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Developing the First Validity of Shared Medical Decision-Making Questionnaire in Taiwan

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Abstract

Due to a lack of valid Taiwanese instruments measuring Shared Medical Decision-making (SMDM) in Taiwan. The purpose of the study is to investigate the reliability and validity of the Shared Medical Decision-making process. Total 350 patients were randomly recruited from a medical centre in Taiwan. As a theoretical basis steps of the SMDM process were defined in an expert panel. Item formulation was then conducted according to the Delphi method and a pool of 16 items was constructed. In addition, the Winstep software was used to examine whether the data fit Rasch test model. Items with outfit or infit MNSQs (mean square errors) not in the range between 0.77 and 1.30 are usually deemed as potential misfits. Successive Rasch analyses were performed until a final set of items was obtained. After eliminating 1 item the remaining 15 form a unidimensional scale with an acceptable reliability for person measures 0.77 and very good reliability for item difficulties 0.97. Analysis of subgroups revealed a different use of items in different conditions. Taiwanese Shared Medical Decision-making Questionnaire (SMDMQ) is a 15 items normative instrument. In addition, a theory-driven instrument to measure the process of SMDM has been developed and validated by use of a rigorous method revealing first promising results. Yet the ceiling effects require the addition of more discriminating items, and the different use of items in different conditions demands an in depth analysis.

Index terms— shared medical decision-making, rasch test model, reliability, validity.

1 Introduction

vidence based patient choice seems based on a strong liberal individualist interpretation of patient autonomy. As the medical information widespread, many patients expressed their opinion and expect to participate in medical decision-making. According to the literatures review [1,2,3,4], the first definition of this concept can be found in a report on making health care decisions by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Published in 1982 it describes SMDM as a process which is based on mutual respect and partnership [5]. According to Charles et al., SMDM implies that at least two individuals are involved in the process of making a treatment decision [6]. In the commission on the page 38 that clearly declares: "the physician or other health professional invites the patient to participate in a Author: School of Medical Informatics, Chung Shan Medical University, and Information Technology Office of Chung Shan Medical University Hospital 110, Sec. 1, Chien-Kuo N. Rd., Taichung, Taiwan. e-mail: changintw@gmail.com dialogue in which the professional seeks to help the patient understand the medical situation and available courses of action, and the patient conveys his or her concerns and wishes". Also on page 44 describe in more detail "Sheared medical decision-making do not attempt to reach the satisfaction of patient, but to improve participate in this process, patients must engage in a dialogue with the practitioner and make their views on well-being clear". In the provision of preventive medical services, AHRQ more actively set up a "prevention into the medical services

group" (Put Prevention Into Practice, PPIP) and the U.S. public and private medical institutions, and require health care providers to provide clinical services such as health screening, vaccination, medical consultation and other services specific practice, this is a government-related agencies to promote patient-centered "shared medical decision-making model".

Furthermore, the U.S. government [7] is sworn by the Federal Court for the "patient informed consent", "patient autonomy" and to emphasize the patient "right to know". In other words, the patient's point of view there are two requirements must be met: The first, "know and understand" the needs (i.e. know where the problem lies and causes pain).The second is the "feel that they are aware and understand" the needs (i.e. if that physicians accept him, and treat him very seriously). In order to satisfied the needs of physicians and patients need that information gathering and exchange between physicians and patients. The resulting instruments of this search measure different aspects of SMDM such as patients' preferences for information and participation, decisional conflict, doctor facilitation of participation and patients' information seeking behavior as well as risk communication and confidence in decision-making, and satisfaction with decision-making.

In the present study, this trend reflects the more researchers participate in this topic. The related clinical practice studies were: Cassileth et al. [8] survey of 256 of a university hospital cancer patients and found that the proportion of patients to participate in decision (Overall: 62.5%, Aged 20-39: 87%, Aged 40-59: 62%, Aged 60 or more: 51%). Strull et al. [9] investigated three different clinics in 210 hypertensive patients in the decision-making role to play: doctors accounted for 78% of key decision makers, decision-making to share 19% of patients, the main decision-makers 3%. Pendleton and House [10] survey of 47 slum outpatients with diabetes, including shared decision-making points about the distribution: the average score of 3.9 (range 0-16; the higher score present the better representative of information and the higher the participation). Deber et al. [11] investigated 300 patients received angiography, the results-oriented problem solving response is the average score of 1.8, the average score in decisionmaking oriented was 3.1 (entirely up by the patient got 1 point, entirely up by the physician got 5 points).Mazur and Hickam [12] University Hospital sampling 467 general outpatients and to investigate the "Who do you like to make a decision?", Was found willing to share decision-making accounted for 68.1%, 21.4% the proportion of doctors, patients share ratio of 10.5%. Charles et al. [6] the literature review for the past authoritarian model, joint decision-making model, patients with different patterns, and further development of medical decision-making model.

The aim of this paper is to assess the validity of these concerns. There have been no previous studies about the SMDM from patients' perspective conducted in Taiwan. Therefore, there is need for psychometrically sound, valid and reliable instruments.

2 II.

3 Methodology

In order to ensure that the scale has good reliability and validity, we based on Churchill [13] on the steps of the scale development. The relative steps were: Definite that patient participation in shared medical decision-making; i. Specify and establish the dimensions of patient participation in shared medical decision-making; ii.

Generate a sample of items and assess validity; iii.

Pre-testing and analyze the result? iv.

Correct the pre-testing scale and establish the official scale; v.

Testing and analyze the result; vi.

Use the Rasch analysis to examine the scale;

vii.

Use the Rasch analysis to establish the formal scale; viii.

Assess validity and reliability. This study based on the four components, there were: i. Patient Autonomy: the rights of individuals to act and make decisions without external constraints; ii. Control preference: the degree of control an individual wants to assume when decisions are being made about medical treatment; iii. Patients' perceived involvement: patients' involvement scale to measure the degree to which individuals perceive that their physicians encourage their involvement in their own healthcare; iv. Risk information communication: open two-way exchange of information and opinion about risk. In order to verify the proposed scale system, we invited 12 experts to examine the content validity and relevance. Further, we integrated all of the opinions and amended repeatedly. Also, we made each item easy to the items. Further, this study will use the Rasch model to analyse the performance of proposed questionnaire by expert panel. Waugh and Chapman [10] has argued that the calculation of scores using the Rasch test model makes it possible to increase the homogeneity of the scales across years and over occasions so that scoring bias can be minimized.

The data were collected between November 2012 and November 2013. All patients were referred to us by their physicians from a medical centre in Taiwan. The physicians explained the study purpose to their patients before referring them to the interviewers. This study was approved by the IRB boards at Chung Shan Medical University Hospital. A trained research nurse interviewed patients in person after their routine consultation. The Winsteps software [15] was used to investigate dimensionality and differential item functioning (DIF) [16]. In general, there are two kinds of item fit statistics, unweighted outfit and weighted infit mean square errors (MNSQs), to examine whether items met the Rasch model's unidimensional requirement. The outfit MNSQs directly squares

and averages standardized residuals, while the infit MNSQs averages standardized residuals with weights [17]. The MNSQs statistics are Chi-square statistics divided by their degrees of freedom. The outfit and infit MNSQs statistics have an expected value of unity when the data meet the model's unidimensional expectation [18]. Two major assumptions must hold to yield interval measures: i. for the assumption of unidimensionality, all items must measure patient's positive changes; a value of MNSQs greater than 1.30 indicates too much noise; ii. for the assumption of conditional (local) independence, item responses must be mutually independent, conditional on the respondent's latent ability. A value of MNSQs less than 0.77 suggests too much redundancy. For rating scales, a MNSQs range of 0.77-1.30 is often recommended as the critical range for the MNSQs statistics [19]. Items with an outfit or infit MNSQs beyond this range are regarded as poor fitting. It has been argued that the Rasch test model is superior to factor analysis in terms of confirming a factor structure [14]. When poor-fitting items are identified and removed from the test, unidimensionality is guaranteed and it can be measured at an interval scale [17]. Evidence of the restriction of range effect can be obtained from the Rasch test model by examining the item estimates. Apart from the examination of item fit statistics, the Rasch test model also permits the investigation of person statistics for fit to the Rasch test model. The item response pattern of those persons who exhibit large outfit mean square values should be carefully examined. If erratic behavior were detected, those persons should be excluded from the analyses for the calibration of the items on the Rasch test model [20]. Finally, calculated according to the measurement data subject and the far the range of values and to delete the item separation reliability in the detection of internal consistency.

4 III.

5 Results

A convenience sample of 350 patients recruited from Chung Shan medical university hospital in Taiwan. The average age of the subjects is 34.68 years old. There are 180 male (51.43%). Among them, 52.8% of the patients were married and 71.43% had passed higher education. A total of 350 valid samples out of the medical fields of General practice (N = 62), Surgery (N = 42), Psychosomatic (N = 36), Family Medicine (N = 44), Ophthalmology (N = 39), Urology (N = 43), Gynecology (N = 41), ENT (Ears, Nose, and Throat) (N = 43) (see Table 1). After completion the questionnaire of 16 questions from the deletion of the original 25 questions by experts. All 16 items were examined by infit and outfit statistics. We investigated whether the 15 items met the requirements of a single construct at a range of infit and outfit MNSQs within a range of 0.77-1.30 [21]. With an outfit of 1.54 item1 was regarded as not fitting the model and eliminated. The remaining items 2-16 all displayed acceptable to good item fit measures (0.82-1. 19). The remaining items were then subjected to further analysis according to the criteria of item fit. Table 2 shows the 16 items in the scale after Rasch analysis and their response fields as well as item fit measures, difficulties and the corresponding theoretical steps. In addition to examining the overall fit of each item, it is also interesting to investigate whether the individual items in this instrument function in the same way for different groups of patients. Winstep software, which is used in this study, has the capability to undertake the differential item functioning (DIF) analysis. In DIF analysis, the presence of item bias is checked and the significance of differences observed between different groups of patients is examined (e.g. medical fields in this study). All items ought to be DIF-free or at least DIF-trivial in order to obtain comparable measures. An investigation of varying subject's difficulties in subsamples revealed the largest differences between conditions. In order to compare different groups of respondents, the test construct must remain invariant across groups. DIF analysis is a way of verifying construct equivalence over groups. If construct equivalence does not hold over all of the groups, meaning that different groups respond to individual items differently after holding their latent trait levels constant, then the estimated measures cannot be compared directly among the groups. The medical fields were tested for DIF in this study, including General practice, Surgery, Psychosomatic, Family Medicine, Ophthalmology, Urology, Gynecology and ENT (Ears, Nose, and Throat). A difference larger than 0.5 logits (equal to an odds ratio of 1.65) in the difficulty estimates between any groups was treated as a substantial DIF [22,23,24,25,26,27]. Once found, DIF items were removed from further analysis.

With reference to Figure **??**, it shows item difficulties for each condition and the average difficulty for the whole sample for each of 16 items of the scale. Especially items 3, 6, 9 and 15 disperse highly with a maximum range of 1.36 logits. The largest deviations from mean item difficulties can be seen in the family medicine sample. As a result of poor person fit measures and differential item functioning for indications the sub-sample family medicine was excluded from further analysis. Further, scale analysis was thus investigated on a reduced sample (N = 306). All 15 items were examined by infit and outfit statistics. Item selection due to analysis of category thresholds and item in fit measure was conducted again and led to the same results as described follow for the original sample. As shown in figure **??**, the mean and standard deviation of patient measures were 1.87 and 2.24 logits. The distribution of patient parameters indicated extremely positive values showing a high ceiling effect. The comparison of patient and item parameters did not result in a good fit. While item difficulties (normal mean = 0, S.D. = 1) could be found in a very limited area between -1.00 and 0.80 logits on the latent dimension. The content validity of the instrument was based on formulating the items from the existing literature, using the results of a series of studies designed to understand how patient involves SMDM can best be achieved in professional practice, followed by subsequent development using an iterative design and assessment cycle. Besides, a moderate reliability score of 0.77 for the person parameter was found which can be compared to the measure

of internal consistency in classical test theory. Besides the analysis of item reliability 0.97 brought very good results showing that item difficulties can be reproduced precisely.

IV.

6 Discussion

The present study aimed to assess the reliability and validity of the Taiwan Shared Medical Decision making questionnaire and, in doing so, to increase confidence in results from future studies in Taiwan using this instrument. This study was application of modern test theory Rasch test model to construct a common medical decision-making in Taiwan Scale reliability and validity of the study.

In general, classical item analysis was able to provide some information about instrument coherence, but appears not to be sensitive to items that fail to conform to the demands of measurement. Wright [22] has been criticized for not being able to deal with missing data nor for situations in which different groups of respondents have different item subsets. Further, measurement involves the processes of description and quantification. Questionnaires and test instruments are designed and developed to measure conceived variables and constructs accurately. Validity and reliability are two important characteristics of measureement instruments. Validity consists of a complex set of criteria used to judge the extent to which inferences, based on scores derived from the application of an instrument, are warranted [23]. Reliability captures the consistency of scores obtained from applications of the instrument. Traditional or classical procedures for measurement were based on a variety of scaling methods. Most commonly, a total score is obtained by adding the scores for individual items, although more complex procedures in which items are differentially weighted are used occasionally. In classical analyses, criteria for the final selection of items are based on internal consistency checks. At the core of these classical approaches is an idea derived from measureement in the physical sciences: that an observed score is the sum of a true score and a measurement error term. That is, there are limitations to using traditional analytical procedures to analyze rating scales which are overcome when Rasch scaling is used to measure item difficulty and abilities estimates of participants engaged in a learning process. Instrument coherence can also be assessed in Rasch analysis by examining items for unidimensionality as indicated by their fit statistics and by looking for differential item functioning.

By using the Rasch measurement model, the measurement properties of the SDM instrument have been investigated; it has been shown that an instrument can be refined by the removal of misfitting items, and item independent estimates of patient locations have been made. In this study, after completion the questionnaire of 16 questions from the deletion of the original 25 questions by experts. Analyses were conducted using survey data from 350 valid samples. We conducted Rasch model analysis of projects suitable, would be inconsistent with the right degree program within the scope of the project 1 ”I will express my preference about treatment option to my doctor ”to delete. This study is the common medical decisionmaking Rasch item separation results of the reliability that it represents research-based full scale after the completion of construction, and its level of internal consistency fairly standard, with good reliability. Construction of the final 15 items asked the common medical decision-making scale.

In conclusion, the Taiwan Shared Medical Decision-making Questionnaire (SMDMQ) has demonstrated good reliability and validity. The results also provide some evidence supporting the acceptability of the SMDMQ in these patients. As a result, in order to provide better medical service, we recommend that both physician and patient have better to participate in SDM and toward to understand patients' wishes. Apart from physician should encourage patient to raise any doubts and idea of the disease, and also should inform the risk of all the treatments in detail. Patients in this study are not yet fully subject to universal, high sampling difficult, so only for ”Chung Shan Medical University Hospital outpatient division” the patient sample. The studies that follow can use validation for the scale, for different ethnic groups, clinics, hospitals, research, re-examine the scale reliability and validity, so the scale to more general principles.

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Figure 1: Fig. 1 :Fig. 2 :

1

	sample characteristics (n=350)		
Variables		Number	Percentage (%)
Age	<20	35	10.00
	21-35	76	21.71
	36-50	98	28.00
	51-65	100	28.57
	>65	41	11.72
Gender			
	Male	180	51.43
	Female	170	48.57
Medical fields			
	General practice	62	17.71
	Surgery	42	12.00
	Psychosomatic	36	10.29
	Family Medicine	44	12.57
	Ophthalmology	39	11.14
	Urology	43	12.29
	Gynecology	41	11.71
	ENT(Ears, Nose & Throat)	43	12.29

Figure 2: Table 1 :

2

No	Item	INFIT MNSQ	ZSTD	OUTFIT MNSQ	
1	I will express my preference about treatment option to my doctor	1.21	2.6	1.54	4.10
2	I will inform my doctor of my family health record	1.12	1.40	1.11	1.30
3	I was able to discuss the different treatment options with my doctor in detail	1.10	1.00	1.19	1.80
4	I know I have a right to appoint agent about my treatment decision	0.88	-1.60	0.86	-1.80
5	I will ask the second opinion to conform with my expectation about treatment option	1.03	0.40	0.98	-0.20
6	I now know which treatment option is the best one for me	1.04	0.60	1.04	0.50
7	My doctor and I weighed up the different treatment options thoroughly and selected a treatment option together	1.14	1.70	1.12	1.40
8	Through the consultation with the doctor, I felt jointly responsible for my further treatment	0.95	-0.50	0.95	-0.50
9	My doctor encourage my question about the tests or treatment	0.86	-1.80	0.86	-1.80
10	During the consultation, I felt included in the treatment decision	0.97	-0.30	1.14	1.80
11	When I had important questions to ask my doctor, I can get answers that I could understand	1.06	0.70	1.06	0.80
12	My doctor is willing to explain the treatment or procedure to me in greater detail	1.14	1.50	1.14	1.60
13	My doctor has explain the purpose of any laboratory tests	1.00	0.00	0.99	0.00
14	My doctor has tell me any risk about treatment in detail	0.94	-0.70	0.97	-0.30
15	My doctor and I discussed the prognostic plan with me together	0.95	-0.50	0.90	-1.10
16	My doctor and I reached an agreement as to how we will proceed	0.90	-1.10	0.82	-2.00

Figure 3: Table 2 :

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