

The Relationship Between Health Related Quality of Life and Disease Activity and Damage in Systemic Lupus Erythematosus

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ABSTRACT. Objective. To evaluate the relationship between self-reported quality of life and disease activity, damage, impairment, disability, and handicap in systemic lupus erythematosus (SLE).

Methods. In this cross sectional study disease activity was measured with the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) and the Systemic Lupus Activity Measure (SLAM), and damage by the Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC/ACR) damage index (SDI). Quality of life was assessed by the Medical Outcome Survey Short Form 36 (SF-36) and the EuroQol (EQ-5D). Multiple linear regression was used to identify significant associations of patients' health status, and logistic regression was used to evaluate the relationship of each of the 5 dimensions of the EQ-5D in terms of impairment, disability, and handicap.

Results. Damage was associated with the Physical Function (PF) and Social Function subscales of the SF-36. Disease activity was associated with the General Health (GH) subscale. Ability to carry out usual activities was strongly related to PF and GH as well as to global rating of the thermometer rating scale of the EQ-5D. Role Physical (RP) and Bodily Pain (BP) of the SF-36 were also associated with the EQ-5D rating scale. In addition, patients' ratings of anxiety and depression were strongly related to the Mental Health (MH) summary scale of the SF-36.

Conclusion. Perceived health status of patients with lupus was associated with disease activity, damage, role physical, bodily pain, capacity for usual activity, and mobility. EQ-5D is a valid instrument for the measure of health related quality of life in SLE. (J Rheumatol 2001;28:525-32)

Key Indexing Terms:

DISEASE ACTIVITY
DISABILITY

DISEASE DAMAGE
HANDICAP

IMPAIRMENT
HEALTH RELATED QUALITY OF LIFE

The survival of patients with systemic lupus erythematosus (SLE) has increased dramatically over the past 20 years^{1,2}. The prolongation of life, however, was not paralleled by an improvement in quality of life, as many studies report poorer health related quality of life (HRQL) for persons with SLE than age and sex matched controls³⁻⁵.

The current literature indicates that SLE has its most profound effect on physical health. Fortin, *et al*³ and Gladman, *et al*^{4,5} have shown that persons with SLE have

scores for physical health that are 30% to 40% lower than age and sex matched peers⁶. Social function was less affected.

Studies of HRQL in SLE^{3-5,7-9} have been inconsistent as to the relationships between disease activity, damage, and HRQL. Out of 4 Canadian studies^{3-5,7}, one³ found a negative relationship between HRQL and disease activity using the Systemic Lupus Activity Measure (SLAM)¹⁰, while 3 others did not find such an association using the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI)¹¹. Two other studies^{8,9}, one from Sweden using SLAM and one from the UK using the British Isles Lupus Activity Group (BILAG)¹² instrument, found that HRQL was related to disease activity and psychological distress.

There are many intervening variables, from biological and physiological variables to health status. According to the World Health Organization classification of the consequences of disease, there is a continuum that starts with etiological and pathological processes that lead to manifestations of disease and to impairments, disabilities, and handicaps. The conceptual model proposed by Wilson and Cleary¹³ suggests that biological and physiological variables influence HRQL through symptoms (impairments) and function (disabilities). Before a conceptual model for

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HRQL in lupus can be put forward, it requires testing. This study was designed to evaluate the relationships between different levels of the WHO model of impairment, disability, and handicap as they relate to lupus.

MATERIALS AND METHODS

Study design and population. This cross sectional study included 55 consecutive patients from the Lupus Clinic of the Montreal General Hospital. Fifty-four patients (> 18 years of age) coming for a regular clinic visit agreed to participate and one refused. SLE was defined by the presence of 4 or more of the revised diagnostic criteria of the American College of Rheumatology^{14,15}.

Measuring instruments. In addition to the HRQL construct, we used the WHO International Classification of Impairment, Disability and Handicap (IDH)¹⁶ as a framework for considering outcome of SLE. The 2 constructs disability and handicap are more positively termed activity and participation.

HRQL was measured by the Medical Outcomes Study 36 item Short Form health survey (SF-36)¹⁷⁻¹⁹ and the EuroQol (EQ-5D)^{20,21}.

The SF-36 was constructed to provide a comprehensive assessment of the physical and mental components of health status^{18,19}. The questionnaire comprises 8 subscales: (1) physical functioning; (2) role-physical; (3) bodily pain; (4) general health perceptions; (5) vitality; (6) social function; (7) role-emotional; and (8) mental health. Scores for each scale range from 0 to 100, with higher scores reflecting better health status. In addition, 2 summary measures⁶ are available: a physical health measure (physical component scale, PCS) and a mental health measure (mental component scale, MCS). These have been standardized to have a mean of 50 and a standard deviation of 10. Higher scores on the scales indicate better health related quality of life⁶.

The EQ-5D is also a generic measure that describes health states in terms of 5 dimensions: mobility (disability), self-care (disability), usual activities (handicap), pain/discomfort (impairment), and anxiety/depression (impairment). Each dimension is divided into 3 levels that together define a total of 243 (3⁵) unique health states. Country-specific weights for each of the health states yield a single valuation on a 0 to 1 scale; Canadian weights are not yet available. In addition, there is a visual analog thermometer rating scale (VAS) that measures the overall perception of health on a 0 to 100 scale. The simplicity of this instrument and the fact that the 5 items span impairment, disability, and handicap make it ideal for use in chronic conditions such as SLE. EQ-5D has a mean of 90 in a healthy population²². It has been tested in a culturally diverse and bilingual Canadian environment and evidence of construct validity has been found²².

Disease activity was assessed using the revised SLAM-2¹⁰, a validated and reliable instrument based on a physician history and examination and a laboratory assessment. The revised SLAM-2 score ranges from 0 (no activity) to 81 (maximum activity). A score over 7 is considered clinically important (moderate to severe clinical activity), as a majority of physicians would consider a change in treatment (initiation or increase in corticosteroids)²³.

A second measure, the SLEDAI¹¹, uses a weighting system to evaluate disease activity in 9 organ systems. The total SLEDAI score can range from 0 (no activity) to 105 (maximum activity). A score of 6 is considered clinically important since it influences treatment decisions²³.

Disease damage was measured using the Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index (SDI)^{24,25}. This is a physician rated index that assesses cumulative organ damage due to the disease, complications of therapy, or intercurrent illness such as cancer. It reports on 12 organ systems. Damage in each system must be present for 6 consecutive months in order to be scored. The total SDI score can range from 0 (no damage) to 47 (maximum damage), but will in practice rarely exceed 10^{26,27}.

Procedure. Fifty-four of 55 patients approached for the study agreed to participate, signed a consent form, and completed self-administered questionnaires for SF-36, EQ-5D, and a global self-assessment of disease

activity on VAS. They underwent examination by their treating physician, who completed a SLAM-2, a SLEDAI, a global assessment of disease activity on a 10 cm VAS, and a SDI. The study protocol was approved by our Research Ethics Committee.

Statistical analysis. To estimate the relationship between HRQL and measures of disease activity, damage, impairments, disabilities, and handicaps, multiple linear regressions were used. Separate models were developed for each outcome measure of HRQL. The SF-36 has 8 separate scales and 2 component summary scales, Physical Health and Mental Health; the EQ-5D has one value derived from the thermometer rating scale. For each model, the predictor variables were (1) sociodemographic characteristics; (2) clinical measures of disease activity and damage; (3) physicians' and patients' ratings of disease activity; and (4) patients' report of impairment (pain/discomfort and anxiety/depression), disability (capacity for mobility and self-care), and handicap (participation in usual activities). Further, the SF-36 subscales were used as predictor variables for the EQ-5D thermometer rating scale.

Because age and duration of disease were correlated ($r = 0.56$, $p < 0.0001$), they could not be in the same model at the same time. We chose to use duration of disease in our models because of its clinical relevance in terms of disease progression. Since there were only 3 men, sex was not evaluated further. In our models we included education, marital status, occupation, race, and year of diagnosis.

The clinical variable scores were SLAM, SLEDAI, SDI, physician and patient global assessments of disease activity on a VAS, and medication use. The measures of impairment, disability, and handicap were derived from the EQ-5D and dichotomized as present or absent.

A multiple linear regression model was built for each of the 3 main outcomes: EQ-5D thermometer rating scale, SF-36 Physical Health, and SF-36 Mental Health. The Akaike Information Criteria (AIC)²⁸ were used to select the final model. To understand the relationships between disease activity and damage and other variables of the conceptual model for HRQL in lupus, we examined the variables associated with impairment (pain/discomfort and anxiety/depression), disability (mobility and self-care), and handicap (usual activities). Because these were dichotomized, logistic regression was used. Logistic regression estimates the probability of a particular outcome as an exponential function of the explanatory variables. The regression parameters are interpreted as odds ratios with 95% confidence intervals (95% CI). As all the associated variables are measured on different scales, it is difficult to appreciate the magnitude of the effect of one measure in comparison to the other. To overcome this, we used standardized regression coefficients. These are interpreted in terms of standard deviation units: for every 1 SD change in an "x" variable the "y" variable changes the value of the coefficient.

RESULTS

Study population. Of the 54 patients, the majority were Caucasian ($n = 45$), 4 were black, 3 Asian, and 2 of mixed racial origin. The average age of participants was 40 years (range 24–80); there were only 3 men. Table 1 summarizes the clinical characteristics of study participants. Mean disease duration was 13 years (SD 8) with a wide range from one to 39 years and a median of 11.5 years. The subjects were in the low to moderate disease activity range.

The SDI indicated that this sample of SLE patients had relatively low disease damage (mean 1.8, SD 2.8); indeed only one person had a score > 3 (score of 17).

SF-36 for Physical Health was on average 38.6 (SD 10.9) and mental health 43.1 (SD 12.3). Examination of the subscale scores indicates that this sample of persons with SLE had the greatest difficulty in meeting role demands

Table 1. Clinical characteristics and health profile of study participants.

Construct (scoring range)	Mean, N = 54	SD
Duration of illness, yrs	13	8
Disease activity		
SLAM-2 (0–81)	6.3	4.1
SLEDAI (0–105)	5.0	5.8
Physician VAS (0–10)	1.7	1.4
Patient VAS (0–10)	3.2	2.3
Disease damage		
SDI (0–47)	1.8	2.8
Health-related quality of life		
Physical Health (0–50)	38.6	10.9
Mental Health (0–50)	43.1	12.3
SF-36 subscales (0–100)		
Physical functioning	64.5	27.3
Role-Physical	41.7	44.5
Bodily Pain	53.3	35.2
General Health	46.9	23.2
Vitality	46.1	22.7
Social functioning	67.8	20.9
Role-Emotional	52.5	46.1
Mental Health	66.6	19.1
Health status (EQ-5D)		
EQ-5D Thermometer Rating Scale (0–100)	68.0	21.0
Mobility, problem, N (%)	13 (24)	
Self-care, problem, N (%)	7 (13)	
Usual Activity, problem, N (%)	25 (46)	
Pain, problem, N (%)	37 (69)	
Anxiety, problem, N (%)	25 (46)	

SLAM: Systemic Lupus Activity Measure, SLEDAI: Systemic Lupus Erythematosus Disease Activity Index, SDI: Systemic Lupus International Collaborating Clinics Damage Index, VAS: visual analog scale.

because of physical health (role-physical: mean 41.7, SD 44.5). The highest score was achieved for social function (mean 67.8, SD 20.9).

Overall, HRQL evaluated using the EQ-5D thermometer VAS was 68.0 (SD 21.0). The most frequent problem was pain, reported by 69% of the sample, followed by anxiety/depression reported by 46%. Difficulty with usual activities was also prevalent (46% of sample); fewer people reported difficulty with walking (24%) or self-care (13%).

As shown in Table 2, physicians' subjective ratings of disease activity correlated with clinical indices and are consistent with previous studies³. Patients' ratings, however, were lower. There was no correlation between patients' ratings and the SLEDAI ($r = -0.05$, not significant), which is an index derived largely from clinical and laboratory findings. This is in contrast to findings of a modest correlation with the SLAM-2 ($r = 0.30$, $p < 0.05$), a measure that requires more input from patients into the ratings. As expected, Physical Health and Mental Health were not correlated. The EQ-5D VAS was highly correlated with Physical Health ($r = 0.66$, $p < 0.0001$) and modestly correlated with Mental Health ($r = 0.3$, $p = 0.03$).

Multivariate associations. The first set of regression analyses examined factors related to the 3 principal outcomes: the EQ-5D thermometer VAS and the two SF-36 summary scales. The best models for these analyses are given in Table 3. Associated with the EQ-5D VAS were the role physical and bodily pain subscales of the SF-36, and these reported difficulty with usual activity, a measure of handicap. Self-care was not significantly associated with the EQ-5D VAS, likely because it was a rare problem in this young sample (see Table 1). For Physical Health, the associated variables were the SDI, patient rating of disease activity (VAS), difficulty with walking (mobility), and difficulty with usual activities. These variables represent the constructs of disease damage, disease activity, disability, and handicap, respectively. Only anxiety was associated with Mental Health. The proportion of variability explained by these models ranged from 0.47 to 0.59. The parameter estimates associated with the significant model variables indicate the magnitude and direction of the relationship. For example, for every 1 SD change in the SF-RP, the EQ-5D thermometer VAS increased by 1.38 units (adjusted for bodily pain and usual activity). As usual activity was scored as a dichotomy, the regression parameter indicates that, compared to people with no problem, people with difficulty reported their health to be 10 points lower (adjusted for SF-RP and SF-BP scores). For Physical Health, the effect of usual activity was to decrease it by 7.13 units (adjusted for all other model variables).

Subsequent analyses examined associations with each of the SF-36 subscales. The results of the multiple linear regression models are shown in Table 4. There were very few common associations of the 11 indices used to measure aspects of HRQL from among the variables measuring disease activity and damage. The SLAM-2 was associated only with general health. The SDI was associated with 3 of the HRQL indices: physical health (data not shown), the physical function subscale (a component of physical health), and, to a lesser extent, with the social function subscale.

There was a more consistent pattern concerning how measures of disease activity, or damage, impairment, disability, and handicap related to the HRQL (Table 5). The predominance of difficulty with usual activity is noted. Anxiety/depression was mainly associated with indices capturing constructs related to mental health.

Other statistical models were developed to examine relationships between intermediate variables on the pathway from disease to HRQL. These intermediate variables are impairment, disability, and handicap. Only pain/discomfort (impairment) and duration of disease were significantly associated with mobility (Table 6). For pain/discomfort (a measure of impairment) (Table 7), the patient's perception of disease activity (P-VAS) was the only significant association: a 2 unit difference on P-VAS was associated with a 10% increase in the odds of having pain (OR 1.1, 95% CI

Table 2. Correlations between physician's or patient's rating of disease activity, disease damage, and HRQL.

	SLAM	Physician VAS	Patient VAS	SDI	PCS	MCS	EQ-5D Rating Scale
SLEDAI	0.45**	0.46**	-0.05	0.21	-0.18	-0.07	-0.31*
SLAM-2		0.60**	0.30*	0.36*	-0.19	-0.15	-0.21
Physician VAS			0.28*	-0.01	-0.08	-0.20	-0.26
Patient VAS				0.14	-0.47**	-0.02	-0.22
SDI					-0.34*	0.02	-0.10
PCS						0.06	0.66***
MCS							0.30*

***p < 0.0001; **p < 0.001; *p < 0.05.

SLAM: Systemic Lupus Activity Measures, SLEDAI: Systemic Lupus Erythematosus Disease Activity Index, SDI: Systemic Lupus International Collaborating Clinics Damage Index, PCS: Physical Health of SF-36, MCS: Mental Health of SF-36, VAS: visual analog scale.

Table 3. Results of multiple linear regression models identifying variables independently related to measures of HRQL.

Health Outcome	Variables	Parameter Estimate (β)*	Standard Error	95% CI	R ²
EQ-5D Thermometer Rating Scale	SF-RP	1.38	0.36	(0.67, 2.09)	0.59
	SF-BP	0.78	0.36	(0.07, 1.49)	
	Usual activity	-9.65	4.17	(-17.8, -1.48)	
Physical Health of SF-36	SDI	-4.65	1.23	(-7.30, -2.00)	0.59
	Patient VAS	-0.24	0.12	(-0.48, -0.01)	
	Mobility	-6.06	2.89	(-11.72, -0.40)	
	Usual activity	-7.13	2.42	(-11.87, -2.39)	
Mental Health of SF-36	Anxiety/Depression	-15.00	2.66	(-20.21, -9.79)	0.47

β is the parameter estimate; β/SE is equivalent to a t test.

*Per 1 SD; SF-RP and SF-BP 6 units; SDI 3 units, patient VAS 2 units.

SF-RP: Role-Physical subscale of the SF-36, SF-BP: Bodily Pain subscale of the SF-36.

1.03–1.17; Table 7). No associations with anxiety/depression were significant. Impairment (pain/discomfort and anxiety/depression) and disability (mobility) variables were significantly associated with handicap (usual activity) (Table 8). The OR for pain/discomfort adjusted for anxiety/depression and mobility was 11.4 (95% CI 1.7–78.4).

DISCUSSION

In our study, the Physical Health (SF-36) of patients with SLE was low (mean 38.6, SD 10.9) in comparison to age predicted norms (mean for women aged 35–44 yrs: 51.4, SD 10); Mental Health also scored lower, 43.1 for SLE vs 48.8

for population norms⁶. For the EQ-5D, the mean thermometer rating VAS was 68 (SD 21), lower than the 82.4 (SD 13.1) derived from a normative population from Montreal, Canada²², but higher than that reported from a large sample (n = 233) of patients with rheumatoid arthritis (mean 56.4)²⁹.

Our observation that scores on the SF-36 physical function subscale were 30% to 40% lower than norms concurs with those of Gladman and Fortin³⁻⁵. The areas of HRQL most affected by SLE were role physical, general health, vitality, and role emotional (Table 1).

The use of the EQ-5D was a unique feature of this study. Not surprisingly, the variables associated with these 3 measures differed. Usual activity was associated with both Physical Health and the EQ-5D VAS. Disease damage, patient's perception of disease activity, and mobility were the other variables associated with Physical Health. The EQ-5D VAS was also associated with the SF-36 subscales Role Physical and Bodily Pain. This would suggest that these 2 measures of HRQL (Physical Health and EQ-5D VAS) capture slightly different constructs, with the EQ-5D being mainly influenced by restriction of activity and Physical Health by a wider variety of constructs, reflecting the multi-dimensional content of this instrument.

Analyses revealed that scores registered on SDI were highly associated with both overall physical health and the physical function subscale of SF-36. Our findings are similar to those of Fortin, *et al*³, where cumulative damage scores were found to affect physical function, general health, and social functioning. It is tempting to postulate that once irreversible damage has occurred, its effect on physical function will be long lasting, while other domains such as mental health or role emotional may adapt and return to normal.

Anxiety/depression of the EQ-5D was the only item associated with the Mental Health component of the SF-36, indicating the congruence of these 2 measures. Our study

Table 4. Results of multiple linear regression models identifying variables independently related to SF-36 subscales.

Outcome, SF-36 Subscales	Variables	Parameter Estimate (B)*	Standard Error	95% CI	R ²
Physical function	Self-care	-26.40	6.56	(-39.26, -13.54)	0.64
	Usual activity	-17.24	5.56	(-28.14, -6.34)	
	SDI	-8.64	2.73	(-15.4, -1.88)	
Role physical	Patient VAS	-0.52	0.26	(-1.15, -0.11)	0.47
	Usual activity	-44.92	7.53	(-59.68, -0.06)	
Bodily pain	Patient VAS	-1.62	0.72	(-2.68, -0.56)	0.18
Vitality	Anxiety/depression	-22.47	8.65	(-39.42, -5.52)	0.40
	Usual activity	-16.35	4.49	(-25.15, -7.55)	
Social function	Anxiety/depression	-12.98	5.04	(-22.86, -3.10)	0.36
	SDI	-6.57	2.61	(-12.40, -0.78)	
	Anxiety/depression	-14.37	4.61	(-23.41, -5.33)	
Role emotional	Pain/discomfort	-9.49	4.10	(-17.53, -1.45)	0.32
	Usual activity	-39.17	9.23	(-57.26, -21.09)	
	Physician VAS	-2.22	1.0	(-4.42, -0.02)	
Mental health	Anxiety/depression	-21.67	4.24	(-29.98, -13.36)	0.42
General health	Usual activity	-20.37	4.00	(-28.21, -12.53)	0.50
	SLAM-2	-11.40	3.54	(-17.40, -5.40)	

B is the parameter estimate; B/SE is equivalent to a t test.

*Per 1 SD; SLAM-2 6 units; SDI 3 units, patient VAS 2 units; physician VAS 2 units.

SDI: Systemic Lupus International Collaborating Clinics Damage Index.

Table 5. Summary of the relationship between impairments, disabilities, and handicaps with measures of health status.

	Usual Activity	Anxiety/Depression	Pain/Discomfort	Self-Care	Mobility
EQ-5D VAS	++++	-	-	-	-
SF-36 summary measures					
Physical health (PCS)	+++	-	-	-	+
Mental health (MCS)	-	++++	-	-	-
SF-36 subscale					
Physical functioning (PF)	+++	-	-	+++	-
Role physical (RP)	++++	-	-	-	-
Bodily pain (BP)	-	+	-	-	-
General health (GH)	++++	-	-	-	-
Vitality (VI)	+++	+	-	-	-
Social functioning (SF)	-	++	+	-	-
Role emotional (RE)	+++	-	-	-	-
Mental health (MH)	-	++++	-	-	-

Each sign represents the p value. Statistical significance of results if marked as follows:

+: p ≤ 0.05; ++: p ≤ 0.01; +++: p ≤ 0.001; ++++: p < 0.0001.

did not include other measures of the psychosocial impact of SLE. Other researchers have pointed out the importance of psychological distress and of patient's perception of the gravity of the illness^{30,31}. Like many others³²⁻³⁴, we did not find a strong association between patients' and physicians' VAS ratings for disease activity (r = 0.28). However, the patients' VAS rating was associated with overall Physical Health, 2 of the SF-36 subscales relating to physical func-

tion and role, and presence of pain or discomfort. This suggests that patients rated their disease activity based on physical manifestations of the disease. The physician's VAS rating was highly correlated with the SLAM and SLEDAI, 2 measures of disease activity evaluated by the physician, indicating that these 3 measures capture the same construct.

One potential limitation of this study was its cross sectional nature. SLE is a chronic disease of long duration

Table 6. Variables related to problem with mobility (disability).

Variables	Problem with Mobility, n = 13	No Problem with Mobility, n = 41	Adjusted OR* [95% CI]
Pain/discomfort			
Yes	12	25	8.87
No	1	16	[1.00, 79.8]
Duration, mean (SD)	16.8 (8.3)	11.1 (7.5)	2.54 [1.67, 3.41]

*Per 1 SD; duration 10 years.

Table 8. Variables related to problem with usual activity (handicap).

Variables	Problem with Usual Activity, n = 25	No Problem with Usual Activity, n = 29	Adjusted OR* [95% CI]
Pain/discomfort			
Yes	23	14	11.36 [1.65, 78.37]
No	2	15	
Anxiety/depression			
Yes	17	8	7.91 [1.75, 35.82]
No	8	21	
Mobility			
Yes	11	2	8.90 [1.45, 54.74]
No	14	27	

Table 7. Variables related to problem with pain/discomfort (impairment).

Variables	Problem with Pain, n = 37	No Problem with Pain, n = 17	OR*	95% CI
Patient VAS, mean (SD)	38.36 (22.06)	18.50 (17.54)	1.10	1.03, 1.17

*Per 1 SD; P-VAS 2 units.

characterized by periods of exacerbation and remission. During remission, patients feel generally well and during an exacerbation they can be acutely ill. It is therefore difficult to confirm a causal relationship in a cross sectional study, since there is doubt about the timing of the relationships. Another limitation is in the variety of constructs measured. We focused here on measures of disease activity and damage and included, in a limited fashion, measures of impairment, disability, and handicap. These latter measures could be expanded to include performance based measures of physical function, community activity, self-efficacy, and self-esteem. However, it would be too burdensome for patients to complete such a large battery of tests at any one time. There is no disease-specific measure of HRQL for SLE and we relied on a generic measure, which may not be detailed enough to fully characterize the impact of SLE³⁵. Several important domains for SLE are not captured in generic measures, specifically, sexual activity, sleep, and family function. Finally, the study sample was rather small to study relationships between variables measured on a dichotomous scale. For this reason, we could not adequately study the correlations between activity or damage and impairment.

One criticism of HRQL measures is that they measure constructs outside the realm of the clinician. For HRQL measures to be used in clinical decision making, they must be shown to add value to the clinician's understanding of the way an individual is affected by his or her disease, over and above the usual clinical measurements³⁶. To appreciate the

added value of measuring HRQL, the amount of variability in the 3 measures of HRQL explained by usual clinical assessments was calculated. The only clinical measures related to Physical Health were the SDI and the patient's VAS; together these 2 measures explained 38% of the variability in Physical Health. Difficulty with mobility and with carrying on usual activities explained another 21% of variability, for a total of 59% (Table 3). For the EQ-5D VAS, the SF-36 subscale of bodily pain was the only associated clinical measure, accounting for only 10% of variability. However, adding difficulty with usual activities and role physical accounted for 59% of variability. No clinical measure was associated with mental health (Table 3).

A key finding from this study was the relationship among variables that are related to HRQL. These relationships begin to suggest an empirical model for HRQL as it applies to SLE. Impairment was associated with handicap, which in turn was associated with HRQL. Disability had a direct association both with HRQL and with handicap. Characteristics of the patient's disease such as disease duration, disease activity, and damage had a broader effect than expected, influencing impairment (primarily pain), disability (primarily mobility), and HRQL. It would not be unusual for any patient with a progressive and potentially life threatening disease to report lower HRQL, even if their actual symptomatology is relatively benign. There, relationships are similar to those proposed by the model of HRQL formulated by Wilson and Cleary¹³. Their model showed that there are many intervening variables between disease

process and HRQL. In addition, a number of modifying factors are potentially important, such as motivation, values, preferences, and environmental factors. We did not include such a wide variety of measures, as the response burden to patients would have been too great. Nor was our study longitudinal. We recommend that future studies focus on one or 2 aspects of this complex relationship and follow a cohort over time.

Another model based on the WHO IDH framework was proposed for rheumatoid arthritis by Fitzpatrick and Badley³⁶. This model is quite linear, and depicts the importance of the environment, resources, and social setting as interacting factors. However, this model goes only as far as handicap and does not illustrate the relationship with HRQL.

No one would doubt the value of how the patient feels. Indeed, this is usually the first question asked in any clinical encounter. "How are you?" can be thought of as a global quality of life question³⁷. Clinical measures of SLE disease activity and damage accounted for only a small proportion of how a patient feels. This would support incorporating standardized health status measures into routine clinical practice to appreciate more fully the effect of this disease on the individual.

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