Psychometric Properties and Construct Validity of the Knowledge Information Profile–Coumadin

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Abstract

Background: Oral anticoagulation therapy using Coumadin (warfarin) requires significant patient involvement. Limited validated instruments exist to test patient knowledge of Coumadin, and low health literacy may impede patient self-management. **Objective:** This article reports the psychometric testing of the Knowledge Information Profile–Coumadin (KIP-C20) to determine (a) minimum number of items and dimensions, (b) reliability, and (c) construct validity. **Methods:** Participants (N = 192) were recruited from outpatient pharmacist-directed anticoagulation clinics associated with an urban teaching hospital in the Midwest United States. Instruments were the Animal Naming test (AN), Rapid Estimate of Adult Literacy in Medicine (REALM), and KIP-C20. Multidimensional item response theory modeling and exploratory factor analyses were used to determine the best fitting model. **Results:** The final instrument, renamed KIP-C14, with 3 factors and 14 items, had a good fit to data ($M_2 = 96.49$, $P < .0001$; root mean square error of approximation = .04), and all factor loadings were .3 or larger. Internal consistency reliability was .65; test–retest correlation was .67. The KIP-C14 correlated positively, as expected, with years of Coumadin treatment. Subscales were differentially correlated with sociodemographic variables. **Conclusions:** The KIP-C14 had nearly identical, slightly higher reliability than the KIP-C20. Still, reliability was lower than expected, indicating a promising clinical assessment scale in need of further refinement.

Keywords

anticoagulation, warfarin, patient knowledge, construct validity

Coumadin (warfarin) is an oral anticoagulant used to prevent blood clots in conditions such as atrial fibrillations, stroke, and deep vein thrombosis. Coumadin is the second most common drug—after insulin—implicated in emergency room visits for adverse drug reactions.¹ These adverse reactions can range from minor complications (bleeding from gums, blood in urine, bloody or dark stool, nosebleed) to systemic complications resulting in life-threatening interactions that can cause severe, possibly fatal bleeding. The primary high-risk factor associated with Coumadin is bleeding related to high intensity of the international normalized ratio (INR > 4.0) or to the patients' age (65 years and older). The risk factors make patient knowledge, medication adherence, and the ability to safely manage medication administration critical to maintaining therapeutic anticoagulation balance.

In response to this concern, a 20-item measure titled the Knowledge Information Profile–Coumadin (KIP-C20) was developed by the study's principal investigator (PI) to

assess patient knowledge of Coumadin. Instrument development began with a search of the literature that included actions, side effects, diet, and self-care medication management and current treatment modalities of Coumadin. The purpose of this research was to examine the reliability and construct validity of the KIP-C20 in a large sample (N = 192) of outpatients recruited from pharmacist-directed anticoagulation clinics and to address the following questions:

1. What is the reliability of the KIP-C20 in this sample of patients?

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2. Can reliability be improved by using item statistics and dimensional analyses to select the best performing subset of items?
3. If reliability cannot be improved by selecting items, can the test be shortened without reducing reliability by removing items that add little to the overall discrimination among individuals?
4. Does the scale consist of one or more than one dimension?
5. What is the construct validity of the scale and/or scales if several are determined?

Assessing Coumadin Knowledge

Due to its side effects, in particular bleeding, and narrow therapeutic window Coumadin can be a difficult drug to manage.² Successful and safe anticoagulation therapy depends on the patient's knowledge about the drug, including the importance of adherence, appropriate diet and alcohol use, over-the-counter drug use, and risk factors from this medication. Studies have shown that patients on anticoagulation therapy may lack basic knowledge about their treatment.³ Generally, research findings have shown serious knowledge deficits among patients with respect to anticoagulation treatment.⁴ Findings from a knowledge survey of homecare patients receiving Coumadin indicated that participants lacked knowledge about the INR and its therapeutic value; most relied solely on their provider to explain the outcomes of the ratio.⁵ Some study participants believed that "blood thinner" meant having less blood and complained that they "felt cold."

Health Literacy and Medication Adherence

Health literacy has emerged as a major factor in nonadherence to desirable health care behavior.⁶ Patients with low health literacy have difficulty comprehending and following health care instructions such as self-administration of medication. A growing body of evidence suggests a strong relationship between low health literacy and poor self-care abilities, high use of health care services, and low participation in health promotion and illness prevention activities.⁷

Youmans and Schillinger^{8(p1726)} described functional health literacy as "a measure of a person's ability to perform basic reading and numeric tasks in the healthcare context, such as reading insurance forms and medication labels, and performing mathematical tasks associated with taking medications (numeracy)." The authors reported a patient's low functional health literacy coupled with poor oral communication skills may impede the health care provider's ability to assess self-medication practices. Furthermore, patients unable to read and understand instructions or medication labels are at risk for unsafe medication self-management. Davis et al⁹ reported that patients with low literacy were

twice as likely to misinterpret prescription drug labels and 3 to 4 times more likely to misinterpret drug warning labels.

Methods

Research Design and Setting

The study used a test-retest design and psychometric analyses to examine and refine the KIP-C20. Also, the literacy levels of study participants were evaluated. The investigation took place in 2 urban, university-affiliated hospital outpatient anticoagulation clinics located in the Midwest United States. All of the patients in the clinics received Coumadin therapy, and patients and pharmacists both used the name Coumadin when referring to the medication. We recruited a convenience sample of 196 patients receiving care at the clinics. Patients 21 years and older, able to speak English, cognitively able to participate, and receiving care at either clinic were eligible for the study. Four participants were excluded because of incomplete data and failing the Animal Naming test (AN; see below), resulting in a sample of 192 participants with useable data.

Instruments

To assess cognitive ability and eligibility to participate in the study, potential participants were administered the AN, a subscale of the MacNeill-Lichtenberg Decision Tree (MLDT).¹⁰ Instruments were then completed by study participants (N = 192): demographic questionnaire, Rapid Estimate of Adult Literacy in Medicine (REALM), and Knowledge Information Profile-Coumadin (KIP-C20).

Animal Naming test. The AN was used as a prescreening tool to assess cognitive functioning. The test is a verbal fluency task requiring the spontaneous naming of as many animals as possible in 60 seconds. The inability to name 10 animals indicates some level of cognitive impairment. The test has been used with participants of different ages, genders, and education levels and had a Cronbach's α level of .90 in the present study.

Demographic questionnaire. The participants self-recorded this information on a questionnaire developed by the PI. The demographic characteristics included age, education, health literacy as measured by the REALM, ethnicity, income, diagnosis related to anticoagulation therapy, and length of time on Coumadin.

Rapid Estimate of Adult Literacy in Medicine. The REALM, a standardized reading test that measures adult literacy in a health care setting, was used to assess the participants' health-related reading skills. The REALM consists of 66 written words presented to participants, beginning with

simple monosyllabic words and advancing to more complex vocabulary. The test is user-friendly and can be administered in approximately 10 minutes. Scores on the REALM are interpreted as equivalent to the following school levels of reading ability: 0 to 18 (3rd grade and below), 19 to 44 (4th to 6th grade), 45 to 60 (7th to 8th grade), and 61 to 66 (high school).¹¹ The REALM had a test-retest reliability of .99 in a prior study.¹²

Knowledge Information Profile–Coumadin. The KIP-C20 administered in the present study contained items derived from the literature and a set of objectives developed by a pharmacist and investigators. It focused on assessing the patient's knowledge of actions and side effects of Coumadin, the food-drug effects of vitamin K on anticoagulation therapy, and sources of foods rich in vitamin K. Questions are scored as correct (1 point), incorrect (0 point), or "don't know" (0 point). The number of correct answers is divided by the total number of items and multiplied by 100 to obtain the percentage score. The KIP-C20 is a unique instrument because the questions are easy-to-read (5th grade level) and can be administered in approximately 10 to 15 minutes in a clinical setting.

The first phase of the present study determined the validity of the items of the KIP-C20. A panel of 10 experts in anticoagulation therapy, including 4 pharmacists, 4 nurse practitioners, and 2 cardiologists, used a template by Mastaglia and colleagues¹³ to assess each item for clarity (clear or unclear), statement fit (yes/no), redundancy (yes/no), and consistency (yes/no). As a result of the assessment, the panel recommended 2 minor adjustments: (a) consistently use the drug name "Coumadin" as opposed to warfarin and (b) rephrase one of the item's sentence structure for clarity.

Procedures

Following institutional review board approval from the Human Investigation Committee of the PI's university, a member of the study team visited the clinic 3 to 4 times per week to enroll participants. Those who were 21 years of age or older, read and spoke English, and were cognitively able to participate (AN assessment) were deemed eligible for this study. After providing written informed consent, a member of the study team administered the demographic questionnaire, REALM, and KIP-C20 to the participants, who completed the instruments in a private examination room at the clinic. Two weeks later, the participants completed the KIP-C20 again at their preferred location, either the clinic or the patient's home.

Data Analysis

Frequency distributions and measures of central tendency were used to describe the study participants. Refinement of

the KIP-C20, including deletion of items and delineation of subscales, was achieved using a combination of item response theory (IRT) models and exploratory factor analyses procedures. Several IRT models and procedures were used to gain quantitative understanding. Test-retest and internal consistency reliability for the total scale and subscales was determined. Reliability estimates were compared with each other and with reliability determined from the test information function. Finally, construct validity was examined by correlating scales from the refined instrument, renamed KIP-C14, with the participants' sociodemographic variables, health literacy levels, and length of time on the Coumadin regimen.

Results

Demographics and Literacy Level of Participants

Sample statistics are presented in Table 1. The participants (N = 192) were predominantly African American (82%); over half were female (56%), and 45% were 61 years of age or older. Self-report of highest education completed indicated that 78% were high school graduates. Health-related reading level, as measured by the REALM score, was 52.9 (SD = 17.9), equivalent to 7th to 8th grade. Mean length of time taking Coumadin was 4.8 years (SD = 6.2). Participants answered 72.86% (SD = 14.38) of KIP-C20 items correctly, and 20% of participants received a score of 60% or less. Test-retest reliability of the KIP-C20 was .67.

Item Analysis for the KIP-C20

Table 2 shows the item statistics for all items and item-to-total statistics for all but the first item that was excluded from this and the following psychometric analysis due to variance < .02. Item-to-total statistics were computed using the usual point-biserial correlation (r , SPSS item analysis) and biserial correlations obtained from the IRT program BILOG-MG (r_b).¹⁴ Biserial correlation is more appropriate for dichotomous items because it estimates the slope of the item characteristic curve (ICC) at the point where 50% of respondents get the answer correct.¹⁵ The biserial correlation can range from -1 to 1 and is not dependent on item difficulty like the point-biserial correlation, which has a maximum correlation of .798 when item difficulty is .5.¹⁶ The item slope is proportional to item discrimination parameter.¹⁷ All but 6 of the biserial correlations were greater than .2, and a total of 10 were greater than .3. A slope coefficient of .3 is often used as a cut score for selecting items in a factor analysis because .3 implies an item that shares less than 10% variance with the common factor. These item-to-total correlations could be misleading if the scale is not unidimensional or if the biserial correlation assumption of underlying multivariate normality is not correct.

Table 1. Characteristics of Study Participants (N = 192).

Variable (Valid Responses)	n	%
Gender (192)		
Female	108	56
Male	84	44
Age (192)		
<50 years	61	32
51-60 years	44	23
61-70 years	54	28
71+ years	33	17
Race (191)		
African American/Black	156	82
Caucasian/White	27	14
Other	8	6
Income (185)		
<\$10 000	82	44
\$10 001-\$30 000	74	40
>\$30 000	29	16
Education (192)		
Less than high school	41	21
High school graduate	77	40
Some college or more	74	38
Take over-the-counter medications (191)		
Yes	83	43
No	108	57
Eat garlic (191)		
Yes	141	74
No	50	26
Take St. Johns Wort (189)		
Yes	3	2
No	186	98
Take vitamins (192)		
Yes	83	43
No	109	57
Use birth control (191)		
Yes	3	2
No	188	98
Have medical insurance (187)		
Yes	181	97
No	6	3

Unidimensional models. Two unidimensional IRT models were fit to the KIP-C items using IRT software.¹⁸ The 1-parameter logistic model (Rasch model) was tried first. The fit of this model was compared to the 2-parameter logistic model. Neither model fit well according to the M_2 goodness-of-fit statistic,¹⁹ or the root mean square error of approximation (RMSEA). However, the 2-parameter model fit significantly better than the 1-parameter model; the difference in $-2 \log$ likelihood statistics was 54.08 with 18 degrees of freedom, $P < .0001$. Seven of the 19 slope parameters were not significant (critical ratio < 1.96). Items with small slopes contribute little information to the total test score.

Multidimensional analyses. Because neither of the unidimensional models fit well, item correlations and standardized residuals ($LD-X^2$)²⁰ were examined to identify sources of misfit. This was followed by exploratory factor analyses that examined 2-, 3-, and 4-factor solutions. Both restricted and unrestricted methods were used. The exploratory factor analyses used tetrachoric correlations and were estimated using unweighted least squares.¹⁵ This heuristic approach does not provide goodness of fit or tests of significance. A 3-factor solution accounted for 48.9% of the variance among the items; 5 items did not load consistently on any one factor and were consequently omitted leaving 14 items. The final 3-factor solution was estimated using the multidimensional IRT software.¹⁸ This model, with 3 factors and 14 items, had a good fit to the data ($M_2 = 96.49$, $P < .0001$; RMSEA = .04; see Table 3) and all factor loadings were .3 or larger. The 3-factor model fit significantly better than the 1-factor model (see Table 3). The final model with standardized factor loadings and standard errors is shown in Figure 1. The 3 factors were positively correlated (.21 to .39), suggesting the possibility of an underlying general factor.

Scale scores, reliability, and validity. One overall scale consisting of the 14 retained items (Total KIP-C14) and 3 subscales corresponding to the factors were computed. Scale statistics are shown in Table 4. The original 20-item KIP-C (Total KIP-C20) is shown for comparison. The Total KIP-C14 estimated overall competency in self-regulation of the therapy and was 4.34 percentage points lower than the Total KIP-C20, $t(191) = 9.52$, $P < .01$. This was due to the fact that the omitted items tended to be answered correctly. Both scales had similar reliability in spite of the fact that the KIP-C14 had 30% fewer items. Coefficient α (internal consistency reliability) and test-retest reliability estimates were generally in good agreement, with the largest difference found for the Side Effects subscale. This was the smallest scale consisting of only 2 items.

Construct validity. It was expected that the KIP-C14 would correlate positively with the REALM and with years of Coumadin treatment. These correlations were confirmed ($P < .01$) and are shown in the bottom row of Table 5. The correlation with the REALM accounted for only 9% of the variance in KIP-C14 total score, leaving a large percentage of unique reliable variance in the KIP-C14 specific to Coumadin health literacy. The pattern of correlations of the REALM and time taking Coumadin with the KIP-C14 subscale scores indicates that the subscales Vitamin K and Other Foods, Beverages, and Medicine were differentially correlated with the REALM and time taking Coumadin, allowing for the contributing effects of overall health literacy and experience. Correlations of the KIP-C14 scales with sociodemographic and health variables were also

Table 2. Item Analysis Statistics and Items Omitted From the Final Version of the Instrument, KIP-C14 (N = 192).

All Items From the Knowledge Information Profile–Coumadin	P	SD	Item Total Correlation ^a		IRT Slope ^b	Crit. Ratio	Omitted Items ^c
			r	r _b			
1. The name of my medicine from this clinic is called Coumadin (T)	.99	.07	—	—			x
2. This medicine will cause my blood to clot (F)	.80	.40	.34	.48	1.16	3.63	
3. I can take over-the-counter medicines like aspirin while I am taking Coumadin (F)	.63	.49	.21	.27	0.68	2.62	
4. This medicine is also called a “blood thinner” (T)	.95	.22	-.06	-.11	-0.09	-0.23	x
5. Foods like collards, turnip, mustard, lettuce, and broccoli are high in vitamin K (T)	.95	.21	.14	.29	0.84	1.95	x
6. Coumadin is an anticoagulation medication (T)	.81	.39	.21	.31	0.75	2.50	
7. If I want to go on a diet, now would be a good time while I am taking Coumadin (F)	.37	.48	.28	.36	0.91	3.03	
8. I should eat the same amount of leafy green vegetables like collard greens, turnip greens, and broccoli each week while taking Coumadin (T)	.83	.38	.14	.21	0.41	1.64	x
9. I can take any amount of laxatives and aspirin while taking Coumadin (F)	.75	.43	.43	.58	1.42	3.16	
10. Lots of vitamin K is good for me while taking Coumadin (F)	.77	.42	.42	.57	1.91	2.85	
11. I should report any feelings of chills, fevers, or sore throat to the doctor (T)	.83	.37	.11	.16	0.23	0.96	x
12. Vitamin K helps Coumadin prevent blood clots (F)	.48	.50	.33	.41	1.29	3.23	
13. It is not safe to drink liquor while on this medicine, but I can have as much beer or wine as I want (F)	.85	.35	.11	.17	0.5	1.92	
14. Foods like fish, mineral water, and tomatoes are high in Vitamin K (F)	.69	.46	.31	.40	1.08	3.60	
15. I can eat any amount of collard greens as I want while taking Coumadin (F)	.92	.27	.27	.50	1.62	2.95	
16. I can take any kind of vitamins I want while I am on Coumadin (F)	.74	.44	.24	.33	0.7	2.80	
17. Indigestion is a side-effect of Coumadin (F)	.57	.50	.14	.19	0.52	2.60	
18. Bleeding from the gum after brushing my teeth is a side-effect of Coumadin (T)	.63	.49	.34	.42	0.69	3.00	
19. Swelling of the hands and feet is a side-effect of Coumadin (F)	.58	.50	.03	.04	0.1	0.53	x
20. Blue or purplish coloration of the skin is a side-effect of Coumadin (T)	.58	.49	.11	.13	0.3	1.50	
Test total score	72.86	14.36					

Abbreviation: KIP-C, Knowledge Information Profile–Coumadin.

^ar = Item–total correlation based on *r* point–biserial; *r_b* = item–total correlation based on biserial correlation.

^bTwo-parameter logistic model with 19 items.

^cItems omitted from final scale.

Table 3. Comparison of 1-Factor and 3-Factor IRT Models for the KIP-C14.

Two-Parameter IRT Models	-2 Log Likelihood	M ₂	df	P	RMSEA
One-factor model	2913.82	208.94	77	<.01	.09
Three-factor model	2821.48	96.49	74	.04	.04
Difference	92.34		3	<.01	

Abbreviations: IRT, item response theory; KIP-C, Knowledge Information Profile–Coumadin; RMSEA, root mean square error of approximation.

interesting. As shown in Table 5, all scales were negatively correlated with age; the correlations with income and education were positive except for the Other Foods, Beverages, and Medicine subscale, which was not significantly different from zero.

Discussion

Internal consistency reliability and test–test reliability of the KIP-C20 were both .63, lower than expected. The psychometric analysis determined that 6 items from the

Figure 1. Knowledge Information Profile–Coumadin (KIP-C14). Three-factor model with standardized factor loadings (SE) ($M_2 = 96.49$, $P < .0001$; RMSEA = .04).

Table 4. Scale Means (% Correct), Standard Deviations, and Reliability Estimates for the KIP-C20 and KIP-C14 Total Scale and Subscales^a.

KIP-C Scales	Mean (% Correct)	SD	Reliability α	Reliability Test–Retest
KIP-C14 Subscales				
Vitamin K	74.56	24.23	.62	.73
Side Effects	60.41	42.13	.65	.51
Other Foods, Beverages, and Medicine	65.19	25.22	.56	.56
Total KIP-C14	68.52	18.69	.65	.67
Total KIP-C20	72.86	14.37	.63	.63

Abbreviation: KIP-C, Knowledge Information Profile–Coumadin.

^aKIP-C14 is a 14-item scale. KIP-C20 is the original 20-item scale included for comparison.

KIP-C20 were not contributing to reliable test variance; these items were omitted. The shorter KIP-C14 scale had nearly identical, slightly higher, reliability than the KIP-C20. Knowledge tests with reliabilities this low are not uncommon in the health literacy literature.²¹

Low reliability can be due to characteristics of the sample. Low internal consistency reliability is a consequence of individual differences in what was learned at a given level of ability. With different exposures to information about warfarin oral anticoagulation therapy, variability in learning is understandable. Low reliability in test–retest is due to inconsistency in recall. Guessing at true/false questions decreases estimates of test–retest reliability.

Exploratory factor analysis of the KIP-C14 revealed 3 knowledge domains—*Vitamin K*, *Side Effects*, and *Other Foods, Beverages, and Medicine*. The reliabilities of these scales were similar to the overall scale reliability regardless

Table 5. Correlations of Knowledge Information Profile-Coumadin (KIP-C14) Scales With Demographic Variables, Literacy (REALM), and Length of Time Taking Coumadin.

KIP-C14 Scales	Age	Income	Education	REALM	Time on Coumadin
Subscales					
Vitamin K	-.16*	.15*	.26***	.37***	.09
Side Effects	-.21**	.24**	.17*	.14*	.04
Other Foods, Beverages, and Medicine Subscale	-.15*	.13	.07	.09	.23**
Total KIP-C14	-.25***	.23**	.24**	.30***	.19**

Abbreviations: REALM, Rapid Estimate of Adult Literacy in Medicine; KIP-C14 is a 14-item scale.

* $p < .05$, ** $p < .01$, *** $p < .001$.

of the smaller number of items on each scale. Low reliability within a knowledge domain indicates inconsistently remembered or fragmented knowledge. For example, factual knowledge about foods containing vitamin K and knowing that it would be risky to eat a large amount of greens is not connected until the principle is understood that a constant level of vitamin K in the diet is what is important.

Good support for construct validity was found with the KIP-C14 scale showing expected positive correlations with health literacy and years of Coumadin therapy. The correlation with health literacy accounted for only 9% of the variance in the KIP-C14 overall score. This small contribution indicates that while the KIP-C14 was correlated with health literacy, the major amount of reliability variance was not accounted for by health literacy alone. The KIP-C14 subscales were differentially correlated with health literacy and years of Coumadin therapy. Years of Coumadin therapy were correlated with the Other Foods, Beverages, and Medicine subscale but not with the Vitamin K subscale, indicating that years of Coumadin therapy alone are not likely to improve knowledge of vitamin K essential for safe and effective self-management of oral anticoagulation therapy. Age was consistently and negatively related to each of the KIP-C14 subscales. Because of the findings in the health literacy literature related to age, this relationship is also support for the instrument's construct validity.

The 3 KIP-C14 subscales—Vitamin K, Side Effects, and Other Foods, Beverages, and Medicine—were differentially correlated with age, income, and education. These differential relations support that the subscales are substantively different and not sample dependent. Because income, education, and reading ability are known to be related to general knowledge level,²² it is possible to speculate that the Vitamin K items and Side Effects items are more dependent on general knowledge and less dependent on specific experience with Coumadin. The items on the Other Foods,

Beverages, and Medicine subscale are not as easily connected by a theme as the items on the Vitamin K and Side Effects subscales.

As stressed earlier in this article, patients' knowledge about their anticoagulation therapy is critical to positive medication adherence, reduction in rehospitalizations, and successful anticoagulation therapy.²³ Although patients in this study showed improved knowledge with increasing time on Coumadin, less knowledge was gained on the Side Effects factor (eg, bleeding gums that don't stop easily or unusual bruising of the skin) and the Vitamin K factor (eg, knowledge of and adverse effects of eating foods high in vitamin K), information important for patients to know.

Scores on the KIP-C14 scales were surprising low for patients who have been taking Coumadin for an average of 4.8 years. This demonstrates a gap in fundamental health literacy knowledge essential to the safe self-management of oral anticoagulation therapy. The National Blood Clot Alliance¹ reported that Coumadin is the second most common drug, after insulin, implicated in emergency room visits. Use of the KIP-C14 will allow providers to conduct a basic evaluation of patient knowledge and, with that information, plan education strategies based on the patient's need.

The Side Effects factor was smaller than anticipated. Omitted items 11 and 19 (see Table 2) were clearly side effects questions that could have loaded here but did not load on any scale. Item difficulty does not seem to be an explanation because item 11 was low in difficulty and item 19 was high in difficulty. Furthermore, item 20, one of the only 2 that defined this factor, would have been omitted if conventional item selection criteria were used prior to dimensional analysis due to its low item-to-total correlation and nonsignificant slope. In the future, researchers who use the KIP-C14 should consider the addition of other side effects items. In this regard, the distinction between side effects that are expected and not of much concern versus those that require immediate attention should be considered.

The results presented here focused on data collected from participants at baseline and again 2 weeks later. It was very interesting to see such high agreement between internal consistency measures of reliability and test-retest reliability. It was somewhat surprising, then, that reliability was not higher than .65 for the total scale.

A patient characteristic addressed in this study was the participant's health literacy. The mean reading level was between 7th and 8th grade even though 78% had completed high school and 38% had some college. Literacy experts and researchers have reported a correlation between medication knowledge and adherence and the individual's literacy.^{6,24} It is important that patients with low literacy taking Coumadin are administered knowledge tests, such as the KIP-C14, and are given easy-to-read education materials

that are reading-level appropriate. Providers need accurate information about the patient's knowledge and understanding of medication so that patient education can be effective. One example of health information that meets the recommended standards of easy-to-read materials is the pamphlet and video about Coumadin titled *Blood Thinner Pills: Your Guide to Using Them Safely*, developed by the Agency for Healthcare Research and Quality.²⁵

Some limitations of the study should be noted. First, because low reliability can be due to sample characteristics, a more representative sample could be selected by using several clinics drawing from different social economic strata. Second, the pool of items used in this study could have been broader and more inclusive. For example, we had many questions about vitamin K but few about side effects and adherence. We did not directly ask about keeping vitamin K constant. Third is the need for more clinically relevant outcome data. It would have been informative to have outcomes such as rehospitalization, adherence, and clinical appointment keeping in addition to years of experience for construct validity. Fourth, the KIP-C14 focuses on assessing medication management knowledge for patients on Coumadin; future modification could include generalizability to newly FDA-approved anticoagulation medications such as dabigatran (Pradaxa), apixaban (Eliquis), and rivaroxaban (Xarelto). In summary, future research on developing measures of patient knowledge of Coumadin should consider a larger sample including different clinics, a broader range of items, more clinically relevant outcome variables, and generalizability to other anticoagulation medications.

Conclusions

The KIP-C14 had nearly identical, slightly higher reliability than the KIP-C20. Still, reliability was lower than expected and indicates a promising clinical assessment scale in need of further refinement.²⁶ Scores on the KIP-C14 scales revealed a surprising gap in fundamental health literacy knowledge essential to the safe self-management of oral anticoagulation therapy.

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