

Patient Interpretation of Neuropathy (PIN) Questionnaire

An instrument for assessment of cognitive and emotional factors associated with foot self-care

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OBJECTIVE — Using the common-sense model of illness behavior, we developed and validated a self-report instrument for assessment of patients' cognitive and emotional representations of diabetic peripheral neuropathy (DPN) influencing foot self-care.

RESEARCH DESIGN AND METHODS — The Patient Interpretation of Neuropathy (PIN) questionnaire, generated from discussions with clinicians and interviews with patients with DPN, was administered to patients with DPN attending U.K. ($n = 325$) and U.S. ($n = 170$) diabetes centers. Psychometric tests of the PIN questionnaire comprised factor analysis, internal consistency, and test-retest reliability. Partial correlations and multivariate regressions established construct and criterion-related validity. The associations of PIN scales to past foot ulceration and foot self-care behaviors were compared with those using a generic measure of illness perception and emotion, the Revised Illness Perception Questionnaire (IPQ-R), which was adapted to neuropathy.

RESULTS — Factor analysis of the PIN questionnaire produced 11 scales, which explained 69% of item variance. Nine factors measured patients' common-sense beliefs about DPN and their levels of understanding of DPN-related medical information. Two factors assessed the emotions of worry about potential consequences and anger at practitioners. Most scales demonstrated adequate internal (Cronbach's $\alpha = 0.62$ – 0.90) and test-retest reliability (Pearson's $r = 0.51$ – 0.64). Partial correlations between the PIN and IPQ-R scales in corresponding domains were significant but modest ($r_p = 0.15$ – 0.26). Finally, PIN scales showed significant associations with past foot ulceration and foot self-care behaviors, thereby confirming criterion validity.

CONCLUSIONS — The 39-item PIN questionnaire is a reliable and valid measure of patients' cognitive and emotional representations of neuropathy affecting foot self-care.

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Foot ulceration and amputations cause an extensive burden on individuals with diabetes, the health care system, and society (1). Yet diabetic foot ulcer-related morbidity could be substantially reduced, as a significant proportion of

foot ulcers could be prevented by patients' active engagement in foot self-care (2). Causal pathways to foot ulceration are well defined, with diabetic peripheral neuropathy (DPN), the key risk factor, predisposing to foot ulceration through mechanisms that

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Abbreviations: CSM, common-sense model of illness behavior; DPN, diabetic peripheral neuropathy; IPQ-R, Revised Illness Perception Questionnaire; PIN questionnaire, Patient Interpretation of Neuropathy questionnaire.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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are either extrinsic to the foot (e.g., unperceived trauma) or intrinsic to the foot (e.g., DPN contributing to foot deformities and high pressure areas) (3,4). Therefore, it seems plausible that a series of relatively simple foot self-care actions should be effective in minimizing the impact of neuropathic risk factors and thereby reducing the incidence of insensate foot ulcers. Published guidelines on diabetic foot self-care define two types of such behaviors: engagement in preventive foot self-care (e.g., having feet measured when buying a new pair of shoes) and avoidance of behaviors which, although appropriate for people with intact sensation in their feet, can potentially damage the feet of people affected by DPN (e.g., barefoot walking) (5–7).

Despite efforts to enhance foot self-care, educational interventions have met with limited success (8–10). Results of randomized controlled trials selected for a systematic review (10) indicate that foot self-care behavioral change is short-lived (11–15). This finding could be attributable to the fact that these interventions have focused solely on foot self-care knowledge and behavioral skills training, and none has addressed the psychosocial processes underlying patients' foot self-care.

In the present study, we used the common-sense model of illness behavior (CSM) (16) to develop an instrument to assess how patients interpret neuropathy, respond emotionally, and make decisions to engage in foot self-care. The CSM postulates that individuals construct cognitive representations (beliefs and understanding) of illness in terms of experienced symptoms and diagnostic labels (both comprising the presence or identity of an illness), antecedent conditions believed to have caused illness (causes), expected duration (timeline), perceptions of cure or controllability (control), and perceived impact of illness (consequences). The model proposes that cognitive representations of illness give rise to and interact with emotional responses in driving illness behaviors. Importantly, the CSM draws attention to discrepancies that may exist between the

patient's common-sense representations of illness and the practitioner's biomedical disease models. If not attended to, these discrepancies may result in ineffective health care actions (17,18).

Studies offering support for CSM components as predictors of health outcomes (19), including studies in diabetes (20–22), have concentrated on patients' representations of an ongoing illness with a focus on symptom experience. Virtually no applications have been made to determine those attributes of illness representations that are relevant for prevention of future health threats (23). Accordingly, existing instruments used to examine illness representations at both generic (24–27) and diabetes-specific (20,28) levels assess patients' reports of experienced symptoms and/or symptom attributions to illness, beliefs about how one has developed an illness and how long it is likely to last, and perceptions of experienced consequences and controllability of an illness. These instruments may not therefore capture adequately those aspects of DPN, a largely asymptomatic medical condition (29), that are important to foot self-care and directed to prevention of foot ulceration.

Moreover, as psychological processes underlying illness behaviors are highly situation-specific (30), currently available measures of patients' perceptions of diabetes (20,28) may not be directly relevant for the assessment of patients' beliefs affecting foot self-care because they focus exclusively on the beliefs shaping the self-management of glycemia (e.g., dietary intake and blood glucose testing).

In the present study, therefore, we describe the development and validation of the Patient Interpretation of Neuropathy (PIN) questionnaire, an instrument for assessment of cognitive and emotional representations of DPN hypothesized to influence adherence to foot self-care. The results with the PIN questionnaire were compared with those obtained using a generic measure of illness representations, the Revised Illness Perception Questionnaire (IPQ-R) (25), which was adapted to neuropathy. It was expected that the PIN questionnaire, a measure of patients' representations of neuropathy as a potential health threat (a risk factor for foot ulceration), would demonstrate more associations with preventive foot self-care than the IPQ-R, which captures the patients' perceptions of neuropathy and its symptoms as an ongoing experience.

RESEARCH DESIGN AND METHODS

The sequence for the development of the PIN questionnaire was as follows: 1) an item development phase that comprised a review of existing instruments developed within the CSM for their suitability for the current study, discussions with an expert panel, and semistructured interviews with patients conducted in the U.K. and U.S.; and 2) a psychometric validation phase that was conducted within a U.K./U.S. collaborative study into the psychological predictors of foot self-care, foot ulceration, and quality of life. Permission to conduct these studies was granted by the institutional review boards at every center. The focus of this study was on the second, psychometric, validation phase.

A sample of 495 patients (325 U.K./170 U.S.) with established DPN and either type 1 or type 2 diabetes were recruited from three sites: Manchester, U.K.; Baltimore, Maryland; and State College, Pennsylvania. Detailed characteristics of the study population and methodology have been published previously (31,32). Patients included had moderate to severe neuropathy (vibration perception threshold >25 V and Neuropathy Disability Score >3). Patients were excluded if they had peripheral vascular disease (defined as <1 palpable foot pulse or previous bypass surgery/angioplasty), had a history of major amputation, were unable to understand English sufficiently well to complete the self-report measures, or had insufficient (corrected) vision to complete the questionnaires.

After explanation of the study and an examination for suitability, written consent was obtained. After neurological and vascular examination, the participants completed the questionnaires. To assess the 4-week test-retest reliability of the PIN questionnaire, patients were mailed the questionnaire with a return envelope 3 weeks after the baseline assessment.

Measures

The PIN questionnaire. An initial 44-item draft instrument covered patients' 1) common-sense misperceptions about the nature of foot complications and their efforts to merge these beliefs with the practitioner's diagnosis of DPN (illness identity), 2) levels of understanding of the causal links between DPN and foot ulceration and the self-care- and/or health care provider-related blame for the development of neuropathy/foot ulceration (causes), 3) perceptions of temporal unpre-

dictability of foot ulceration (acute timeline), 4) foot self-care efficacy beliefs and the perceptions that health care providers can prevent foot ulcers (controllability), 5) anticipation of foot ulceration and/or amputation (potential consequences), and 6) worry about these consequences and anger directed at health care providers stemming from a perceived lack of a clear explanation about neuropathy and perceived lack of compassion (emotions). Responses to each statement were scored on a 5-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = uncertain, 4 = agree, and 5 = strongly agree).

The IPQ-R. Following the recommendations of the authors of the IPQ-R, items were adapted to DPN by replacing the generic term "illness" with the phrase "reduced feeling in my feet." The participants were asked to indicate on a 5-point Likert response scale, ranging from 1 = strongly disagree to 5 = strongly agree, how much they agreed with a series of statements that assessed 1) beliefs about the efficacy of treatment in managing DPN (treatment control), 2) perceptions of self-efficacy in managing DPN and its symptoms (personal control), 3) overall sense of comprehension of DPN (illness coherence), 4) beliefs that DPN is either a chronic or an acute condition (chronic timeline), 5) perceptions of the temporal changeability of DPN and its symptoms (cyclical timeline), 6) experienced consequences of DPN, and 7) emotions of DPN-related anger, anxiety, and depression. The reliability coefficients of the IPQ-R scales for this sample were acceptable ($\alpha = 0.75\text{--}0.87$).

Foot self-care behaviors. Items to assess foot care behaviors were based on the diabetic foot care guidelines (5–7). Ten items assessed preventive foot self-care behaviors (e.g., "During the past week how often did you: Examine your feet? Wash your feet? Use moisturizing creams for your feet? Test water temperature with your hand/elbow? Check inside shoes? Change socks?" and "In general, how often do you: Have your feet measured when buying a new pair of shoes? Wear lace-up shoes? Cut toenails straight across?"). Eight items assessed potentially foot-damaging behaviors (e.g., "During the past week how often did you: Walk barefoot indoors/outdoors? Wear shoes without socks?" and "In general, how often do you: Rely on feeling the fit of the shoes when buying a new pair? Use heating pads to warm cold feet? Use chemical agents to remove corns? Treat corns/

Table 1—Characteristics of the study population

	U.K.	U.S.	Total
<i>n</i>	325	170	495
Male sex (%)	72.2	66.7	70.2
Age (years)	61.50 ± 11.54	62.56 ± 9.82	61.86 ± 10.98
Education (%)*			
Primary	4.1	1.8	3.4
Secondary	58.5	41.7	54.0
Some college	23.1	11.9	19.7
College graduate	7.3	25.6	14.0
Postgraduate	4.4	19.5	8.9
Marital status (has partner) (%)	64.9	73.2	67.8
Diabetes type (type 1) (%)*	34.5	16.7	28.3
Number of diabetes complications	1.57 ± 1.06	1.54 ± 1.18	1.56 ± 1.10
Number of concomitant disorders*	0.74 ± 0.89	1.43 ± 1.24	0.98 ± 1.07
Neuropathy disability score	7.33 ± 2.17	7.63 ± 2.12	7.43 ± 2.17
Vibration perception threshold*	39.30 ± 9.33	44.39 ± 9.33	41.06 ± 9.63
Past foot ulceration (%)*	29.1	48.8	36.0
PIN_ID1: good circulation = healthy feet*	3.58 ± 0.67	2.93 ± 0.69	3.52 ± 0.62
PIN_ID2: accurate interpretation of DPN	3.84 ± 0.60	4.01 ± 0.48	3.90 ± 0.56
PIN_ID3: foot ulcers would be painful†	3.14 ± 0.83	2.61 ± 0.92	3.26 ± 0.63
PIN_C1: physical causes of ulcers†	3.48 ± 0.57	3.61 ± 0.61	3.52 ± 0.58
PIN_C2: self/practitioner blame	2.74 ± 0.67	2.68 ± 0.70	2.71 ± 0.68
PIN_TL: acute foot ulcer onset*	3.49 ± 0.60	3.81 ± 0.60	3.60 ± 0.62
PIN_CC1: efficacy of foot self-care†	3.59 ± 0.64	3.41 ± 0.67	3.52 ± 0.62
PIN_CC2: practitioner-foot ulcer control*	3.04 ± 0.79	2.70 ± 0.81	2.92 ± 0.82
PIN_Cons: anticipated consequences†	3.84 ± 0.69	4.05 ± 0.53	3.91 ± 0.64
PIN_Em1: worry about consequences‡	3.59 ± 0.87	3.76 ± 0.82	3.65 ± 0.86
PIN_Em2: anger at practitioners	2.37 ± 1.00	2.46 ± 1.05	2.40 ± 1.02
IPQ-R chronicity	3.59 ± 0.62	3.67 ± 0.53	3.60 ± 0.60
IPQ-R experienced consequences†	3.11 ± 0.84	3.38 ± 0.77	3.20 ± 0.83
IPQ-R personal control	3.27 ± 0.67	3.29 ± 0.76	3.27 ± 0.70
IPQ-R treatment control	3.12 ± 0.71	2.99 ± 0.73	3.07 ± 0.72
IPQ-R emotions	2.89 ± 0.88	2.96 ± 0.83	2.91 ± 0.87
IPQ-R coherence†	2.62 ± 0.84	2.86 ± 0.88	2.87 ± 0.87
IPQ-R cyclical	2.92 ± 0.91	2.80 ± 0.89	2.88 ± 0.90
Preventive foot self-care*	0.54 ± 0.14	0.65 ± 0.14	0.58 ± 0.15
Potentially foot-damaging behaviors†	0.25 ± 0.09	0.22 ± 0.10	0.24 ± 0.10

Data are percentages or means ± SD. PIN and IPQ-R scales were computed by calculating the mean value of the items in the subscale. Thus, means and SDs are based on the original Likert scale scoring of the items. For foot self-care behaviors, responses were rated on a 6-point scale for “during the past week” questions (twice a day, daily, every other day, twice a week, once a week, or never) and on a 4-point scale for “in general” questions (always, most of the time, occasionally, or never). Because of this difference in scaling, items were converted to a 0 to 1 scale before scoring. Mean scores were computed for each subscale. Significant differences between study sites are denoted by footnote symbols in the first column. χ^2 tests were used to evaluate categorical variables and independent samples *t* test were used to evaluate continuous variables. **P* < 0.001; †*P* < 0.01; ‡*P* < 0.05.

calluses with the blade? Wear sandals or slip-ons?”). Responses were rated on a 6-point scale for “during the past week” questions (twice a day, daily, every other day, twice a week, once a week, or never) and on a 4-point scale for “in general” questions (always, most of the time, occasionally, or never). Higher scores indicate more preventive and potentially foot-damaging behaviors. The internal consistency coefficients for preventive foot self-care and potentially foot-damaging behaviors were 0.58 and 0.32, respectively, and the 4-week test-retest reliability coefficients for preventive foot self-

care and potentially foot-damaging behaviors were 0.76 and 0.46, respectively.

Statistical methods

SPSS 13.0 was used for all analyses. To assess the structural validity of the PIN questionnaire, principal component factor analysis using varimax rotation was performed on the 44 items, with selection of eigenvalues > 1. Interitem consistency was measured by Cronbach's coefficient α . Stability over time was assessed by Pearson correlations between the PIN scales completed at baseline and 4 weeks

after the baseline assessment. Convergent validity was assessed by partial correlation coefficients (r_p , controlling for country) between PIN and IPQ-R scales. Criterion validity of the PIN questionnaire was established by a series of multivariate linear ordinary least-squares regression analyses performed separately for each PIN cognitive and emotion scale. The associations between PIN scales and two types of criteria were assessed: 1) past foot ulceration (“known group” validity) and 2) two types of foot self-care (preventive foot self-care and potentially foot-damaging behaviors).

Table 2—PIN questionnaire: factor structure, internal, and test-retest reliability of the scales

PIN questionnaire (items)	CC1	Em1	Cons	CC2	C1	ID1	ID3	C2	Em2	TL	ID2
Lost or reduced feeling means poor circulation in my feet.						0.68					
Good circulation in the feet means that I will not get foot ulcers (open sores).						0.73					
Good circulation in the feet means healthy feet.						0.73					
If the feet feel warm to the touch, it means healthy feet.						0.56					
Lost or reduced feeling means damage to the nerves in my feet.											0.56
It is possible to have lost or reduced feeling and at the same time have pain in the feet.											0.74
It is possible to have reduced feeling in the feet in spite of having sensitivity to touch.											0.80
If I had a foot ulcer (an open sore) I would get pain in my feet.							0.87				
When a foot ulcer (an open sore) gets worse it would be painful.							0.84				
I could develop a foot ulcer (an open sore) without feeling any pain.							−0.54				
Lost or reduced feeling in my feet was caused by poor medical care in the past.								0.76			
Lost or reduced feeling in my feet was caused by not taking good care of my diabetes.								0.71			
Foot ulcers (open sores) are caused by poor medical care.								0.59			
Foot ulcers (open sores) are caused by not taking care of oneself.								0.56			
Changes in foot shape can cause foot ulcers (open sores).					0.57						
Ill-fitting shoes can cause foot ulcers (open sores).					0.65						
Excessive hard skin formation (callus) can cause foot ulcers (open sores).					0.82						
Dry skin on the feet can cause foot ulcers (open sores).					0.79						
Foot ulcers (open sores) take a long time to develop.											−0.63
Foot ulcers (open sores) can develop very fast.											0.79
I can develop a foot ulcer (an open sore) at any time.											0.63
Diabetes doctors can prevent foot ulcers (open sores) from occurring.				0.83							
My family doctor can prevent foot ulcers (open sores) from occurring.				0.84							
Foot care specialists can prevent foot ulcers (open sores) from occurring.				0.78							
Checking my feet every day can prevent foot ulcers (open sores) from occurring.	0.75										
Seeing my foot care specialist regularly can prevent foot ulcers from occurring.	0.67										
Wearing shoes that fit properly can prevent foot ulcers (open sores) from occurring.	0.83										
Moisturizing feet can prevent foot ulcers (open sores) from occurring.	0.72										
Removing hard skin (callus) can prevent foot ulcers (open sores) from occurring.	0.72										

Continued.

Table 2—Continued.

PIN questionnaire (items)	CC1	Em1	Cons	CC2	C1	ID1	ID3	C2	Em2	TL	ID2
Lost or reduced feeling in my feet could lead to injuries to my feet.			0.75								
Lost or reduced feeling in my feet could lead to foot gangrene.			0.89								
Lost or reduced feeling in my feet could lead to foot ulcers (open sores).			0.82								
Lost or reduced feeling in my feet could lead to amputation.			0.86								
Lost or reduced feeling in my feet makes me worry about what is going to happen next.		0.87									
Lost or reduced feeling in my feet makes me worry about a foot injury.		0.90									
Lost or reduced feeling in my feet makes me worry about a foot ulcer (an open sore).		0.87									
Lost or reduced feeling in my feet makes me worry about losing a leg.		0.81									
Lost or reduced feeling makes me angry about docs who don't seem to care about me.									0.91		
Lost or reduced feeling makes me angry about docs not telling me what is really going on with my feet.									0.91		
Eigenvalue	3.31	3.20	3.19	2.74	2.68	2.38	2.10	1.91	1.89	1.85	1.71
% variance explained	7.89	7.62	7.60	6.53	6.38	5.66	5.00	4.54	4.50	4.40	4.07
Internal reliability	0.85	0.90	0.89	0.89	0.77	0.71	0.76	0.62	0.90	0.70	0.56
4-week test-retest reliability	0.60	0.64	0.54	0.52	0.52	0.63	0.56	0.56	0.51	0.62	0.51

Data are results of principal component analysis with varimax rotation performed on a total scale of 39 items. Item loadings of <0.40 are not shown. Illness identity: ID1, good circulation = healthy feet; ID2, accurate interpretation of neuropathy; ID3, ulcers accompanied by pain; causes: C1, physical causes for ulcers; C2, self/practitioner blame; timeline: TL, acute ulcer onset; cure/controlability: CC1, efficacy of foot self-care; CC2, practitioner-foot ulcer control; consequences: Cons, anticipated consequences; emotions: Em1, worry about consequences; Em2, anger at practitioners.

RESULTS — Patient characteristics are presented in Table 1. Subjects had moderate to severe neuropathy on objective testing, and 36% had previous foot ulceration. There were differences between U.K. and U.S. participants: U.S. patients had higher levels of college/postgraduate education, and more of them had type 2 diabetes and concomitant disorders. U.S. patients also had greater neuropathy deficits on objective testing, and a greater proportion had past foot ulceration. Because of these differences, all bivariate and multivariate analyses controlled for country; multivariate analyses also controlled for sex, age, marital status, education, diabetes type, number of diabetes complications other than neuropathy, and number of comorbid disorders.

Psychometric analyses

Initial factor analysis of the 44-item PIN questionnaire led to elimination of five items that either loaded on more than one factor and/or showed unsatisfactory item-scale correlations. Factor analysis of the 39 items produced 11 factors, which together explained 69% of item variance

(Table 2). The derived factors showed good convergent and discriminant validity: all items loaded >0.5 on the hypothesized factor and <0.4 on the other factors. Nine factors represented the cognitive domains of CSM, and two represented the emotional domain. Specifically, the illness identity domain was represented by three factors: two patient misperceptions (ID1: good circulation = healthy feet, four items, e.g., “Good circulation in the feet means that I will not get foot ulcers [open sores]”; and ID3: foot ulcers would be painful, three items, e.g., “If I had a foot ulcer [an open sore], I would get pain in my feet”) and one correct patient perception (ID2: accurate interpretation of DPN, three items, e.g., “It is possible to have lost or reduced feeling and at the same time pain in the foot”). The causal domain comprised two factors (C1: physical causes of foot ulcers, four items, e.g., “Changes in foot shape can cause foot ulcers [open sores]”; and C2: self/practitioner blame, four items, e.g., “Foot ulcers [open sores] are caused by poor medical care”). Two factors represented the cure/controlability domain

(CC1: efficacy of foot self-care, four items, e.g., “Checking my feet daily can prevent foot ulcers [open sores] from occurring”; and CC2: practitioner-foot ulcer control, four items, e.g., “My family doctor can prevent foot ulcers [open sores] from occurring”). A single factor captured foot ulcer temporal unpredictability beliefs (TL: acute foot ulcer onset, three items, e.g., “I can develop a foot ulcer [an open sore] at any time”). One factor measured anticipated neuropathy consequences (Cons: anticipated consequences, four items, e.g., “Reduced feeling in my feet could lead to injuries to my feet”). Finally, the emotion domain comprised two factors (Em1: worry about consequences, three items, e.g., “Lost or reduced feeling makes me worry about losing a leg”; and Em2: anger at practitioners, two items, e.g., “Lost or reduced feeling in my feet makes me angry about docs who don't seem to care about me”).

Internal consistency of the derived factors was acceptable with α values ranging from 0.56 to 0.90 (Table 2). Factor analysis performed separately for each study site produced essentially identical

Table 3—Criterion validity: the associations of PIN and IPQ-R scales with past foot ulceration, preventive foot self-care, and avoidance of potentially foot-damaging behaviors

Scales	β		
	Past foot ulceration	Preventive foot self-care	Foot-damaging behaviors
PIN_ID1: good circulation = healthy feet	-0.19*	-0.10†	0.13‡
PIN_ID2: accurate interpretation of DPN	0.00	0.15‡	0.03
PIN_ID3: foot ulcers would be painful	0.39*	-0.15‡	0.22*
PIN_C1: physical causes of foot ulcers	0.26*	0.23*	-0.10†
PIN_C2: self/practitioner blame	-0.04	-0.05	0.02
PIN_TL: acute foot ulcer onset	0.45*	0.23*	-0.18*
PIN_CC1: efficacy of foot self-care	-0.00	0.14‡	0.00
PIN_CC2: practitioner-foot ulcer control	0.01	-0.01	0.05
PIN_Cons: anticipated consequences	0.12‡	0.20*	-0.07
PIN_Em1: worry about consequences	0.18*	0.13‡	-0.02
PIN_Em2: anger at practitioners	0.04	-0.10†	0.01
IPQ-R chronicity	0.06	0.10†	-0.07
IPQ-R experienced consequences	0.18*	0.19*	-0.06
IPQ-R personal control	-0.03	-0.05	0.05
IPQ-R treatment control	0.07	-0.03	0.08
IPQ-R emotions	-0.02	0.10†	0.08
IPQ-R coherence	0.05	0.04	-0.12†
IPQ-R cyclical	-0.01	0.03	0.13‡

Each cell represents a separate analysis. Cell entries are standardized regression (β) coefficients, controlling for country, age, sex, education, marital status, type of diabetes, and diabetes complications other than neuropathy and concomitant diseases. * $P < 0.001$; † $P < 0.05$; ‡ $P < 0.01$.

factor structure (results not shown). In general, U.S. patients reported higher levels of understanding about DPN than U.K. patients (Table 1). For example, U.S. patients were less likely to agree that good circulation means healthy feet and that foot ulcers would be painful, had better understanding about the causal links between DPN and ulceration, and had stronger foot ulcer temporal unpredictability beliefs.

Of the 495 subjects, 432 (87%) completed the PIN questionnaire 4 weeks after the baseline assessment. Pearson's correlation coefficients among the PIN scales completed at these times ranged from 0.51 to 0.64.

Validation analyses

Convergent validity of constructs validation. Partial correlations (controlling for country) between the PIN and IPQ-R scales in corresponding domains were significant but modest. Specifically, the IPQ-R treatment and personal control scales were positively correlated with the PIN foot self-care efficacy scale ($r_p = 0.18, P < 0.001$ and $r_p = 0.19, P < 0.001$, respectively). Positive correlations were observed between the IPQ-R experienced and the PIN anticipated consequences scales ($r_p = 0.26, P < 0.001$) and between the IPQ-R chronic timeline for

DPN and the PIN acute timeline or temporal unpredictability of foot ulceration scales ($r_p = 0.26, P < 0.001$). The IPQ-R emotion scale positively correlated with both the PIN worry-about-consequences scale ($r_p = 0.18, P < 0.001$) and the PIN anger-at-practitioners scale ($r_p = 0.18, P < 0.001$). Finally, the IPQ-R coherence scale, measuring the patient's overall sense of comprehension of DPN, showed positive correlations with PIN scales of accurate DPN representations (ID2: accurate interpretation of neuropathy, $r_p = 0.15, P < 0.01$; and TL: acute foot ulcer onset, $r_p = 0.19, P < 0.001$) and negative correlations with PIN common-sense misperception scales (ID1: good circulation = healthy feet; $r_p = -0.21, P < 0.001$; and ID3: foot ulcers would be painful, $r_p = -0.21, P < 0.001$).

Criterion validity. Associations of the PIN questionnaire and the IPQ-R with past foot ulceration ("known group" validity) were analyzed. Five cognitive and one emotional scale from the PIN demonstrated significant associations with past foot ulceration (Table 3). As expected, patients with past ulceration were less likely to report misperceptions that good circulation means healthy feet and that the development of ulceration would be painful. Further, past foot ulceration was positively associated with understanding

of the causal links between DPN and foot ulcers and with perceptions of temporal unpredictability of foot ulceration. Moreover, past foot ulceration was positively associated with anticipation of DPN-related consequences and the emotion of worry about these consequences. With the exception of the experienced consequences scale, there were no significant associations between past foot ulceration and IPQ-R scales.

Associations of the PIN questionnaire and IPQ-R with foot self-care were in the predicted direction (Table 3); i.e., more accurate representations of DPN were significantly associated with more preventive foot self-care, whereas less developed understanding of neuropathy was associated with more potentially foot-damaging behaviors. Specifically, accurate interpretation of neuropathy diagnosis, understanding of the causal links between neuropathy and foot ulceration, beliefs about foot self-care efficacy, perceptions of foot ulcer temporal unpredictability, and anticipation of and worry about DPN-related consequences were associated with more preventive foot self-care. In contrast, the common-sense misperceptions that good circulation means healthy feet and that foot ulcers would be painful were associated with more

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potentially foot-damaging behaviors. The PIN questionnaire demonstrated 19 significant associations (57%) with the 3 criteria, compared with 6 significant associations (29%) observed between the IPQ-R and the criteria.

CONCLUSIONS— With this study, we describe the development and validation of a theory-based, self-report instrument to assess patients' cognitive and emotional representations of neuropathy influencing foot self-care. Factor analysis of the PIN produced nine scales covering the five cognitive domains of the CSM and two scales representing its emotional domain. Internal consistency and test-retest reliability of the derived scales was adequate for the most part, given the relatively small number of items comprising the scales. Both internal consistency and stability over time should improve with the inclusion of the additional items in future studies.

Expected correlations were obtained between the PIN and IPQ-R scales, thereby supporting validity of its constructs. The small to moderate size of correlations between the PIN and IPQ-R scales indicate that, although conceptually related, these instruments are tapping different aspects of neuropathy representations.

The significant associations between PIN scales and past foot ulceration attest to its criterion (known group) validity. Most importantly, PIN scales demonstrated meaningful and statistically significant associations with foot self-care behaviors, thereby providing evidence for the potential of the PIN questionnaire to meet its main objective of assessing psychological factors affecting foot self-care.

Development of the PIN questionnaire has several theoretical and practical implications. At the theoretical level, the PIN questionnaire defines those aspects of illness representations that influence preventive behaviors, thereby departing from currently existing measures, which concentrate exclusively on attributes of an ongoing illness and its symptoms. The observed associations of the PIN and IPQ-R scales with foot self-care behaviors support the value of approaching DPN as a risk factor when studying adherence to foot self-care, as more PIN than IPQ-R scales demonstrated significant associations with foot self-care behaviors. However, in a recent study, the IPQ-R neuropathy scales were found to predict depressive symptoms (32). Taken together, these studies suggest that the de-

velopment of an instrument of illness representations and the choice of an existing measure should be guided by the criterion under investigation; whereas the PIN questionnaire better captures those aspects of neuropathy representations that influence foot self-care, the IPQ-R is more relevant to neuropathy experience that generates negative affect.

The development of PIN questionnaire embodies the refinement of concepts of illness representations and the construction of new scales to measure these concepts. For example, illness identity, rather than being characterized as mere symptom reports, is conceptualized and measured as the confluence between practitioners' diagnosis of DPN with patients' common-sense beliefs about diabetic foot complications. Similarly, the PIN emotion domain, rather than combining anger, anxiety, and depression into one scale (IPQ-R), is represented by two separate scales, each of which assesses a different type and source of DPN-specific emotional experience (worry about foot ulceration and amputation and anger at practitioners). Such an approach to illness emotion uncovers the differential effects of specific emotions on foot self-care: worry is a motivator of adherence, whereas anger hinders foot self-care actions. At the practical level, the PIN questionnaire identifies patients' characteristic misperceptions about neuropathy, their levels of understanding of neuropathy-related medical information, and their specific emotional responses, thereby providing clinicians and behavioral scientists with specific targets for designing more efficacious foot self-care interventions.

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