Original Investigation

The Wisconsin Predicting Patients' Relapse questionnaire

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Abstract

Introduction: Relapse is the most common smoking cessation outcome. Accurate prediction of relapse likelihood could be an important clinical tool used to influence treatment selection or duration. The aim of this research was to develop a brief clinical relapse proneness questionnaire to be used with smokers interested in quitting in a clinical setting where time is at a premium.

Methods: Diverse items assessing constructs shown in previous research to be related to relapse risk, such as nicotine dependence and self-efficacy, were evaluated to determine their independent contributions to relapse prediction. In an exploratory dataset, candidate items were assessed among smokers motivated to quit smoking who enrolled in one of three randomized controlled smoking cessation trials. A cross-validation dataset was used to compare the relative predictive power of the new instrument against the Fagerström Test for Nicotine Dependence (FTND) at 1-week, 8-week, and 6-month postquit assessments.

Results: We selected seven items with relatively nonoverlapping content for the Wisconsin Predicting Patient's Relapse (WI-PREPARE) measure, a brief, seven-item questionnaire that taps physical dependence, environmental factors, and individual difference characteristics. Cross-validation analyses suggested that the WI-PREPARE demonstrated a stronger prediction of relapse at 1-week and 8-week postquit assessments than the FTND and comparable prediction to the FTND at a 6-month postquit assessment.

Discussion: The WI-PREPARE is easy to score, suggests the nature of a patient's relapse risk, and predicts short- and medium-term relapse better than the FTND.

Introduction

Relapse ultimately claims the majority of those attempting to quit smoking (Fiore et al., 2000; Piasecki, Fiore, McCarthy, & Baker, 2002; Shiffman et al., 1986). Initially abruptly, but later, gradually and inexorably, the relapse rate rises across the postquit period, eventually claiming the majority of smokers who make a quit attempt (Brown, Lejuez, Kahler, Strong, & Zvolensky, 2005; Centers for Disease Control and Prevention [CDC], 2002; Kenford et al., 1994; Shiffman et al., 1986). In 2000, 15.7 million (41%) daily smokers quit for more than 1 day but only 4.7% maintained abstinence for 3–12 months (CDC, 2002). The ubiquity of relapse and the high costs associated with a return to regular smoking underscore the importance of understanding and assessing relapse proneness (e.g., Piasecki et al., 2000; 2006).

The ability to assess relapse proneness accurately in individuals wanting to quit smoking would be valuable for several reasons. Knowledge of the degree of relapse risk might help clinicians provide individuals with optimal treatments by identifying those in need of more aggressive interventions. Such interventions might include higher doses or longer durations of pharmacotherapy or more frequent or more intense psychosocial interventions. In addition, to the extent that relapse vulnerability could be attributed to particular risk factors, interventions could be targeted at specific relapse risk factors.

Considerable research shows that multiple factors predict the likelihood of relapse. For instance, relapse is related to measures of nicotine dependence (Breslau & Johnson, 2000; Piper, McCarthy, & Baker, 2006; Shiffman, Waters, & Hickcox, 2004), exposure to environmental smoking cues or opportunities to smoke (Garvey et al., 2000; Lee & Kahende, 2007), and person factors such as

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socioeconomic and educational status (Lee & Kahende, 2007), as well as motivation to quit and abstinence self-efficacy (Condiotte & Lichtenstein, 1981; Copeland & Brandon, 2000; Curry, Grothaus, & McBride, 1997; DiClemente, 1999; Gwaltney, Shiffman, Balabanis, & Paty, 2005; Gwaltney et al., 2001; Shiffman et al., 2000). Therefore, an empirical approach to questionnaire development should not be restricted to measuring a single dimension of risk (e.g., dependence). Rather, analyses of a large variety of measures should be conducted to determine which provide the strongest and most consistent predictors of relapse.

At an initial stage of this research, we compiled a broad range of measures that, on the basis of substantive and empirical grounds, we believed had the potential to influence relapse likelihood. Many of these measures were brief or single-item measures so as to reduce assessment burden. We sought to develop a clinical relapse proneness questionnaire that met two criteria. First, to be of greatest utility in a clinical setting where time is at a premium (Gilchrist et al., 1993; Stange et al., 1998), the ideal relapse proneness measure should be short and easy to use. A large number of items or complex scoring procedures are prohibitive in most clinical settings and in some research settings as well. Second, a new relapse proneness measure should possess predictive validity that is equal or superior to existing measures used to predict relapse. To the extent that relapse can be influenced by many (possibly weakly correlated) causes (Dijkstra & de Vries, 2000; Gulliver, Hughes, Solomon, & Dey, 1995; Kenford et al., 2002; Matheny & Weatherman, 1998; McCarthy, Zhou, & Hser, 2001; Piasecki et al., 2002), we should not expect the items to be internally consistent (Borsboom, Mellenbergh, & van Heerden, 2004). Indeed, we should seek less internal consistency to the degree that we desire each item to account for unique variance in relapse likelihood.

In sum, this questionnaire development method departs from the traditional approach in which multiple similar items are combined to assess a construct in a reliable manner (Nunnally & Bernstein, 1994; Wiggins, 1973). As noted by Borsboom et al. (2004), items that are highly correlated with one another can be useless for prediction due to multicollinearity (see also Lord & Novick, 1968). The traditional approach was relinquished because we wanted the questionnaire to be brief, we believed that individuals could reliably report on the basis of single items, and previous research showed that relapse reflected the contributions of multiple, often weakly correlated factors.

The Fagerström Test for Nicotine Dependence (FTND; Heatherton, Kozlowski, Frecker, & Fagerström, 1991; see also Fagerström, 1978), although developed as a measure of physical nicotine dependence, is probably the most frequently used measure of relapse proneness and physical dependence severity. Evidence suggests that the FTND can predict relapse and can be used to tailor pharmacotherapy (e.g., Alterman, Gariti, Cook, & Cnaan, 1999; Campbell, Prescott, & Tjeder-Burton, 1996; Patten, Martin, Calfas, Lento, & Wolter, 2001; West, 2005; Westman, Behm, Simel, & Rose, 1997; see also Fagerström & Schneider, 1989). However, these findings are not consistent (e.g., Borrelli, Spring, Niaura, Hitsman, & Papandonatos, 2001; Gilbert, Crauthers, Mooney, McClernon, & Jensen, 1999; Kenford et al., 1994; Procyshyn, Tse, Sin, & Flynn, 2002; Silagy, Mant, Fowler, & Lodge, 1994). Some data suggest that the lion's share of predictive validity is concentrated in only a subset of FTND items (e.g., the number of cigarettes smoked per day, time to first cigarette; Dale et al., 2001; Heatherton, Kozlowski, Frecker, Rickert, &

Robinson, 1989; Razavi et al., 1999; Shiffman, Dresler, Hajek, Gilburt, Targett, & Strahs, 2002; Transdisciplinary Tobacco Use Research Center [TTURC] Tobacco Dependence Phenotype Workgroup et al., 2007). Because the FTND is widely used and tends to predict relapse better than other measures (Breslau & Johnson, 2000; TTURC Tobacco Dependence Phenotype Workgroup et al., 2007), we used it as a comparison measure for the new relapse prediction assay. That is, one criterion for a new measure would be that it has equal or superior predictive validity in comparison to current practice. In addition, we wished to keep the scale brief and ensure that it would be easy to use. As noted earlier, relapse is multiply determined, and variables other than those assessed by the FTND may contribute to relapse prediction. The Wisconsin Predicting Patient's Relapse (WI-PREPARE) questionnaire is an attempt to assess briefly multiple-item domains that contribute to prediction.

In our approach to developing a measure of relapse proneness for clinical use, we started with the assumption that nicotine dependence measures would constitute a core or base element (e.g., Heatherton et al., 1991; Piasecki et al., 2002; Shiffman et al., 1986). This assumption was based on a great deal of previous research that showed that at least some elements of measures of nicotine dependence possessed substantial predictive validity. Thus, we included items that assessed smoking heaviness and strength of urges upon awakening (i.e., withdrawal after overnight deprivation). Using theoretical models of relapse (Piasecki et al., 2002; Shiffman et al., 1986), we then systematically examined other factors or domains that were theoretically linked to relapse but not highly correlated or redundant with physical dependence, for example, external events such as stressors and temptations (Piasecki et al., 2002; Shiffman et al., 1986) and environmental factors such as the presence of smokers in an individual's environment or social network (e.g., Derby, Lasater, Vass, Gonzalez, & Carleton, 1994 [in women only]; Garvey et al., 2000; Mermelstein, Cohen, Lichtenstein, Baer, & Kamarck, 1986; Osler & Prescott, 2001). We determined whether items tapping this social–environmental domain incrementally improved predictive validity beyond that of nicotine dependence items alone. In addition, we determined whether many other types of measures contributed to relapse prediction (see Appendix A). The research described below addresses the ability of a brief questionnaire tapping physical dependence, environmental factors, and individual difference characteristics to predict short- and long-term relapse.

Methods

The goal of this research is the identification of a small number of items that collectively function in an effective way to predict relapse following a quit attempt. This secondary data analysis was based on data derived from three randomized, double-blind placebo-controlled clinical trials of smoking cessation treatments. The total sample ($N = 1,481$) was randomly split into two datasets each containing 703 respondents, after removing individuals with missing data, thus allowing for an initial exploratory search of predictive items using one dataset followed by a cross validation of the resulting scale using the second dataset.

Participants

Sample one. In this study, 608 adult smokers were randomly assigned to one of three experimental conditions: (a) bupropion

SR (150 mg, twice daily) and 4-mg nicotine gum, (b) bupropion SR and placebo gum, or (c) placebo bupropion and placebo gum. All participants also received three 10-min individual counseling sessions. Pharmacotherapy began 1-week prequit and lasted 8 weeks postquit. To be eligible, participants had to report smoking at least 10 cigarettes/day, have an expired carbon monoxide (CO) reading of greater than 9 parts per million (ppm), report being motivated to quit smoking, and meet medical and psychiatric inclusion criteria (e.g., no contraindications for bupropion, such as high blood pressure or alcohol dependence). For demographic and smoking history information, see Table 1.

Sample two. In this study, 463 adult smokers were randomized to one of four experimental conditions: (a) active bupropion SR (150 mg, twice daily) and counseling, (b) active bupropion SR without counseling, (c) placebo bupropion SR and counseling, and (d) placebo bupropion SR without counseling. Counseling consisted of two prequit and six postquit 10-min individual sessions in the first month after the quit date. Pharmacotherapy started 1-week prequit and continued for 8 weeks postquit. Table 1 provides demographic and smoking history information for these participants. Eligibility criteria were the same as for sample one.

Sample three. In this study, 410 adult smokers were randomly assigned to one of four experimental conditions: (a) nicotine lozenge (2 or 4 mg) and quitline services, (b) nicotine lozenge (2 or 4 mg) and a self-help brochure, (c) nicotine gum (2 mg) and quitline services, or (d) nicotine gum (2 mg) and a self-help brochure. The quitline services consisted of four telephone counseling sessions, initiated by the quitline. The self-help brochure was the 2000 U.S. Public Health Service "You Can Quit" brochure. Pharmacotherapy started 1-week prequit and continued for 8 weeks postquit. Table 1 provides demographic and smoking history information for these participants. Eligibility criteria were the same as for sample one.

Procedure

The procedures for the three studies were similar. Participants attended an orientation session, at which they learned about the study and provided written informed consent. Participants then attended assessment sessions, during which they were screened for eligibility and completed a series of questionnaires (described in the Measures section). Eligible individuals were then randomized to a treatment group. Participants completed the treatment phase and were followed-up monthly after treatment to assess continuous and 1-week point prevalence abstinence. Individuals who reported point prevalence abstinence at 6 months were invited to come back to the clinic for a CO test to confirm their abstinence.

Measures

Demographics and smoking history. A demographics questionnaire assessed characteristics such as gender, ethnicity, age, marital status, education level, and employment. The Smoking History Questionnaire included items such as the number of cigarettes smoked per day, age at smoking initiation, number of quit attempts, longest time abstinent after smoking initiation, and presence of other smokers in the household.

Direct Assay of Dependence Criteria. The Direct Assay of Dependence Criteria comprised 14 items designed to assess three nicotine dependence–related constructs: relapse likelihood, withdrawal symptoms, and cigarette self-administration. Each item was answered on a 7-point Likert scale. This measure was developed by the study authors for use in the clinical trials described earlier.

Fagerström Test for Nicotine Dependence. The FTND (Heatherton et al., 1991) is a six-item scale designed to measure physical dependence. Each item has its own individual response scale that varies by item. The FTND is a revision of the original Fagerström Tolerance Questionnaire and has fair internal consistency ($\alpha = .61$; Heatherton et al., 1991).

Nicotine Dependence Syndrome Scale. The Nicotine Dependence Syndrome Scale (NDSS; Shiffman et al., 2004) is a self-report measure designed to assess various dimensions of nicotine dependence. It consists of 19 items that load onto five different subscales: drive ($\alpha = .76$), priority ($\alpha = .69$), tolerance ($\alpha = .55$), continuity ($\alpha = .63$), and stereotypy ($\alpha = .70$); total internal consistency is .84 (Shiffman & Sayette, 2005).

Table 1. Demographic information

	Sample one ($n = 608$)		Sample two ($n = 463$)		Sample three ($n = 410$)	
	Number of subjects	%	Number of subjects	%	Number of subjects	%
Women	352	57.9	233	50.3	224	55.4
Hispanic	10	1.6	5	1.1	9	2.2
White	449	76.0	414	90.8	281	71.3
Black	130	22.0	25	5.5	102	25.9
Married	283	46.5	198	40.3	143	35.5
High school education only	186	30.7	104	22.6	122	30.4
Employed for wages	414	69.2	332	73.0	233	56.8
Household income <US$25,000	174	29.2	141	30.1	167	41.6
Household income $50,000 or greater	208	34.9	154	33.9	100	24.9
	M	SD	M	SD	M	SD
Age at first cigarette, years	13.83	3.95	13.80	3.83	14.33	4.15
Number of cigarettes smoked per day	22.44	9.87	21.93	10.44	23.11	9.86
Number of previous quit attempts	6.06	13.28	5.96	10.54	4.58	8.07
Carbon monoxide level, parts per million	27.11	11.69	24.51	11.80	27.36	11.52

Positive and Negative Affect Schedule. The Positive and Negative Affect Schedule (PANAS; Watson, Clark, & Tellegen, 1988) is a self-report measure designed to assess positive and negative affect. It consists of 20 adjectives used to describe emotions (10 positive and 10 negative), and individuals are asked to rate, on a scale of 1–5, how much they felt each of these emotions during the past 24 hr.

Tobacco Dependence Screener. The Tobacco Dependence Screener (TDS; Kawakami, Takatsuka, Inaba, & Shimizu, 1999) is a self-report measure designed to assess 10 of the *DSM-IV* criteria for tobacco dependence; 0 indicates lack of the symptom and 1 indicates endorsement. The sum of symptoms, from 0–10, allows for a fairly continuous measure of dependence. The TDS has shown good internal consistency (alpha values ranging from .76 to .81 across three studies; Kawakami et al., 1999). TDS scores also were significantly correlated with number of cigarettes smoked per day, years smoking, and CO levels.

Wisconsin Inventory of Smoking Dependence Motives. The Wisconsin Inventory of Smoking Dependence Motives (WISDM-68; Piper et al., 2004) comprises 68 items designed to assess 13 different theoretically derived motivational domains. Each item is answered on a 7-point Likert scale ranging from 1 = "not true of me at all" to 7 = "extremely true of me." The subscales demonstrated good internal consistency (α = .88–.94) in samples one and two.

Wisconsin Smoking Withdrawal Scale. The Wisconsin Smoking Withdrawal Scale (WSWS; Welsch et al., 1999) is a 28-item scale that assesses seven different withdrawal symptoms (anger, anxiety, difficulty concentrating, craving, hunger, sadness, and sleep). Each item is answered on a 5-point Likert scale ranging from 1 = "strongly disagree" to 5 = "strongly agree."

Data analyses

Item responses from all the measures described here were used in analyses (see Appendix A). These items assessed a range of constructs thought to be related to relapse that might augment assessment of current dependence, including history of use, smoking in the environment, self-efficacy, withdrawal, affect, and demographics. The collective pool of items across surveys yielded a total of 211 possible items for development of the WI-PREPARE.

Results

Exploratory analyses

In exploratory analyses, stepwise logistic regression analyses were performed in which the outcome (relapse 8 weeks following the quit attempt) was modeled with respect to all the items from the various survey instruments described in the Data analyses section. This timepoint was selected because it captures a midpoint in the postquit period and is a time when predictors still have strong predictive validity (prediction models tend to lose predictive validity as the prediction interval grows increasingly long). Items were entered individually as predictors based on the magnitude of their corresponding Wald statistics; items were entered until no remaining item in the collective pool yielded a statistically significant ($p < .05$) Wald statistic. Items were entered in this way to identify a small item set that not only would be

predictive of relapse but also would consist of items that were nonoverlapping in accounting for likelihood of relapse.

Once the stepwise logistic regression procedure was completed, the process was repeated, now omitting from the collective pool of potential predictors those items that had been entered previously as predictors in the first logistic regression. The result of this second analysis is a second item set predictive of relapse, likely possessing substantial overlap with the first item set. This process was repeated a total of four times, each time omitting items that had been identified as significant predictors in all prior analyses. In the end, 26 items were identified as predictors of relapse across the five analyses. The purpose of iteratively repeating the analysis was to lend greater insight into the underlying characteristics of the items that made them important predictors of relapse. Items associated with common factors measured by other significant predictors were viewed as being more likely to yield significance in the cross-validation analysis.

The responses to the 26 items were next analyzed using exploratory factor analysis. A maximum likelihood solution was obtained and interpreted following Promax rotation. Several common factors emerged, most notably factors related to "morning smoking," "strength of cravings," "environmental smoking," and "number of cigarettes smoked."

The items for the final WI-PREPARE were selected based on two criteria: (a) measurement of a common factor and (b) magnitude of Wald statistic in logistic regression analysis. For each common factor, only the item with the highest factor loading was chosen as a representative of the factor. A total of seven items were selected for the WI-PREPARE, including four items representing the factors identified above—FTND item 1 as a "morning smoking" item, WISDM-68 item 49 as a "strength of cravings" item, WISDM-68 item 22 as an "environmental smoking" item, FTND item 4 as a "number of cigarettes smoked item"—and three items that displayed high Wald statistics despite not loading on a common factor (Smoking History Questionnaire items regarding smoking restrictions at home and work and a demographic item related to education level). For the items and responses, see Appendix B.

Items not included in the final questionnaire did not contribute meaningful predictive validity relative to the other items already in the final item set. This includes seemingly important items addressing self-appraisal of addiction, self-efficacy/outcome expectancy, smoking reinforcement appraisal/expectancies (multiple dimensions), withdrawal severity (multiple dimensions), and depression history, for example (see Appendix A). Therefore, each item was tested against the entire pool of other items. The items not included were not significantly related to outcomes, or their predictive validity overlapped considerably with that of other items.

Another analysis was used to determine a strategy for scoring the items. The magnitude of the logistic regression coefficients for three items, specifically, FTND items regarding time to first cigarette and cigarettes per day, and the demographic item related to education level, relative to their item score range, were generally higher than those of the other items. Thus, to maximize the predictive power of the total sum score across items, these three items were effectively weighted more heavily by introducing a wider range of score values to these three items. FTND items 1 and 4 were scored using the same traditional scoring as on the FTND

(0–3), whereas the education level item was scored as 0, 1, or 2, corresponding to education levels of less than a high school degree (2), high school degree or equivalent (1), and some college experience (0). The education level item is scored in reverse direction to be consistent with its predictive effects on relapse. The remaining four items were scored as binary (see Appendix B).

Cross-validation analyses

To evaluate the effectiveness of the WI-PREPARE constructed using the exploratory analyses and the derivation sample, a series of cross-validation analyses were conducted using the second sample of 703 respondents. In this validation sample, the average WI-PREPARE score was 6.16 ($SD = 2.29$). The predictive validity of the WI-PREPARE was compared against that of the FTND. Because two of the FTND items are included in the WI-PREPARE, the comparison performed here was ultimately concerned with the relative value of the five non-FTND items introduced to the WI-PREPARE against the four FTND items not included in the WI-PREPARE (i.e., FTND items 2, 3, 5, and 6). The FTND items not included in the WI-PREPARE are displayed in Table 2.

Table 3 reports results from logistic regression analyses predicting abstinence from smoking 1 week, 8 weeks, and 6 months postquit as a function of either the FTND total score or the WI-PREPARE total score in the cross-validation sample. The item scoring approach determined from the exploratory analysis (shown in Appendix B) was applied for the WI-PREPARE analysis; the traditional scoring approach was used for the FTND. For each abstinence outcome, statistical significance was achieved for each form. The amount of prediction, as assessed by the Nagelkerke R^2, was consistently highest for assessing short-term abstinence. We compared the incremental validity of the non-FTND item score (the sum of WI-PREPARE items 1, 2, 3, 4, and 7) after the FTND was first entered as a predictor of abstinence. Results revealed that the novel WI-PREPARE items significantly incremented prediction of relapse at 1 week postquit ($\chi^2 = 39.19$, $p < .01$) and at 8 weeks postquit ($\chi^2 = 40.33$, $p < .01$) but not at 6 months postquit ($\chi^2 = 2.08$, $p = .15$).

Table 2. FTND items 2, 3, 5, and 6

FTND items	Item stem	Item scoring
2	Do you find it difficult to refrain from smoking in places where it is forbidden, i.e., in church, at the library, in a cinema, etc.?	
	No	=0
	Yes	=1
3	Which cigarette would you hate most to give up?	
	First in the morning	=1
	Any other	=0
5	Do you smoke more frequently during the first hours after waking than during the rest of the day?	
	No	=0
	Yes	=1
6	Do you smoke when you are so ill that you are in bed most of the day?	
	No	=0
	Yes	=1

Pharmacotherapy produced the only significant treatment effect in each of the three studies. When active pharmacotherapy was included as a control variable, the pattern of results was similar (although overall R^2 values increased due to treatment effects). We also examined the ability of other dependence measures, specifically the WISDM and NDSS, to predict relapse likelihood. The WISDM total predicted relapse only at 1 week postquit, and the NDSS total predicted relapse at both 1 week and end of treatment. However, even when the WISDM or the NDSS were significant predictors of relapse, the amount of prediction, as assessed by the Nagelkerke R^2, was minimal.

To further explore the relative contributions of individual items to the prediction observed in Table 3, additional logistic regression analyses were performed in which each item was entered as a separate predictor. Tables 4–6 display results for the 1-week, 8-week, and 6-month abstinence outcomes, respectively. Wald statistics are reported for each item entered as the sole predictor of the relapse outcome and for each item when entered with all other items. In each case, separate analyses were performed for the FTND and WI-PREPARE items. At both 1 week and 8 weeks postquit, virtually all items on both the FTND and the WI-PREPARE displayed significant prediction when entered as sole predictors. The exceptions were FTND item 6 (Do you smoke when you are so ill that you are in bed most of the day?) and WI-PREPARE item 3 (I'm around smokers much of the time), neither of which was a significant predictor at 1 week. When all items from each form were entered simultaneously, fewer displayed statistical significance, particularly at 8 weeks, which can be attributed in part to the overlap of variance they explained. However, the regression coefficients were generally in the expected direction. In addition, the Nagelkerke R^2 values were consistent with those observed when using the total score as predictor, with the WI-PREPARE items consistently providing better prediction than the FTND. The strongest contributor to this improvement appeared to be the education variable, which displayed a Wald statistic even greater than that observed for FTND item 1. Again, results were similar after controlling for active pharmacotherapy treatment.

At 6 months postquit, the predictive effects of all items on both the FTND and the WI-PREPARE were substantially eroded (see Table 6). In both cases, FTND item 1 was the sole significant predictor when all items were entered simultaneously, although the education variable was found to be statistically related to abstinence at 6 months in the univariate logistic regression analysis. With all other items in the model, however, the Wald statistic was nonsignificant.

The FTND has a suggested cutoff score of 0–4 for low dependence and 5 or greater for high dependence (Fagerström, Heatherton, & Kozlowski, 1991). Results from our cross-validation logistic regression analysis suggest that scores of 4 imply relapse rates of approximately 50% eight weeks after a quit attempt; scores of 7 imply relapse rates of approximately 75%. However, larger and more diverse samples may be needed to make confident interpretations of the WI-PREPARE score scale.

Discussion

Using data from three randomized controlled clinical trials of smoking cessation, we identified several specific factors related to relapse, including morning smoking, strength of cravings,

Table 3. Logistic regression results using FTND and WI-PREPARE total scores as predictors, cross-validation analysis

Outcome	FTND				WI-PREPARE			
	b (OR)	Wald	p value	Nagelkerke R^2	b (OR)	Wald	p value	Nagelkerke R^2
1 week postquit abstinence	−.26 (0.77)	45.72	<.001	.094	−.35 (0.71)	73.75	<.001	.160
8 weeks postquit abstinence	−.22 (0.80)	32.97	<.001	.068	−.32 (0.73)	61.77	<.001	.133
6 months postquit abstinence	−.14 (0.87)	9.36	.002	.023	−.15 (0.86)	11.46	.001	.028

Note. FTND, Fagerström Test for Nicotine Dependence; WI-PREPARE, Wisconsin Predicting Patients' Relapse. Odds ratio (OR) indicates the change in likelihood of abstinence for each unit of change in the independent variable. The ORs for the FTND and the WI-PREPARE are not directly comparable.

environmental smoking, and number of cigarettes smoked. From these factors, we selected seven items with relatively non-overlapping content that were found to yield relatively strong predictions of relapse as individual items. The combination of these items, which we have labeled the WI-PREPARE, is short and easy to score and it predicts short- and long-term relapse as well as or better than the FTND among smokers interested in quitting. Recent data show that the time to first cigarette item is the key FTND predictor of relapse (TTURC Tobacco Dependence Phenotype Workgroup et al., 2007). The WI-PREPARE uses the FTND item 1 as well as additional items that augment the prediction of short-term relapse.

These results indicate that, although the FTND assessment of nicotine dependence was predictive of relapse, a combination of relatively independent content domains, as seen in the WI-PREPARE, results in superior relapse prediction. This improved prediction is consistent with other evidence that relapse is influenced by multiple factors, including smoking characteristics (e.g., physical dependence), individual characteristics (e.g., edu-

cation), and environmental influences (e.g., smokers in the environment; Lee & Kahende, 2007).

Prediction with both the FTND and the WI-PREPARE decreased greatly by 6 months postquit. This finding may reflect the contributions to relapse of several types of factors that are difficult to measure with the single administration of a questionnaire early in a quit attempt. For example, some factors might be assessed accurately when the questionnaire is administered but become less relevant over time. Whereas the FTND or the WI-PREPARE may measure nicotine dependence accurately, dependence level per se may change substantially with the passage of time since the quit date. This would make dependence-related processes such as withdrawal relatively moot in predicting relapse at 5 or 6 months postquit. Similarly, contextual features such as smoking restrictions also might change over time. Whereas early relapses may reflect the influence of measurable dimensions such as dependence, later relapses may reflect somewhat random, stochastic processes (fortuitous exposure to a stressor, fluctuations in self-efficacy; Gwaltney et

Table 4. Logistic regression results using FTND and WI-PREPARE item scores as predictors of abstinence, 1 week postquit, cross-validation analysis

	Single-item predictions			Multiple-item predictions		
	b (OR)	Wald	p value	b (OR)	Wald	p value
FTND						
1. Time to first cigarette in the morning	−.611 (0.543)	42.10	<.001	−.469 (0.625)	17.45	<.001
2. Smoking where it is forbidden	−.726 (0.484)	12.78	<.001	−.477 (0.621)	4.71	.030
3. Cigarette most hate to give up	−.401 (0.669)	5.94	.015	.026 (1.027)	0.02	.892
4. Number of cigarettes per day	−.483 (0.617)	21.57	<.001	−.240 (0.787)	4.38	.036
5. Smoke more in the morning	−.676 (0.509)	17.38	<.001	−.276 (0.758)	2.10	.147
6. Smoke when ill	−.308 (0.735)	3.72	.054	.135 (1.144)	0.57	.450
Nagelkerke R^2						.111
WI-PREPARE						
1. Household smoking restriction	−.549 (0.577)	11.73	.001	−.325 (0.723)	3.20	.074
2. Work smoking restriction	−.743 (0.476)	21.50	<.001	−.593 (0.553)	11.40	.001
3. Smokers in environment	−.140 (0.869)	0.70	.403	.062 (1.064)	0.11	.737
4. Craving	−.447 (0.639)	7.36	.007	−.127 (0.880)	0.47	.494
5. Time to first cigarette in the morning	−.611 (0.543)	45.11	<.001	−.399 (0.671)	13.47	<.001
6. Number of cigarettes per day	−.483 (0.617)	22.23	<.001	−.196 (0.822)	2.65	.103
7. Education	−.959 (0.383)	55.45	<.001	−.799 (0.450)	33.13	<.001
Nagelkerke R^2						.199

Note. FTND, Fagerström Test for Nicotine Dependence; WI-PREPARE, Wisconsin Predicting Patients' Relapse. Odds ratio (OR) indicates the change in likelihood of abstinence for each unit of change in the independent variable. The ORs for the FTND and the WI-PREPARE are not directly comparable.

Table 5. Logistic regression results using FTND and WI-PREPARE item scores as predictors of abstinence, 8 weeks postquit, cross-validation analysis

	Single-item predictions			Multiple-item predictions		
	b (OR)	Wald	p value	b (OR)	Wald	p value
FTND						
1. Time to first cigarette in the morning	−.596 (0.551)	42.43	<.001	−.541 (0.582)	22.64	<.001
2. Smoking where it is forbidden	−.514 (0.598)	6.55	.011	−.318 (0.728)	2.13	.145
3. Cigarette most hate to give up	−.486 (0.615)	8.47	.004	−.164 (0.849)	.71	.398
4. Number of cigarettes per day	−.308 (0.735)	9.15	.002	−.061 (0.941)	.29	.593
5. Smoke more in the morning	−.436 (0.647)	7.14	.008	.065 (1.067)	.11	.737
6. Smoke when ill	−.342 (0.710)	4.42	.035	.018 (1.018)	.01	.919
Nagelkerke R^2						.087
WI-PREPARE						
1. Household smoking restriction	−.528 (0.590)	10.51	.001	−.276 (0.759)	2.29	.130
2. Work smoking restriction	−.486 (0.615)	9.00	.003	−.336 (0.715)	3.60	.058
3. Smokers in environment	−.455 (0.635)	6.79	.009	−.331 (0.718)	3.12	.077
4. Craving	−.451 (0.637)	7.20	.007	−.157 (0.855)	.70	.402
5. Time to first cigarette in the morning	−.596 (0.551)	42.43	<.001	−.442 (0.643)	16.35	<.001
6. Number of cigarettes per day	−.308 (0.735)	9.15	.002	.010 (1.010)	.01	.936
7. Education	−.921 (0.398)	49.27	<.001	−.767 (0.464)	29.86	<.001
Nagelkerke R^2						.171

Note. FTND, Fagerström Test for Nicotine Dependence; WI-PREPARE, Wisconsin Predicting Patients' Relapse. Odds ratio (OR) indicates the change in likelihood of abstinence for each unit of change in the independent variable. The ORs for the FTND and the WI-PREPARE are not directly comparable.

al., 2005) that would be almost impossible to predict via a static measure applied months earlier. Finally, late relapse may be influenced by progressive phenomena that occur at measurable levels only late in the postquit period (e.g., quitting fatigue; Piasecki et al., 2002). Such factors would be difficult to measure accurately prior to their development.

A potential advantage of using the WI-PREPARE is that its content domains might be relevant to treatment planning. For instance, individuals who report heavy smoking, early morning smoking, and strong craving may especially benefit from higher doses or longer term pharmacotherapy (Herrera et al., 1995; Shiffman et al., 2002; but see also Garvey et al., 2000). Individuals

Table 6. Logistic regression results using FTND and WI-PREPARE item scores as predictors of abstinence, 6 months postquit, cross-validation analysis.

	Single-item predictions			Multiple-item predictions		
	b (OR)	Wald	p value	b (OR)	Wald	p value
FTND						
1. Time to first cigarette in the morning	−.348 (0.706)	10.24	.001	−.297 (0.743)	4.87	.027
2. Smoking where it is forbidden	−.444 (0.642)	2.98	.086	−.324 (0.724)	1.39	.239
3. Cigarette most hate to give up	−.274 (0.760)	1.75	.187	−.073 (0.929)	0.10	.758
4. Number of cigarettes per day	−.263 (0.769)	4.20	.040	−.119 (0.887)	0.71	.401
5. Smoke more in the morning	−.299 (0.741)	2.16	.143	−.004 (0.996)	0.00	.987
6. Smoke when ill	−.114 (0.892)	0.31	.576	.156 (1.169)	0.50	.478
Nagelkerke R^2						.030
WI-PREPARE						
1. Household smoking restriction	−.261 (0.770)	1.64	.200	−.056 (0.946)	0.07	.799
2. Work smoking restriction	−.120 (0.887)	0.35	.555	.005 (1.005)	.00	.981
3. Smokers in environment	−.189 (0.828)	0.76	.384	−.124 (0.883)	0.31	.576
4. Craving	−.097 (0.907)	0.22	.640	.134 (1.143)	0.36	.546
5. Time to first cigarette in the morning	−.348 (0.706)	10.03	.002	−.266 (0.767)	4.43	.035
6. Number of cigarettes per day	−.263 (0.769)	4.17	.041	−.141 (0.868)	0.96	.327
7. Education	−.380 (0.684)	6.09	.014	−.299 (0.742)	3.52	.061
Nagelkerke R^2						.036

Note. FTND, Fagerström Test for Nicotine Dependence; WI-PREPARE, Wisconsin Predicting Patients' Relapse. Odds ratio (OR) indicates the change in likelihood of abstinence for each unit of change in the independent variable. The ORs for the FTND and the WI-PREPARE are not directly comparable.

reporting considerable exposure to either smoking cues or other smokers may benefit from behavioral changes to reduce these exposures. This might include creating a smoke-free home or discussing with other smokers in the environment how to minimize exposure to cues such as cigarettes, lighters, ashtrays, and the like.

We are unsure how to interpret the finding that individuals with lower levels of education are more likely to relapse. Research has shown that education is related to factors that may affect cessation success, including whether cessation advice is offered at doctors' visits and consistent health care services are available (Frazier et al., 2001; Houston, Scarinci, Person, & Greene, 2005), whether individuals can be reached to schedule treatment (Macken, Wilder, Mersy, & Madlon-Kay, 1991), exposure to financial and other stress (De Vogli & Santinello, 2005; McKee, Maciejewski, Falba, & Mazure, 2003; Siahpush & Carlin, 2006), living with smokers or having a partner who smokes (Chandola, Head, & Bartley, 2004; Graham, Inskip, Francis, & Harman, 2006; Honjo, Tsutsumi, Kawachi, & Kawakami, 2006), others smoking at work or in one's peer group, (Honjo et al., 2006), and having a blue collar job (Sorensen, Gupta, & Pednekar, 2005). Thus, a person's educational status may indicate not only their ability to understand treatment materials (which should be at an appropriate reading level) but also their access to treatment, exposure to stressful events, and exposure to other tobacco smokers. Future research may reveal associations between education level and causal paths to relapse. At present, the WI-PREPARE merely informs clinicians of the risk posed by this variable.

Although the present study supports the use of the WI-PRE-PARE for predicting relapse, some limitations and concerns need to be addressed with future research. First, this measure was designed to be short and easy to use in a clinical setting, but it was developed in the context of placebo-controlled, randomized clinical trials. Therefore, the results need to be replicated in broader populations of smokers (i.e., other than those who volunteer for intensive experimental cessation treatments) because they may not generalize beyond smokers who are strongly motivated to quit. Second, although the predictive validity of this measure has been evaluated across three clinical trials that differed in ethnic composition of the samples, all three trials were from the same region of the country. Therefore, these findings need to be replicated in other areas, with additional populations, to support their external validity. Third, the WI-PREPARE was developed using secondary data analysis of clinical trial data, and the final seven WI-PREPARE items have never been administered together as a cohesive questionnaire. The psychometric characteristics of the items might change when all items are presented together on a single form. Fourth, future research is needed to determine whether the WI-PREPARE can predict relapse in the context of different treatments, either different pharmacotherapies or different psychosocial interventions. Further, it is possible that other sorts of items (e.g., motivation) or broader assessment of certain constructs (e.g., self-efficacy) also might improve the predictive validity of the WI-PREPARE. In the present study, however, all participants were screened for motivation to quit. Therefore, the range of motivation was truncated, and such items were not included among candidate items. In sum, the WI-PREPARE needs further testing, to compare it with other sorts of relapse predictors, to test it in additional populations, and to include other assessment domains to improve its validity. Until then, the WI-PREPARE must be viewed as a promising instrument that may benefit from further validation research. Finally, although

the WI-PREPARE might be useful for treatment planning, no data exist that reveal its effectiveness for this purpose.

With the development of the WI-PREPARE, researchers and clinicians now have at their disposal a brief, seven-item measure of relapse proneness that is effective for predicting both short- and long-term relapse among smokers interested in quitting. In addition, the content domains may help provide further insight into the problem of relapse and how to prevent it.

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Appendix A. Items examined for inclusion in the WI-PREPARE

Item	Source
Age	Demographics
Gender	Demographics
Hispanic ethnicity	Demographics
Marital status	Demographics
Household income	Demographics
Would you say that in general your health is …?	Demographics
Have you ever been diagnosed with depression, treated for depression, or had significant problems with depression?	Demographics
Education	Demographics
How motivated are you to stop smoking at this time	Telephone screen
How old were you the first time you smoked a cigarette, even one or two puffs?	Smoking history
Have you smoked at least 100 cigarettes in your entire life?	Smoking history
How old were you when you first started smoking daily/every day?	Smoking history
What is the total number of years you have smoked daily? Do not include any time you stayed off cigarettes for at least 6 months or longer.	Smoking history
How often do you now smoke cigarettes?	Smoking history
On average, about how many cigarettes do you currently smoke per day?	Smoking history
For how long have you been smoking this much?	Smoking history
Which of the following best describes your pipe smoking?	Smoking history
Which of the following best describes your cigar smoking?	Smoking history
Which of the following best describes your use of smokeless tobacco?	Smoking history
Do you currently live with a spouse or partner who smokes cigarettes?	Smoking history
Do any of the other people that you currently live with, other than a partner, or spouse, smoke cigarettes?	Smoking history
How many of your friends smoke or use tobacco?	Smoking history
If someone in your household wants to smoke, does he/she have to leave in order to smoke?	Smoking history
Which of these statements best describes your place of work's smoking policy for work areas?	Smoking history
How you ever tried to quit smoking?	Smoking history
How many times have you tried to quit smoking?	Smoking history
How long has it been since you last tried to quit smoking?	Smoking history
What method did you use when you last tried to quit smoking?	Smoking history
After you started smoking regularly, what is the longest time you ever went without smoking?	Smoking history
The last time you tried to quit smoking, why did you try to quit?	Smoking history
How addicted to cigarettes are you?	Direct Assay of Dependence Criteria
If you tried to quit smoking, how likely is it that you would succeed?	Direct Assay of Dependence Criteria
How strong are your urges when you first wake up in the morning?	Direct Assay of Dependence Criteria
On average, how long can you go without smoking before you have strong urges?	Direct Assay of Dependence Criteria
I have unpleasant feelings and moods if I go without smoking for a long time.	Direct Assay of Dependence Criteria
How difficult is it for you to not smoke when you have strong urges to smoke?	Direct Assay of Dependence Criteria
On average, how many cigarettes do you smoke each day?	Direct Assay of Dependence Criteria
How much does smoking provide immediate relief for your withdrawal symptoms?	Direct Assay of Dependence Criteria
If I am out of cigarettes I will drop everything to get more.	Direct Assay of Dependence Criteria
On average how long do you go between cigarettes?	Direct Assay of Dependence Criteria
After you wake up in the morning, how much do you have to smoke to feel comfortable?	Direct Assay of Dependence Criteria
6 FTND items	Fagerström Test for Nicotine Dependence
10 TDS items (tap *DSM* nicotine dependence criteria)	Tobacco Dependence Screener
28 WSWS items	Wisconsin Smoking Withdrawal Scale
20 PANAS items	Positive and Negative Affect Scale
19 NDSS items	Nicotine Dependence Syndrome Scale
68 WISDM items	Wisconsin Inventory of Smoking Dependence Motives

Appendix B. The WI-PREPARE and scoring key

Please answer the questions below using the responses listed.

1. If someone in your household wants to smoke, does he/she have to leave in order to smoke?

    Yes   No

2. Which of these statements best describes your place of work's smoking policy for work areas?

    - Smoking is not allowed in any work areas
    - Smoking is allowed in some work areas
    - Smoking is allowed in all work areas
    - N/A, I do not work outside the home

3. I'm around smokers much of the time.

    Not true at all   Extremely true of me
          1   2   3   4   5   6   7

4. When I haven't been able to smoke for a few hours, the craving gets intolerable.

    Not true at all   Extremely true of me
          1   2   3   4   5   6   7

5. How soon after you wake up do you smoke?

    - After 60 minutes
    - 31–60 minutes
    - 6–30 minutes
    - Within 5 minutes

6. How many cigarettes a day do you smoke?

    - 10 or less
    - 11–20
    - 21–30
    - 31 or more

7. What is the highest grade or year of school that you completed?

    - Never attended, or only attended kindergarten
    - Grades 1–8 (elementary)
    - Grades 9–11 (some high school)
    - Grade 12 or GED (high school graduate)
    - College 1 to 3 years (some college or technical school)
    - College 4 years or more (4-year college graduate)

Questions 1 and 2 came from the Smoking History Questionnaire, questions 3 and 4 came from the WISDM, questions 5 and 6 came from the FTND, and question 7 came from the demographics questionnaire.

Sum all items to create a total score using the key below.

Item	Scoring
1	No = 1
	Yes = 2
2	Smoking is not allowed in any work areas = 0
	Smoking is allowed in some work areas = 1
	Smoking is allowed in all work areas = 1
	N/A, I do not work outside the home = 1
3	1–4 = 0
	5–7 = 1
4	1–4 = 0
	5–7 = 1
5	After 60 min = 0
	31–60 min = 1
	6–30 min = 2
	Within 5 min = 3
6	10 or less = 0
	11–20 = 1
	21–30 = 2
	31 or more = 3
7	Never attended, or only attended kindergarten = 2
	Grades 1–8 (elementary) = 2
	Grades 9–11 (some high school) = 2
	Grade 12 or GED (high school graduate) = 1
	College 1–3 years (some college or technical school) = 0
	College 4 years or more (4-year college graduate) = 0