

Title: An instrument to evaluate patient counseling provision on herbs and dietary supplements

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Running head: An instrument to evaluate HDS patient counseling

Abstract: (135 words)

Objective: To develop a measure of pharmacists' provision of herbs and dietary supplements (HDS)-related patient counseling.

Design: A systematic process for item generation, testing, and validation of a measure was employed. Because the pharmacist-patient encounter may involve a potential indication for HDS that does not necessarily result in the recommendation of an HDS product and *vice versa*, the instrument was bifurcated into two distinct components: (1) patient counseling in general (PC-G); and (2) HDS-related counseling (PC-HDS).

Assessment: The instrument demonstrated high reliability and desirable construct validity. After adjusting for item difficulty, it appeared that participant pharmacists tended to provide more counseling related to the PC-G than on the PC-HDS.

Conclusion: This instrument can be applied to assess the quality of counseling provided by pharmacists and pharmacy students, and the outcomes of educational outreach on HDS.

INTRODUCTION (word count: 2862)

Use of herbs and dietary supplements (HDS) has been on the rise in the United States.^{1,2} Compared to prescription and nonprescription drugs, HDS products have less stringent regulations and looser manufacturing oversight in the U.S.³ and are readily available at many retail outlets, including community pharmacies, grocery stores, health food stores, as well as on the Internet. Consumers often obtain information on HDS from their family, friends, magazines, books, or infomercials^{4,5} rather than from healthcare professionals. Because the evidence on HDS products is often lacking or conflicting, it can be a challenge for healthcare professionals to make informed and consistent recommendations of HDS to their patients using evidenced-based approaches.⁶

An estimated 16 to 42% of patients used prescription drugs concomitantly with HDS,⁷⁻⁹ and 22 to 50% of patients took HDS products prior to surgeries and/or during preoperative care.¹⁰⁻¹² The extensive use of HDS among higher-risk patients poses a potential safety concern that could be mitigated by pharmacist counseling on the appropriate use of HDS products. Pharmacists have been encouraged to integrate professional HDS counseling and education services into their daily practice,^{13,14} yet counseling services on the appropriate use of HDS from pharmacists are often lacking.¹⁵⁻²⁰ Possible explanations for insufficient counseling on HDS by pharmacists include an insufficient education and knowledge on HDS, unfavorable attitude towards HDS products, a limited evidence-base in the literature on HDS, and a lack of time dedicated to patient counseling.

Although provision of HDS-related self-care instruction by pharmacists is indispensable,²¹ concerns about pharmacists' ability to address HDS-related issues have

been expressed by pharmacy educators, individual pharmacists, pharmacy managers, patients and other health professionals.^{14-15,22} The educational provisions associated with HDS toward pharmacy students in schools and pharmacy practitioners through postgraduate continuing education programs is not commensurate with the widespread use of HDS in the United States. As of 2005, some colleges/schools of pharmacy still did not offer course instruction in natural products or herbal supplements.^{14,16,23-26} Shah and colleagues (2005) recommended the establishment of guidelines for curricular content on herbal supplements in pharmacy education,²⁴ and revised Accreditation Council for Pharmacy Education (ACPE) guidelines for evaluating and improving pharmacy curricula include topics regarding knowledge and expected competencies on complementary and alternative medicine, including HDS.²⁷ A systematic review reported a majority of practicing pharmacists perceived they were not satisfactorily educated about herbal products and other types of alternative medicines during pharmacy school.²⁸

Several instruments that assess patient counseling related to medication-related issues are available, with varying evidence to support the validity of the scales.²⁹⁻³² The focus of these instruments is on the performance of medication-related counseling or on counseling for specific self-care products. Of these studies, few describe a conceptual framework to guide instrument development and item generation, or they generate a checklist rather than an instrument with a meaningful metric.

The aim of this study is to describe the development of an instrument that assesses the extent to which HDS-related counseling activities are performed by pharmacists. This study was part of a broader study included in the development and implementation

of knowledge, attitude, and behavior (KAB) surveys to gather information, describe current practice, and potentially assess the effects of initiatives to refine the practice, education, and training of pharmacists with respect to HDS.

METHODS

Instrument development

The goal of the instrument was to quantify the provision of HDS-related patient counseling by pharmacists. Specifically, the performance of HDS patient counseling was the construct of interest, whereby “patient counseling” was defined as an individualized counseling process when the pharmacist helps the patient treat his/her HDS-related problems through providing appropriate guidance using a problem-solving approach.³³

Upon conducting a literature review, several relevant measures were identified:

Kemper’s communication practice scale,³⁰ USP Medication Counseling Behavior Guideline^{29,34} and other measures.³¹⁻³² Upon further evaluation, these instruments did not satisfy our measurement goals. Specifically, the pharmacist-patient encounter may begin with an HDS inquiry but may not result in an HDS-related recommendation, and *vice versa*. As a consequence, the performance of drug/HDS counseling was conceptualized as two measures: a general patient counseling [PC-G] measure and a HDS-specific counseling [PC-HDS] measure.

When considering HDS for an individual patient, the American Dietetic Association /American Pharmacists Association recommends health professionals use the SOAP format (i.e., Subjective, Objective, Assessment, Plan).^{35,36} This approach was followed in conceptualizing the patient-pharmacist consultation process³⁷ for a drug/HDS-related

encounter (Figure 1). The counseling process includes six factors that characterize effective patient-centered communication (e.g., fostering relationships, exchanging information, responding to patients'/consumers' emotions, managing uncertainty, making a decision, enabling patient/consumer self-management).³⁸ When operationalized, the construct was conceptualized as having three main domains (i.e., foster relationships/information gathering, assessment, and plan/follow-up), each with 2-3 components (Figure 2). Items were generated by the authors and from existing literature and measures.^{31-33, 36, 39-45}

Instrument refinement and validation

Item pools were created with a sufficient number of items covering a broad spectrum of pharmacists' provision of HDS-related counseling. Once the item pool was generated, internal expert panel discussions were conducted to identify irrelevant, redundant items, and items with bias towards different characteristic of respondents. Two lay persons without a pharmacy background reviewed the structure and wording of the instrument as a final check. An external reviewer accessed the created web-based survey draft and provided suggestions on each item and the survey administration process.

Item performance assessment

Each item on the pharmacists' HDS counseling measure used a five-point Likert-type scale labeled as "none of the time," "a little of the time," "some of the time," "most of the time," and "all of the time." Proportion scores were derived by dividing the maximum obtainable total scores into the total observed scores, where the expected

total score was equal to the number of items multiplied by 5 (five-point Likert type scale). The higher the score, the more frequently a pharmacist performed patient counseling tasks related to HDS.

The properties of each measure were evaluated using kernel regression-based nonparametric item response theory (KIRT) models⁴⁶⁻⁴⁷ to examine the properties of each measure (i.e., testing of items with monotonic response pattern, variant item ordering, sufficient number of functional category responses) along with classical test theory based approaches (i.e., internal consistency [Cronbach's α], exploratory factor analysis [EFA]).⁴⁸ Items with poor psychometric properties were revised for content and/or eliminated, resulting in a final set of items related to each patient counseling instrument. At least two strata of difficulty (i.e., participant ability strata) were deemed necessary for the measure to have a sufficient span of ability to interpret the construct defined by the items.⁴⁹ Only items contributing to an acceptable level of reliability (i.e., $\alpha \geq 0.7$) were retained.⁵⁰

Subject recruitment

Practicing pharmacists with various levels of HDS knowledge and practice behaviors were asked to complete the instrument so the appropriateness and difficulty of items could be examined in the pilot study. In a subsequent larger scale validation study, pharmacists who were employed in healthcare settings and had regular patient contact were recruited. The studies were approved by the Institutional Review Board of the University of Illinois at Chicago (Protocol # 2007-0505).

Data analysis

The proportion score and the logit score for the two measures (PC-G and PC-HDS), were compared using an independent *t* test, or if not appropriate, the Mann-Whitney test, based on the results obtained from one sample Kolmogorov-Smirnov test.⁵¹ Differences in participant characteristics across two administration stages of the study (i.e., pilot, large-scale) were examined using *t* tests to identify differential item functioning (DIF). 95% confidence intervals were computed by employing the bootstrap method.⁵² Person measure scores (i.e., in logit units) obtained in the validation study were used when conducting bivariate analyses, i.e., *Pearson* correlations. The corresponding nonparametric analyses were performed whenever the parametric assumption of normality was violated. These approaches were performed to examine the association between background information (e.g., including personal, workplace information, HDS information/ training resources) and logit scores of pharmacists' performance of HDS-related patient counseling, respectively. A significance level of $\alpha \leq 0.05$ was set *a priori*. All analyses were performed using SPSS 16.0 version and in using "R" software.

RESULTS

Of the 34 pilot study participants, 20 (58.8%) completed the KAB survey instrument in its entirety, whereas 179/330 participants (54.4%) completed the revised survey instrument administered in the larger scale validation study.

Instrument Refinement

Of 46 items constructed in the initial item pool, 17 items were revised and retained for the patient counseling - general measure (PC-G). Eleven items were generated for the measure of performance patient counseling on HDS (Table 1). The proportion of items measuring each component of patient counseling in the general construct (PC-G) was similar to the initial item pool. However, no items were retained which measured pharmacists' tasks related to gathering subjective or objective information from patients within the HDS counseling construct (PC-HDS).

Instrument Validation

Table 2 and Table 3 present the psychometric properties of the two measures. Prior to refinement in the pilot study, the Cronbach's α of PC-G was 0.91 (95% interval= 0.84, 0.95) for the 17-item measure. With the removal of poorly performing items, the reliability of 10-item version was reduced to 0.86 (0.71, 0.93). In the larger validation study with sufficient sample size to apply the EFA, two factors were extracted for general counseling. Consequently, five items (i.e., PC-G2, PC-G4, PC-G5, PC-G7 and PC-G14) loaded on one factor (named as information gathering) and another five items (PC-G6, PC-G9, PC-G10, PC-G12, PC-G13) loaded onto a second factor (named as facilitating decision making). The two factors were strongly correlated ($r_{f-f} = 0.68$), which inferred these items might account for only one construct. While the PC-G possessed a fairly good level of reliability, two items (PC-G2 and PC-G9) did not demonstrate monotonicity. Upon removal of these items, the eight remaining items were able to distinguish at least three groups of respondents' performance behavior (participant strata = 3.09). The internal consistency of the PC-G was acceptable ($\alpha = 0.81$).

For the PC-HDS construct, the α slightly increased from 0.84 to 0.86 in the pilot

study after removing four items. Two items related to the tasks of subjective information gathering and recommendations were removed from the PC-HDS. In the larger validation study, the remaining seven items possessed a good level of reliability ($\alpha = 0.89$ [SD = 0.01]) and satisfied other psychometric criteria, and were able to stratify HDS patient counseling into more than 4 ability groups (participant strata = 4.13). Upon the EFA, two items indicating the monitoring (i.e., PC-HDS10, PC-HDS11) were loaded in one stand alone factor and the remaining five items (i.e., PC-HDS1, PC-HDS3, PC-HDS6, PC-HDS7, PC-HDS8) assessing pharmacists' performance on the tasks associated with assessment and plan of HDS counseling were loaded into another factor. These two factors were strongly correlated ($r_{f-f} = 0.93$) and could be recognized as one construct, which corresponded to one of the KIRT assumptions, "unidimensionality".

Quantifying pharmacists' provision of HDS-related counseling

The proportion scores of two measures (i.e., PC-G, PC-HDS), which quantify pharmacists' provision of HDS-related counseling, were significantly higher in the pilot study than in the larger scale study ($p < 0.05$). After adjusting for item difficulty, the person logit scores on the PC-G and PC-HDS were significantly higher in the pilot study than in the larger scale study ($p < 0.05$), which indicated that respondents seemed more likely to perform more activities in the pilot study than in the large-scale study.

Table 4 presents the strength of correlations between the pharmacists' background information and their person scores for each measure based on the correlation coefficients. There were zero to weak correlation values (r ranged from $|0.001|$ to $<|0.2|$) between the majority of pharmacists' demographic information and their person logit scores, even if

there were some exceptions. Experience with disease state management was positively correlated with the PC-G ($r_s \geq 0.2$). Performance of HDS counseling was positively correlated, e.g. $r = 0.20$ to 0.35 with pharmacists' own experience taking herbs and other supplements, practicing in community pharmacy, counseling OTC/ self-care, offering HDS and offering HDS information with the PC-HDS ($r_s \geq +0.2$).

In addition, strong correlations existed between pharmacists' person scores of PC-G and PC-HDS (mean of r [95% Interval] = 0.53 [$0.40, 0.64$] for logit unit and 0.55 [$0.45, 0.73$] for proportion score, respectively).

DISCUSSION

Pharmacists and other clinicians are expected to help consumers by evaluating the effectiveness and safety evidence for HDS products and sharing this information with consumers.¹⁴ In this study, a newly developed instrument for assessing the performance of counseling by pharmacists was supported by the evidence of validity and reliability. We propose that the well-validated instrument can be used for self-assessment by pharmacists, evaluation of student competencies by pharmacy faculty and preceptors, and quality improvement initiatives by pharmacy managers. This instrument fills a gap in the assessment of quality of care associated with HDS-related professional services.

The instrument for the assessment pharmacists' provision of counseling was bifurcated into two measures: general counseling and HDS-specific counseling. This was necessary because the pharmacist-patient encounter may or may not begin with an HDS inquiry. It may, however, result in an HDS-related recommendation, and *vice versa*. This instrument implicitly captures the quality of patient counseling encounters by focusing on the main components of the counseling process and the frequency in

which they are conducted. Although not all tasks performed by the pharmacist related to a counseling encounter are captured, the instrument quantifies key elements involved in patient counseling associated with HDS.

Previous measures related to counseling have demonstrated evidence of validity and reliability using primarily classical test theory based approaches which assume for instance, that scores are normally distributed and that the measure is unidimensionality.³⁰⁻³⁴ In contrast, the KIRT used in the present study does not invoke assumptions of normality, and the results demonstrated good construct validity and internal consistency for each measure. Additional convergent validity of the patient counseling measures was presented based on significant relationships with related factors.

In this study, pharmacists were requested to indicate their frequency of HDS provision in the context of statements to describe different activities related to HDS patient counseling. In contrast, previous studies used different approaches to operationalizing item responses related to specific or general activities about HDS counseling. Some studies used one or more dichotomous questions.^{16,18-19,24,53-55} For instance, pharmacists were asked whether they had received inquiries from patients about natural products on a weekly or monthly basis in Dolder's study.¹⁹ Some studies inquired about the length of pharmacists' encounters^{15,18} or asked pharmacists to rate the frequency using a Likert-type scale. For example, Brown's study demonstrated pharmacists rated (1=never, 5= always), on average, 2.5 ± 0.9 , they inquired about the patients' use of CAM.⁵³

In the current study, the average person proportion score of PC-G of 0.65 would be analogous to endorsing 26/40 points, or alternatively respondents endorsing "some of

the time” to all eight items. The average person proportion score of PC-HDS of 0.46 would be equivalent to endorsing 16/35 points, which would indicate that pharmacists responded, on average, with at least “a little of the time” to all seven items. This implies respondent pharmacists tended to spend at least “a little of the time” on either patient counseling, in general, or HDS specifically in their daily practice. After adjusting for item difficulty, the average person logit score on the PC-G was dramatically higher than the scores on the PC-HDS. Given the strong correlation between pharmacists’ person scores of PC-G and PC-HDS, these results imply pharmacists who provided more general counseling tended to provide more HDS- specific counseling and *vice versa*. Moreover, pharmacists who personally use herbs, amino acid, vitamins, other supplements, and who worked in the community settings, and who worked in the settings which offered the HDS and provided HDS related information tended to spend more time on counseling patients about HDS-related matters. These results intuitively mimic current pharmacy practice behaviors.

In fact, many patients tend not to disclose HDS product use experience to their primary health care professionals.^{1,56-57} With these findings, the results in this study can help to guide the development of interventions, specifically for pharmacy managers and preceptors, which target pharmacists’ awareness and pharmacy students’ professional performance regarding patient care with respect to the appropriate use of HDS products. The 15-item patient counseling measure could be used for quality and performance assessment in pharmacy practice, experiential training (e.g., IPPE, APPE), postgraduate continuing education, and for allied health clinicians. The 8-item PC-G scale could be used as a stand-alone measure for general patient counseling of medication, while the

7-item PC-HDS could be modified for use in patient counseling concerning other self-care OTC products as well. Nevertheless, the authors encourage further validation and application of the instrument to evaluate educational outreach, experiential training and quality assurance in diverse settings. Regardless, these results were exploratory in nature and further use of the instrument in other samples of pharmacists, pharmacy trainees or clinicians would greatly enhance its generalizability.

CONCLUSION

Although it is known there exists no single, standardized patient counseling measure or instrument applicable for all pharmacy practice or experiential training scenarios, the psychometric properties of this newly developed measure support its use in assessing pharmacists' counseling behaviors on HDS products. Findings suggest the instrument can be used as a tool for quality assurance and training assessment to ensure a standard level of HDS-related patient counseling is being provided.

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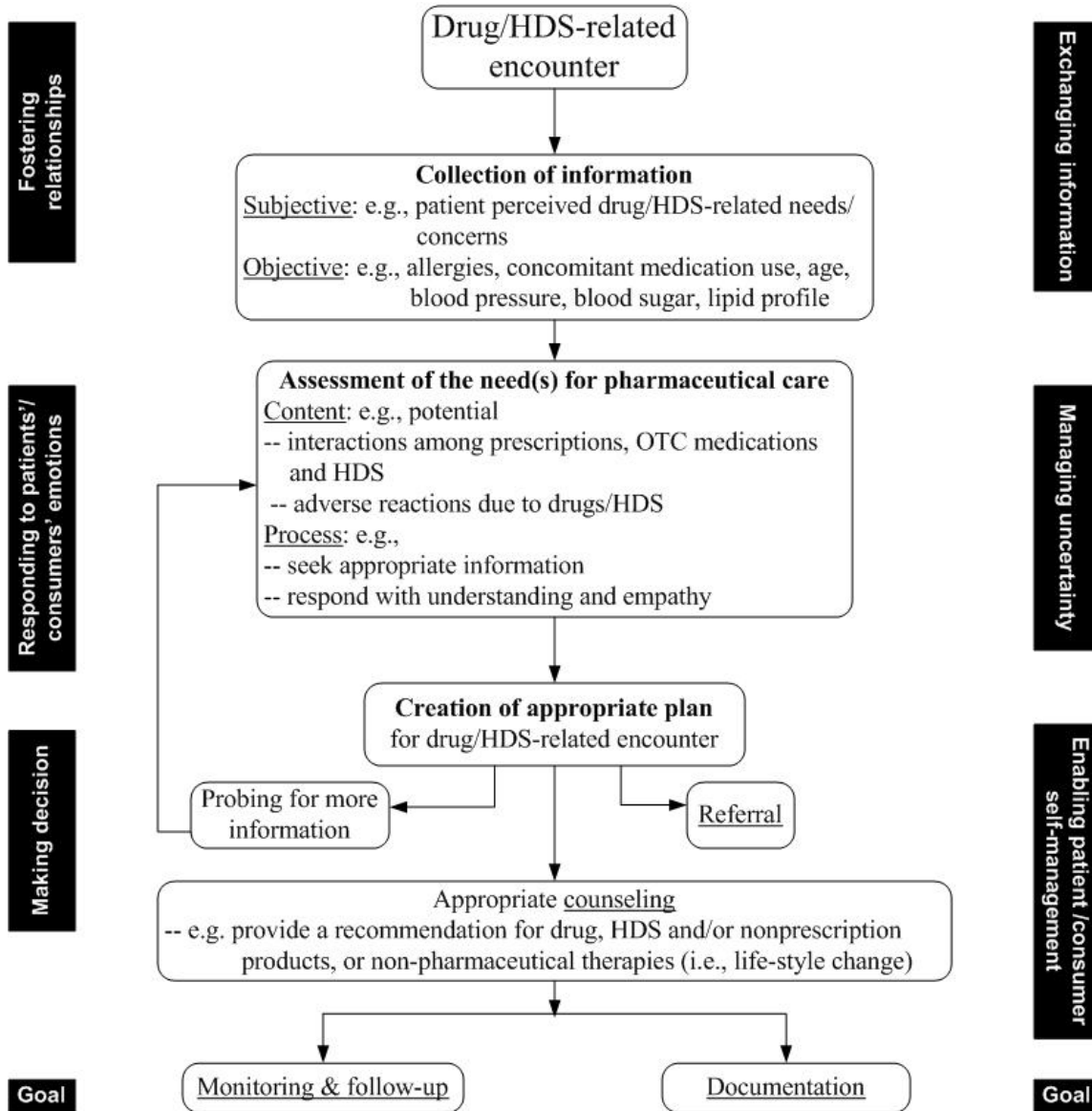


Figure 1: Effective patient/consumer-pharmacist consultation process for a clinical encounter related to HDS in a community pharmacy

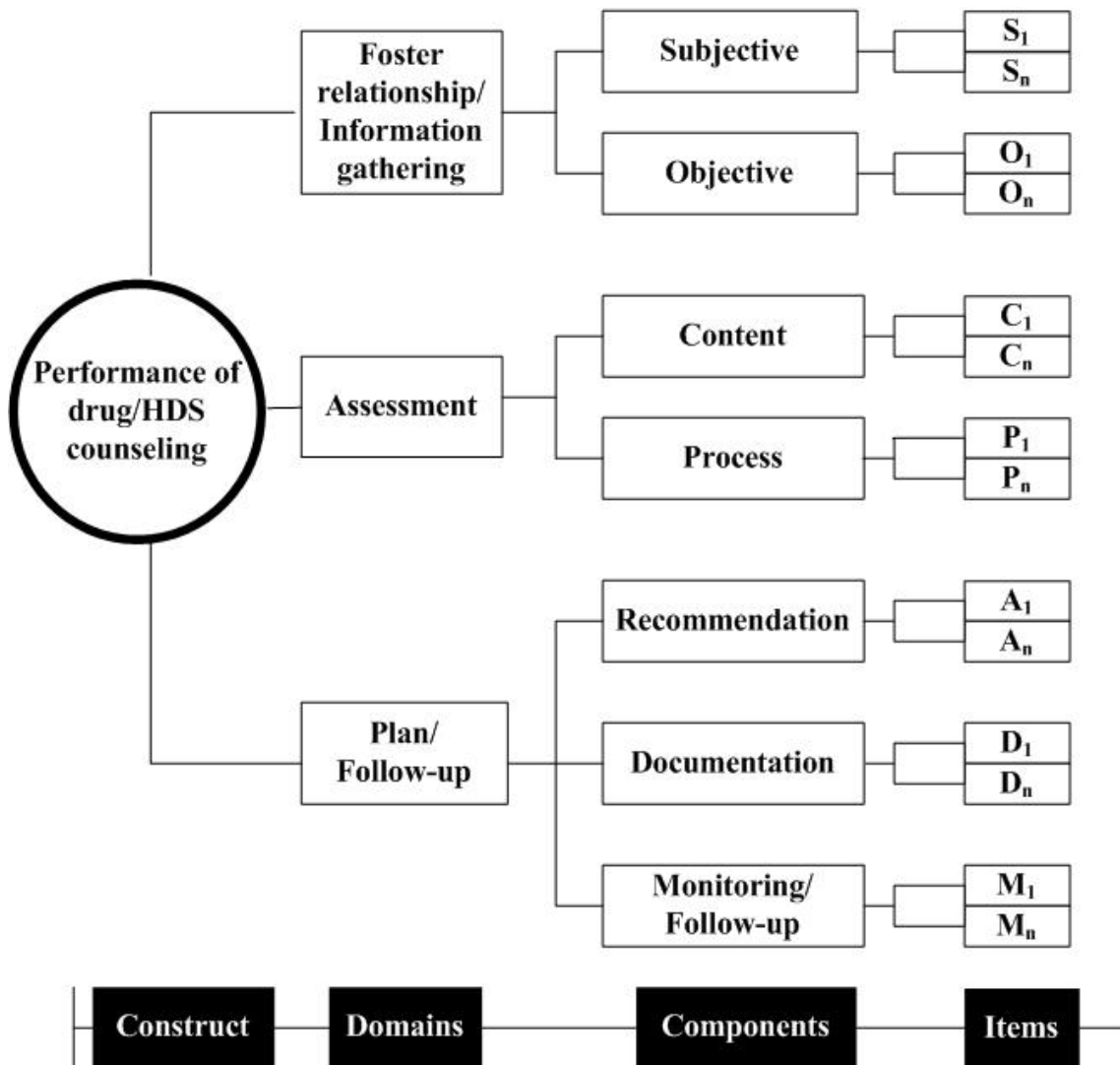


Figure 2: Conceptualization of a measure of performance of HDS counseling

Table 1: Item content included in patient counseling measures in the pilot study

Domain (N)	Component (N)	Item content to be examined	Item ID^b
Patient counseling - general (N= 17 items)			
Foster relationship/ Information gathering (5 items)	Subjective (3 items)	Patient's self-care needs	PC-G1
		Patient's feeling	PC-G2 ^a
		Patient's health concerns	PC-G3
	Objective (2 items)	Patient's relevant medical history	PC-G4 ^a
		Patient's current medication use	PC-G5 ^a
Assessment (5 items)	Content (2 items)	Identify potential solutions	PC-G7 ^a
		Consider the benefits/risks of options	PC-G8
		Identify patient's preference of options	PC-G9 ^a
	Process (2 items)	Seeking literature	PC-G6 ^a
		Decide the need of referral	PC-G13 ^a
Plan/ Follow-up (7 items)	Recommendation (4 items)	Advise about self-care	PC-G10 ^a
		Advise in lay terms	PC-G11
		Offer general management approaches	PC-G12 ^a
		Suggest consult physicians	PC-G17
	Documentation (1 item)	Document the inquiry	PC-G14 ^a
	Monitoring (2 items)	Follow-up on treatment effectiveness	PC-G15
		Follow-up on undesired effects	PC-G16
Patient counseling - HDS-related (N= 11 items)			

Assessment (4 items)	Content (2 items)	Explain effectiveness	PC-HDS2
		Explain the <i>pros</i> and <i>cons</i> of HDS use	PC-HDS3 ^a
	Process (2 items)	Ensure product quality.	PC-HDS1 ^a
		Identify undesired/adverse effects	PC-HDS8 ^a
Plan/ Follow-up (7 items)	Recommendation (4 items)	Refer patient for medical care as a result of HDS misuse.	PC-HDS4
		Make an evidence-based recommendation	PC-HDS5
		Ensure appropriate HDS dosage	PC-HDS6 ^a
		Provide written information	PC-HDS7 ^a
	Documentation (1 item)	Document the use	PC-HDS9
	Monitoring (2 items)	Follow-up on treatment effectiveness	PC-HDS10 ^a
		Follow-up undesired effects	PC-HDS11 ^a

^a: Items were retained in the instrument prepared for the larger scale validation study

^b: Item ID represents item order in the instrument prepared for the pilot study.

Table 2: Psychometric properties of patient counseling - general measure (PC-G) in two stages of validation studies

Psychometric properties\construct	Pilot study		Larger scale study	
Refinement	Prior	After	Prior	After
# of items	17	10	10	8
Reliability				
Mean (sd)	0.91 (0.03)	0.86 (0.06)	0.85 (0.02)	0.81 (0.02)
95% interval	(0.84, 0.95)	(0.71, 0.93)	(0.82, 0.88)	(0.76, 0.85)
KIRT results				
Participant strata	4.57	2.70	3.51	3.09
Person proportion scores	-	0.73(0.09)	-	0.65(0.08)
Person logit scores				
Mean (sd)	1.27 (0.98)	0.58 (1.48)	0.69 (0.64)	0.67 (0.68)
95% interval	(0.08, 3.43)	(-2.76, 2.18)	(-0.4, 1.99)	(-0.4, 2.21)
Item logit scores				
Mean (sd)	-1.15 (0.59)	-0.72 (0.98)	-0.65 (0.34)	0.61 (0.36)
95% interval	(-2.23, -0.23)	(-2.54, 0.75)	(-0.97, 0.04)	(-0.93, 0.07)
# non-monotonic item(s)^a	0	0	2	0
# pair(s) of items with variant item ordering	17	0	0	0
# items caused variant	3	0	0	0

item ordering

items with less than n-2 **3** **0** **0** **0**

functional category

responses (n= # of

category responses)

^a:proportion respondents endorsing higher item levels not increasing as the latent trait level increases

95% interval refers to the 2.5% and 97.5% of the corresponding scores

Table 3: Psychometric properties of patient counseling – HDS measure (PC-HDS) in two stages of validation studies

Psychometric properties\construct	Pilot study		Larger scale study	
Refinement	Prior	After	Prior	After
# of items	11	7	7	
Reliability				
Mean (SD)	0.84 (0.10)	0.86 (0.08)	0.89 (0.01)	-
95% interval	(0.55, -0.94)	(0.67,- 0.95)	(0.85,0.91)	-
KIRT results				
Participant strata	3.39	2.70	4.13	-
Person proportion scores	-	0.55(0.09)	-	0.46(0.11)
Person logit scores				
Mean (SD)	0.13 (0.87)	0.29 (1.29)	-0.12 (0.8)	-
95% interval	(-0.76,2.54)	(-1, 3.88)	(-1.35, 1.41)	-
Item logit scores				
Mean (SD)	0.06 (0.3)	-0.11 (0.33)	0.14 (0.43)	-
95% interval	(-0.52,0.39)	(-0.55, 0.33)	(-0.42, 0.63)	-
# non-monotonic item(s)^a	3	0	0	-
# pair(s) of items with	1	0	0	-
variant item ordering				
# items caused variant	1	0	0	-

item ordering

items with less than n-2 1 0 0 -

functional category

responses

(n= # of category

responses)

^a :proportion respondents endorsing higher item levels not increasing as the latent trait level increases

95% interval refers to the 2.5% and 97.5% of the corresponding scores

Table 4: The strength of correlations between the performance of HDS counseling and the pharmacists' background information

Pearson\Spearman rho\Kendall's <i>tau</i> _b	PC-G	PC-HDS
Gender	0.01	-0.14
Ethnicity/Race	-0.08	0.01
Language	-0.05	-0.01
Age	-0.02	0.04
Degree		
B.S. in Pharm	-0.08	0.05
Pharm. D.	0.13	0.00
Residency	0.03	-0.02
Residency and or Fellowship	0.09	0.17
Masters	-0.01	-0.06
Others	-0.08	0.05
Year of practice	-0.03	0.03
Used or taken any kind of HDS product	0.07	0.17
Herbs or other botanicals	0.22*	0.32*
Amino Acids	0.17	0.20*
Minerals	0.10	0.12
Other Supplements (e.g., melatonin)	0.12	0.25*
Vitamins	0.28*	0.29*
Others	-0.12	0.07

Pearson\Spearman rho\Kendall's τ_b	PC-G	PC-HDS
Practice in community pharmacy or not	0.00	0.24*
Current position (yr)	-0.03	0.07
Health food store nearby	0.02	0.01
Average daily Rx	-0.04	-0.07
Practice activity		
Counseling pt about Rx	0.17	0.11
Counseling pt about OTC/self-care	0.10	0.21*
Disease state management	0.23*	0.06
Management functions	0.02	0.11
Receiving/dispensing prescriptions	-0.20	-0.06
Others	0.04	0.04
Employer-sponsored training of HDS	0.08	0.14
Offer HDS	0.05	0.21*
Offer HDS information	0.06	0.27*

*: the correlation coefficient was greater than $|\pm 0.2|$