered dual responsibilities for basic medical care and public health, becoming the main force in chronic disease prevention and control [4]. Primary medication experience refers to the sum total of all medication-related events that patients encounter when seeking care at community health service centers, township health centers, and village clinics. It encompasses patients' perceptions of benefits and burdens from pharmacotherapy, including effectiveness, adverse reactions, convenience, affordability, and guidance from healthcare providers [5-9]. Medication experience serves both as an outcome variable influenced by pharmaceutical policies and pharmacy services and as a precursor to medication adherence, significantly impacting disease outcomes and quality of life [10]. Therefore, developing scientifically reliable measurement tools for chronic disease patient medication experience is crucial for accurately assessing current experiences. Although numerous international studies have developed medication experience instruments for chronic disease patients, significant cultural differences limit their applicability to Chinese populations [11-13].

The concept of perceived value first appeared in Peter Drucker's *The Frontiers of Management*, which noted that consumers purchase not only products but also value components. Initially applied in consumer market research and practice (also termed customer perceived value or customer transaction value), perceived value theory has since expanded beyond consumer contexts. While definitions and applications vary, the theory generally measures value experi-

ences and individual perceptions through two or more dimensions [14-15]. This study developed a Primary Medication Experience Scale based on perceived value theory and grounded in China's primary healthcare practice for chronic disease management, aiming to inform pharmacy services and management at primary healthcare institutions.

## Methods

### 1.1.1 Literature-Based Identification of Scale Dimensions and Items

Using search terms including “chronic disease patients,” “medication experience,” “primary medication experience,” “chronic disease patient medication,” “patient medication experience,” and their English equivalents ( “Patients with chronic diseases,” “Medication Experience,” “chronic patients,” “experience with medication” ), we conducted literature searches across CNKI, Wanfang, VIP, Web of Science, PubMed, and Embase without time restrictions. After reviewing content and screening studies on medication experience measurement tools, we identified eight commonly used instruments: the Treatment Satisfaction Questionnaire for Medication (4 dimensions, 11 items) [16], Treatment Satisfaction with Medicines Questionnaire (6 dimensions, 17 items) [17], Patient Satisfaction with Medication Management Instrument (3 dimensions, 9 items) [18], Satisfaction with Information about Medicines Scale (2 dimensions, 17 items) [19], Living with Medicines Questionnaire (8 dimensions, 41 items) [20], Medication-Related Burden Quality of Life scale (5 dimensions, 31 items) [21], Patient-Reported Outcomes Measure of Pharmaceutical Therapy for Quality of Life (8 dimensions, 40 items) [22], and Experience of Patients with Chronic diseases (3 dimensions, 10 items) [23]. This review yielded 14 dimensions related to medication experience, including impact on daily life or functional role limitations, doctor-patient relationships and medication communication, effectiveness, medication-related behaviors and attitudes, side effects, practicality or difficulties, cost-related burden, patient self-management, convenience, healthcare service satisfaction, potential medication problems or safety, drug information or knowledge, psychological impact or burden of medications, and drug availability or accessibility.

### 1.1.2 Semi-Structured Interviews for Initial Item Pool Development

Semi-structured interviews were conducted with chronic disease patients of different conditions to deeply understand their primary care medication experiences and distill these into measurable items, enriching the preliminary item pool. Interview guides were developed based on prior literature analysis: (1) What is your current medication regimen? (2) How do you feel about your medications and why? (3) What problems have you encountered when obtaining medications at primary healthcare institutions, and what is the greatest difficulty? (4) Can primary healthcare providers influence your medication experience? (5) What suggestions do you have for improving your medication experience and why?

Two team members familiar with the content conducted interviews. Participants were numbered N1-N17, with informed consent obtained and interviews recorded. Recordings were transcribed and named according to participant numbers. Following the principle of information saturation [24], we recruited chronic disease patients from primary healthcare institutions. To ensure representativeness and information diversity, inclusion criteria were: (1) diverse basic characteristics, (2) medication experience with independent self-management ability, and (3) capacity to clearly articulate medication experiences. Exclusion criteria were: (1) severe conditions preventing cooperation, (2) unwillingness to participate, (3) hearing or intellectual impairments preventing independent interview completion, and (4) premature termination for other reasons. Seventeen patients meeting criteria were enrolled (see Appendix Table 1 ).

Interviews revealed that long-term medication users reported acceptable side effects despite strong drug dependence, often continuing medications despite known adverse effects and creating vicious cycles of additional treatments. Some respondents noted reduced drug efficacy with long-term use, affecting medication experience. Others mentioned difficulties swallowing or carrying medications. Patients expressed trust in primary healthcare providers but reported insufficient communication and guidance. Text coding identified six recurring themes: (1) side effects from long-term medication use, (2) drug resistance and variable efficacy despite symptom relief, (3) substantial economic burden, (4) inconvenience in obtaining or using medications, (5) impact on daily life and activities, and (6) insufficient medication guidance and lack of humanistic care from primary healthcare providers. These were organized into measurement dimensions to supplement and adjust the item pool (see Appendix Table 2 ).

Based on literature analysis and interview findings, combined with the actual conditions of chronic disease patients in China' s primary care settings, we constructed an item pool with eight dimensions and 40 items: medication convenience (9 items), affordability (5 items), safety (3 items), effectiveness (6 items), adequacy of medication guidance (4 items), humanistic aspects of medication guidance (5 items), impact of medication on life (3 items), and social impact of medication (4 items). Fifteen items were added based on interview findings, while 25 were adapted from international scales.

Perceived value refers to patients' and families' subjective evaluations comparing perceived quality with outcomes and costs throughout healthcare encounters [25], providing a structured, systematic perspective for measuring medication experience. Based on perceived value theory, we organized first-order dimensions into functional value, emotional value, and social value. Functional value satisfies functional needs in medication experience, including three second-order dimensions: effectiveness, safety, and affordability. Emotional value satisfies emotional needs, including convenience, adequacy of medication guidance, and humanistic aspects of guidance. Social value satisfies social identity needs, including impact of medication on life and social impact. Details are shown in Table 1 .

### 1.1.3 Delphi Expert Consultation for Scale Validation and Refinement

**Expert Selection Criteria:** (1) Inclusion: Primary care clinicians, pharmacy staff, health administrators, and scholars with experience in clinical medicine, general practice, health administration, or public health; bachelor's degree or higher. (2) Exclusion: Non-voluntary participants or those failing to respond within two weeks.

**Consultation Materials:** (1) Cover letter explaining scale development background, core concepts, initial dimensions and items, and consultation objectives. (2) Expert consultation questionnaire using a 5-point Likert scale to rate dimension and item importance and sensitivity, with higher scores indicating greater importance and sensitivity. Experts were also invited to provide revision suggestions with brief justifications. (3) Expert demographic survey including gender, age, occupation, position, education, professional title, specialty, years of experience, familiarity with the topic, and primary basis for judgment.

**Results:** (1) Nineteen experts participated across two consultation rounds (11 female [57.9%], 8 male [42.1%]; mean age  $43.11 \pm 1.67$  years). Six were clinical medicine specialists (31.6%  $\pm$  \$2.40 years, with two holding senior professional titles (10.5%), 11 associate senior titles (57.9%), and six intermediate titles (31.6%). First-round consultation distributed 20 questionnaires with 19 returned (95% response rate) and 100% valid completion. Second-round distributed 19 questionnaires with all 19 returned and valid. Both rounds exceeded 90% effective recovery, indicating strong expert engagement. (2) Expert authority coefficients averaged 0.86 in the first round and 0.88 in the second, both  $>0.80$ , demonstrating high credibility. (3) First-round importance scores for first-order dimensions ranged 3.947-4.895 and sensitivity scores 3.474-4.368. Second-order dimension importance scores ranged 3.736-4.894 and sensitivity 3.316-4.737. Item importance scores ranged 3.052-4.947 and sensitivity 2.894-4.894. Sixteen revision suggestions were collected, requiring modifications to five dimensions: effectiveness, convenience, adequacy of guidance, impact on life, and social impact. Based on feedback, nine items were deleted, two modified, one merged, and the life impact and social impact dimensions were combined into a single life impact dimension. (4) In the second round, first-order dimension importance scores ranged 4.368-4.947 and sensitivity 3.947-4.684. Second-order dimension importance ranged 4.421-4.947 and sensitivity 3.316-4.737. Item importance ranged 3.789-4.947 and sensitivity 3.158-4.737. With expert opinions converging, consultation concluded. The refined scale contained seven dimensions with 29 items: effectiveness (4 items), affordability (4 items), convenience (4 items), adequacy of guidance (4 items), humanistic aspects of guidance (4 items), safety (4 items), and impact of medication on life (5 items).

### 1.1.4 Linguistic Adaptation

Based on the refined scale, 30 chronic disease patients were randomly sampled from primary healthcare institutions in October 2023 for field testing (8-10

minutes per questionnaire). Linguistic adaptations were made to improve comprehension of academic wording. For example, Item 12 ( “I find it difficult to accept the properties of my medication” ) was revised to “I find it difficult to accept the taste, size, or texture of my medication,” Item 22 ( “My medication causes physical functional impairment” ) became “Medication causes physical dysfunction such as fatigue or weakness,” and Item 23 ( “My medication causes mental functional impairment” ) became “Medication causes mental dysfunction such as reduced thinking ability or judgment.” See Table 2 for details.

## 1.2 Reliability and Validity Testing

### 1.2.1 Study Participants

Using random sampling, we conducted field surveys at primary healthcare institutions in Shandong Province in October 2023. Inclusion criteria were: (1) chronic disease patients at primary healthcare institutions, (2) medication experience, and (3) clear cognition. Exclusion criteria were: (1) cognitive impairment and (2) refusal to cooperate. Following the principle of 5-10 participants per item [26] and considering potential invalid responses, 330 questionnaires were distributed, with 325 returned (98% response rate). After excluding 12 invalid questionnaires, 313 valid responses remained (96% valid response rate). The study was approved by the Shandong Second Medical University Medical Ethics Committee (2021YX-066).

### 1.2.2 Study Instrument

The research instrument was a self-developed questionnaire using a 5-point Likert scale. Part one collected demographic data (gender, age, residence, marital status, education, chronic conditions). Part two was the Primary Medication Experience Scale comprising the seven refined dimensions.

### 1.2.3 Survey Procedure and Quality Control

The survey team comprised faculty and students majoring in social medicine and health administration, trained by experienced experts before deployment. Questionnaires were primarily self-administered; when patients could not complete independently, interviewers used a question-and-answer format. Researchers explained survey purposes, requirements, and precautions. Anonymous surveys included informed consent forms, with on-site supervision to address questions and record issues. Completed questionnaires were screened for omissions, errors, and logical inconsistencies; those with <80% completion were excluded.

## 1.3 Statistical Analysis

SPSS 23.0 and AMOS 21.0 were used for statistical analysis. Normally distributed continuous data were expressed as  $(\bar{x}\pm s)$ . The critical ratio method was employed for item analysis [27]. (1) **Reliability testing:** Cronbach’ s

$\alpha$  coefficient assessed internal consistency, split-half reliability tested stability and consistency, and test-retest reliability was conducted on 20 randomly selected patients (approximately 6%) by the same investigator after completion, calculating intraclass correlation coefficients (ICC) for external consistency [28]. (2) **Validity testing:** Data were split into two parts. One part underwent exploratory factor analysis using principal axis factoring and oblique rotation in SPSS 23.0, with Kaiser-Meyer-Olkin (KMO) and Bartlett's sphericity tests guiding structural adjustments. The other part was used in AMOS 21.0 for confirmatory factor analysis based on exploratory results. Given correlations among dimensions, a first-order seven-factor model was constructed and adjusted using modification indices. Construct reliability (CR) and average variance extracted (AVE) assessed convergent validity, while discriminant validity was evaluated by comparing inter-dimension correlation coefficients with the square roots of AVE values [29-30].

## Results

### 2.1 Participant Characteristics

Among 313 participants, 190 were female (60.7%) and 123 male (39.3%). The vast majority (296, 94.6%) were over 50 years old, and most (297, 94.9%) resided in rural areas. Most were married (242, 77.3%), with 68 divorced or widowed (21.7%). Education levels were predominantly primary school or below (232, 74.1%), followed by junior high school (50, 16.0). Most were unemployed or without work (228, 72.8%), with 61 currently employed (19.5%).

### 2.2 Item Analysis

Critical ratio analysis of the 29 items showed  $P < 0.05$  for all, indicating good discriminability (see Appendix Table 3).

### 2.3 Reliability Analysis

The total scale Cronbach's  $\alpha$  coefficient was 0.818, with all dimension coefficients  $> 0.8$ , indicating good internal consistency. Split-half reliabilities exceeded 0.7 for the total scale and all dimensions, demonstrating good stability and consistency. ICC values exceeded 0.8 for the total scale and all dimensions (all  $P < 0.001$ ), indicating excellent external consistency (see Table 3).

### 2.4 Validity Analysis

**2.4.1 Structural Validity** Exploratory factor analysis using principal axis factoring and oblique rotation yielded  $KMO = 0.799$  and Bartlett's sphericity test  $P < 0.001$ , extracting seven factors consistent with the hypothesized structure and explaining 79.19% of total variance. However, the item "My medication negatively affects my diet (e.g., appetite loss, dietary restrictions)" in the life impact dimension had communality  $< 0.5$  and factor loadings  $< 0.6$  in both pattern

and structure matrices with cross-loadings, leading to its deletion. Re-analysis of the remaining 28 items yielded  $KMO=0.795$ , Bartlett' s  $P<0.001$ , seven factors explaining 80.195% of variance, with all items adequately representing their factors (see Appendix Tables 4-6 ).

Based on exploratory results showing inter-dimension correlations, modification indices suggested freeing error covariances e30-e31, e7-e8, e23-e24, and e30-e31. The adjusted model demonstrated excellent fit (see Figure 1 [Figure 1: see original paper] and Table 4 ).

**2.4.2 Convergent Validity** Convergent validity analysis of the final 7-dimension, 28-item scale showed all CR values  $>0.7$  and AVE values  $>0.5$ , indicating good convergent validity (see Table 5 ).

**2.4.3 Discriminant Validity** Results showed that the square root of AVE for each dimension exceeded its correlations with other dimensions, demonstrating good discriminant validity (see Table 6 ).

## 2.5 Final Scale Formation

Based on these findings, the final Primary Medication Experience Scale for chronic disease patients was established, comprising seven dimensions with 28 items: effectiveness (4 items), affordability (4 items), convenience (4 items), adequacy of medication guidance (4 items), humanistic aspects of medication guidance (4 items), safety (4 items), and impact of medication on life (4 items) (see Table 7 ).

## Discussion

### 3.1 Feasibility of the Primary Medication Experience Scale

This study developed the scale using mixed methods grounded in perceived value theory. Literature analysis and semi-structured interviews systematically identified relevant dimensions and items, while Delphi consultation provided scientific validation. Two rounds of expert consultation achieved good consensus, participation rates, and authority coefficients, ensuring scientific rigor. Field testing demonstrated excellent internal consistency, split-half reliability, and test-retest reliability, along with strong structural, convergent, and discriminant validity. The scale meets psychometric standards, combining theoretical foundations with practical applicability to China' s primary care context. The final 28-item scale requires 5-8 minutes to complete, facilitating authentic responses and ensuring practical feasibility.

### 3.2 Practical Value of the Scale

Compared with international instruments, this scale better assesses medication experiences of Chinese chronic disease patients in primary care settings. It

includes dimensions specific to China's context, such as adequacy and humanistic aspects of medication guidance, measuring provider-patient communication, guidance clarity, and follow-up care. The safety dimension was adapted to Chinese patients' experiences, measuring physical, emotional, and mental functional impacts. The life impact dimension was localized to measure effects on work, social relationships, family dynamics, and social activities, reflecting Chinese patients' lived experiences. These features provide culturally appropriate, easily understood tools for future research.

This study provides both theoretical tools and practical management approaches for primary pharmacy services, offering important implications for improving chronic disease patient experiences and management effectiveness. However, limitations exist: literature review and qualitative research were relatively simple and fragmented, and expert consultation had constraints. The scale requires further validation. The literature search was limited to keywords without formal search strategies, potentially yielding fragmented results. Expert scoring rationales were not collected, introducing potential subjectivity. Qualitative research was limited to Shandong Province, raising questions about nationwide applicability. Additionally, recall bias and social desirability may affect accuracy. Future research should expand sampling, conduct further qualitative and quantitative studies, and refine the scale through ongoing expert validation.

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