Preliminary Development of a Self-Assessment Scale for the Ability of Outpatients with Chronic Diseases to Participate in Medication Safety Based on the Delphi Method: Postprint

Authors: FENG Zhengwen, CHEN Xiaolei, LI Hui, ZHU Chenli, SHAO Shuang, DU Juan*

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Abstract

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FENG Zhengwen, CHEN Xiaolei, LI Hui, ZHU Chenli, SHAO Shuang, DU Juan*

School of General Practice and Continuing Education, Capital Medical University, Beijing 100069, China

Corresponding author: DU Juan, Professor; E-mail: cuckoo@ccmu.edu.cn

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Abstract

Background: Patient medication safety has become a global priority in healthcare, and patients play an important role in promoting their own medication safety. **Objective:** To develop a self-assessment scale for the ability of outpatients with chronic diseases to participate in medication safety based on the Delphi method and provide objective criteria for assessing and promoting their abilities to participate in medication safety. **Methods:** A literature review and semi-structured interviews were used to formulate the initial items of the scale. According to the study objectives, 28 experts from Beijing, Shanghai, Guangdong, Tianjin, Zhejiang, and Inner Mongolia participated in two rounds of correspondence using the Delphi method. Experts rated their familiarity and judgment basis of the dimensions, and the importance and feasibility of the items were rated using a five-point Likert scale. The first round of expert correspondence was conducted from September 30 to October 12, 2021, and the second round was conducted from November 5 to 15, 2021. Final items of the scale were determined through an expert panel discussion. The questionnaire recovery rate was calculated as a reflection of expert motivation; the degree of authority of the correspondence results was measured using the authority coefficient; the degree of coordination of expert opinions was evaluated using the coefficient of variation and Kendall' s W coordination coefficient. The arithmetic mean of importance and feasibility scores ≥ 3.5 and coefficient of variation < 0.25 were used as the initial reference for item selection, with final adjustments decided after thorough discussions among research team members and the expert panel combined with expert opinions. **Results:** In both rounds of correspondence, 28 questionnaires were sent out and 28 questionnaires were returned, with a positive coefficient of 100% and an expert authority coefficient of 0.877. The expert coordination coefficient Kendall' s W for the importance and feasibility of items in the second round increased compared to the first round. The mean importance scores of items in the two rounds ranged from 3.964 to 4.964 and 4.321 to 5.000, with coefficients of variation from 0.038 to 0.211 and 0 to 0.168, respectively. The mean feasibility scores ranged from 3.964 to 4.821 and 4.036 to 4.893, with coefficients of variation from 0.081 to 0.265 and 0.064 to 0.186, respectively. The final self-assessment scale was determined after two rounds of expert correspondence and an expert panel discussion, including four dimensions: medication knowledge, medication belief, participation in medication decision-making, and medication self-management, with 33 items. **Conclusion:** This study constructed a self-assessment scale containing four dimensions and 33 items that can assess the ability of outpatients with chronic diseases to participate in medication safety and provide a reference for developing appropriate measures to promote patient participation in the medication process and improve medication safety.

Keywords: Chronic diseases; Patient participation; Medication safety; Self-evaluation; Delphi technique

Introduction

The number of chronic disease patients in China is continuously increasing. According to statistics, there are currently 270 million hypertensive patients in China, and the number of patients with strokes and coronary heart disease each exceeds 10 million. Nearly 100 million people suffer from diabetes and chronic respiratory diseases [1]. Long-term medication treatment is an effective means to prevent complications of chronic diseases and reduce the risk of disease exacerbation. However, there is a risk of unsafe medication use among chronic disease patients. Most chronic disease patients will use medication at home for a long period after visiting a medical institution and obtaining medicine, especially after the implementation of long-term prescription policies that allow some patients to extend prescriptions to three months at a time. While this meets patients' medication needs and reduces the number of visits to medical institutions [2], it also increases hidden safety hazards during the medication period, reduces communication between patients and doctors, and makes it difficult for doctors to understand problems that exist in the patients' medication process in a timely manner [3-4]. Research shows that patients using cardiovascular and antidiabetic drugs are prone to adverse medication events, with about 50% of patients in community settings (home or care institutions) experiencing medication errors and 27% experiencing adverse drug reactions [5].

With the development of the "patient empowerment" concept, there is increasing emphasis on patient-centered care, tapping the potential of patients, and recognizing the importance of patient engagement [6]. Researchers worldwide advocate that patients should actively participate in the treatment process, develop and utilize knowledge and abilities, build confidence, and be able to participate in decisions and manage themselves, thereby controlling diseases and promoting health [7-9]. Patients play a significant role in ensuring their medication safety, and studies have shown that patients' active participation in the medication process can effectively reduce the occurrence of medication errors and improve medication safety [10]. The World Health Organization presented the third global patient safety challenge, "Medication Without Harm," in 2017, emphasizing empowering patients, family members, or caregivers to actively participate in treatment or decision-making, raise questions, identify medication errors, and manage medication to improve medication safety [11]. Therefore, it is necessary to empower patients, help them acquire medication knowledge, enhance medication beliefs, actively participate in medication decisions and self-management, fully play the role of patients, and reduce the occurrence of adverse medication events.

Understanding the level of chronic disease patients' involvement in medication safety is essential. Previous studies in China have mostly focused on assessing the ability of hospitalized patients to participate in medication safety, and there is a lack of assessment tools suitable for outpatient chronic disease patients [12-18]. This study uses the Delphi method to preliminarily compile a self-assessment scale for the ability of outpatient chronic disease patients to

participate in medication safety, providing a reference basis for formulating corresponding measures to promote patient participation in medication safety.

1 Materials and Methods

1.1 Selection of Experts

The typical number of experts consulted using the Delphi method ranges from 20 to 30 [19]. In accordance with the study' s objectives, 28 experts from Beijing, Shanghai, Guangdong, Tianjin, Zhejiang, and Inner Mongolia were invited for consultation.

Inclusion criteria for the experts: (1) Experts engaged in family medicine, pharmacy, or health care management in medical institutions or medical colleges; (2) Having at least 5 years of working experience; (3) Possessing intermediate or higher professional titles; (4) Having enthusiasm for this study and being willing to respond to the consultation questionnaire.

Exclusion criteria: Experts who cannot ensure continuous participation in several rounds of consultation during the study period.

1.2 Research Steps

1.2.1 Formation of the Research Group The group consisted of 6 members, including a professor of family medicine at a medical college, an associate professor of family medicine, and four graduate students specializing in family medicine. The professor and associate professor were responsible for the overall design of the research, selecting and contacting consulting experts, and chairing expert group meetings, while the graduate students were responsible for literature review, interviews, formulating and distributing expert consultation questionnaires, data organization and analysis, etc. All team members discussed the selection and supplement of the item pool and the revision of items after expert consultation.

1.2.2 Development of Delphi Expert Consultation Questionnaire This study reviewed literature related to patient empowerment, summarized and analyzed concepts and theories proposed by different scholars, extracted the core elements of patient empowerment according to the research purpose, and established four dimensions including medication knowledge, medication beliefs, participation in medication decisions, and medication self-management. Using search terms like patient participation, medication safety, and patient safety, literature on patients participating in medication safety domestically and internationally was retrieved from databases including CNKI, Wanfang, VIP, Pubmed, and Web of Science. The item pool was formed after discussion by the research team. The first draft of the self-assessment scale for outpatient chronic disease patients' capability to participate in medication safety was formed, consisting of 4 dimensions and 31 items. The expert consultation questionnaire,

which included research purposes and background, basic information of experts, item evaluation table, and the degree of expert authority, was developed based on the initial draft of the scale.

1.2.3 Expert Consultation The first round of expert consultation was conducted from September 30 to October 12, 2021. The consultation questionnaire was distributed to experts via email and WeChat. Experts were asked to score the familiarity of the 4 dimensions and judgment basis, and use the Likert 5-point scale to score the importance and feasibility of the items. Importance ranged from "very unimportant" to "very important," and feasibility from "very poor" to "very good," assigned values from 1 to 5. Experts were also encouraged to provide modification suggestions for disputed items. The first round of consultation results were collected and organized, and the research team held a meeting to discuss the addition, merging, deletion, or modification of items, forming the second round of consultation questionnaire. The second round of consultation was conducted from November 5 to 15, 2021. The consultation provided results and item modification explanations from the first round for reference. Experts were asked to score the items again and provide opinions on disputed items. After collecting and organizing the second round of consultation questionnaires, items were modified according to the experts' opinions. A panel meeting of experts who provided more suggestions during the two rounds of consultations was held. After detailed discussions and revisions of highly disputed items, the final items were determined when all 6 experts had no objections.

1.3 Quality Control

A comprehensive search for literature related to patients participating in medication safety was conducted at the initial stage of scale compilation. The interviews were conducted by trained members of the research team. Any disagreements in the analysis of interview results were resolved through discussion among all team members until a consensus was reached. During the Delphi expert consultation phase, experts were selected strictly according to the inclusion and exclusion criteria to ensure professionalism, authority, and enthusiasm. The collected questionnaires were carefully checked, and any issues were promptly communicated with the experts. Data accuracy was ensured by double-checking data entry.

1.4 Statistical Processing

Data were entered using Excel 2019 and analyzed using SPSS 26.0. The questionnaire recovery rate, reflecting the enthusiasm of the experts, was calculated. The demographic characteristics of the experts were described using frequency distribution. The degree of authority of the consultation results was measured by the authority coefficient (Cr), determined by the experts' familiarity (Cs) and judgment basis (Ca): Cr = (Cs + Ca)/2. The Cs was assigned values of: 0.9 = very familiar; 0.7 = somewhat familiar; 0.5 = neutral; 0.3 = not very familiar;

0.1 = not familiar at all. The Ca was assigned values based on theoretical analysis, practical experience, reference literature, and intuitive feelings. A Cr value ≥ 0.7 was considered acceptable. The coordination degree of expert opinions was evaluated using the coefficient of variation (CV) and Kendall' s W coordination coefficient. The arithmetic mean of importance and feasibility scores ≥ 3.5 and CV < 0.25 were used as preliminary references for item selection. The final item adjustment results were determined after full discussion among research team members and expert panel meetings, considering the experts' opinions.

2 Results

2.1 Basic Information of Experts and Their Enthusiasm

In both rounds of expert consultation, 28 questionnaires were distributed and all were returned, resulting in a 100% response rate. Among the participating experts, 26 were from medical institutions, including 24 family doctors and 2 clinical pharmacists; the remaining 2 were from higher medical institutions. The majority (89.3%, 25/28) specialized in family medicine, followed by pharmacy and health service management. 64.3% (18/28) held master' s degrees or higher, and 75.0% (21/28) possessed senior or higher professional titles. 96.4% (27/28) had over 10 years of work experience. The detailed information of the experts is shown in .

2.2 Authority of Experts

The results showed a Cs of 0.818, a Ca of 0.937, and a Cr of 0.877, as detailed in .

2.3 Coordination Degree of Expert Opinions

The smaller the coefficient of variation (CV), the more consistent the opinions of the experts. In the first round of consultation, the CV of the importance of all items was < 0.25, and the feasibility of two items had a CV ≥ 0.25. In the second round, both the importance and feasibility of all items showed a CV < 0.25. The coordination coefficient of expert opinions is represented by Kendall' s W value, with a range of 0-1; the larger the W value, the better the coordination. The coordination coefficients of item importance and feasibility in the two rounds are shown in .

2.4 Results of Expert Consultation and Panel Consultation

2.4.1 First Round of Consultation The first round showed that scores for item importance ranged from 3.964 to 4.964, with a CV of 0.038 to 0.211. Feasibility scores ranged from 3.964 to 4.821, with a CV of 0.081 to 0.265. The feasibility CV for two items, "awareness of precautions during medication (dietary restrictions, drug interactions, etc.)" and "checking if the medication information matches the prescription when getting medication," exceeded 0.25,

being 0.265 and 0.253, respectively, but were retained after discussion by the research team. Adjustments to items were made based on expert feedback, with 5 items merged, 7 added, 4 deleted, and 8 modified, as shown in . This resulted in 31 items across 4 dimensions for the second round of evaluation.

2.4.2 Second Round of Consultation The second round showed importance scores ranging from 4.321 to 5.000, with a CV of 0 to 0.168, and feasibility scores ranging from 4.036 to 4.893, with a CV of 0.064 to 0.186. According to expert opinions, one item was added: "I can increase, decrease, or change medication under the guidance of a doctor based on my condition." Several items were rephrased and some were merged into one comprehensive item, "actively informing the doctor of my health and medication status (current diseases and medication history, medication efficacy, past adverse reactions, allergy history, etc.)," detailed in .

2.4.3 Panel Consultation After two rounds of expert consultation, the research team believed that a panel consultation was necessary for further discussion on certain items. Six experts who had provided extensive suggestions during the consultation were invited for a panel consultation via Tencent Meeting. Under the coordination of the moderator, the scoring and revision of controversial items after the second round were introduced. The experts discussed the revisions, improved the descriptions of some items, and reached a consensus on the final modifications. The self-assessment scale for the ability of outpatient chronic disease patients to participate in medication safety was finalized, consisting of 4 dimensions and 33 items, as shown in .

This patient self-assessment scale uses the Likert 5-point scoring method. The options for the medication knowledge dimension included "completely unaware," "not very aware," "neutral," "somewhat aware," and "very aware." The options for medication belief dimension ranged from "strongly disagree" to "strongly agree." The options for participation in medication decision and medication self-management dimensions included "never," "occasionally," "sometimes," "often," and "always," scored from 1 to 5. Patients selected the corresponding option based on their actual situations; a higher score indicates stronger ability to participate in medication safety.

3 Discussion

Measurement tools for patient participation in medication safety both domestically and internationally typically encompass aspects like knowledge, attitude, willingness, self-efficacy, and behavior. However, most of these tools are limited in dimension or application scope and are not widely applicable for a comprehensive assessment of patient involvement in medication safety. In China, considerable research has been conducted on measurement tools for inpatients' participation in medication safety [12-15], yet some items are not applicable to outpatients with chronic diseases. Chronic disease patients play a crucial

role in ensuring their medication safety, but the extent and capability of their participation in the medication process remain unclear in China.

The scale developed in this study provides a basis for assessing the capability of outpatient chronic disease patients to participate in medication safety. Patients can enhance their understanding of medication safety participation through self-assessment, recognizing their role in promoting medication safety. Healthcare professionals can also identify existing issues in the patient' s medication process through assessment results, which can be referenced to develop intervention measures.

In this study, experts were selected considering their professional fields and work experience. Most of the chosen experts are from medical institutions, engaged in chronic disease treatment or patient medication management, and are familiar with chronic patients' participation in medication safety. Additionally, two experts from higher medical institutions engaged in scientific research are chronic disease patients themselves and provide opinions from a patient' s perspective, enhancing the reliability of the expert consultation. The effective recovery rate of questionnaires from the two rounds of expert consultation was 100%, and multiple experts proposed item modifications, indicating high enthusiasm. Cr > 0.7 is generally acceptable, and the average Cr of 0.877 in this study indicates trustworthy consultation results. The coordination coefficients of item importance and feasibility in the second round increased, and all CVs were < 0.25. The expert opinions were converging towards consensus after comprehensive consideration of coordination coefficients and CVs from both rounds.

The scale in this study is guided by patient empowerment theory, references related literature on patient participation in medication safety both domestically and internationally, and considers the actual medication situation of outpatient chronic disease patients in China. It constructs a patient self-assessment scale comprising four dimensions: medication knowledge, medication belief, participation in medication decision-making, and medication self-management. Previous studies have shown that patients' lack of medication knowledge, especially regarding adverse drug reactions, correct medication timing, and storage methods, may lead to frequent medication errors or adverse events [20-23]. The medication knowledge dimension in this study is comprehensive, incorporating items like drug names, appearance, effects, usage, storage methods, side effects and adverse reactions, precautions, and handling of medication errors. Some experts also believed that it is essential for patients to understand simple handling methods when adverse drug reactions (such as hypoglycemia) occur during medication and that regular monitoring of drug treatment effect indicators could help patients understand changes in their conditions. Therefore, "methods to handle side effects or adverse reactions" and "drug treatment effect monitoring indicators" were included in the medication knowledge dimension.

Patients' medication beliefs significantly impact medication adherence. Some patients might adjust their medication regimens due to the lack of visible short-term effects or concerns over long-term adverse reactions, leading to poor disease

control or adverse medication events, subsequently increasing hospitalization and mortality rates [24-25]. Therefore, enhancing patients' medication beliefs is an effective measure to ensure their active cooperation in drug treatment and medication safety. In this study, the medication belief dimension encompasses patients' understanding of the importance of following medical advice, the effectiveness of drug treatment, the necessity of long-term medication for chronic diseases, and the pros and cons of medication, offering a comprehensive assessment of their beliefs regarding chronic disease medication.

The initial draft of the scale had rather simplistic content in the dimension of participation in medication decision-making, with only four items related to patients informing doctors about their medication status. Therefore, multiple experts provided feedback on this section. Aligning with concepts related to shared decision-making [26], it was clarified that the participation of outpatient chronic disease patients in medication decisions includes informing doctors about their health and medication status, expressing their concerns, medication needs, and preferences, weighing the pros and cons of various medication plans, and reaching consensus with doctors.

For chronic disease patients, who often take medication at home for extended periods, self-management ability is particularly crucial to promote medication adherence, ensure medication safety, and improve health outcomes [27]. Besides adhering to medical advice, this study incorporated drug checking, storage, efficacy monitoring, and adverse event handling abilities into the medication self-management dimension to highlight patients' role in preventing adverse medication events. Moreover, patients can also utilize auxiliary measures like labeling, using partitioned medicine boxes, or seeking help from family members for medication management. In the first round of consultation, the feasibility CV for "checking if the medication information matches the prescription when getting medication" was > 0.25. After considering expert opinions and interview results, it was decided to retain this item as most patients check the name and quantity of drugs after obtaining them from the pharmacy.

Through literature research, semi-structured interviews, Delphi expert consultation, and expert panel consultations, this study preliminarily compiled a self-assessment scale for outpatient chronic disease patients' ability to participate in medication safety. It can comprehensively assess patients' ability to participate in medication safety from four dimensions, identify existing deficiencies and obstacles, and provide references for developing corresponding intervention measures to enhance patient participation and improve the safety of chronic disease medication. This study only conducted qualitative evaluations of the scale items through Delphi expert consultation, so there are certain limitations. The next step will involve evaluating the scale' s performance through reliability and validity tests.

Author Contributions: Feng Zhengwen and Du Juan identified the primary research objectives, were responsible for the conception and design of the study, conducted the research, and wrote the paper. Feng Zhengwen, Chen Xiaolei, Li

Hui, and Zhu Chenli were involved in data collection, organization, and statistical processing. Shao Shuang and Du Juan revised the manuscript. Du Juan ensured quality control and review of the article, taking overall responsibility and supervision management.

Conflicts of Interest: There are no conflicts of interest associated with this article.

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Note: Figure translations are in progress. See original paper for figures.