Review of Quality of Life Instruments for the Restless Legs Syndrome/Willis-Ekbom Disease (RLS/WED): Critique and Recommendations

Arthur S. Walters, M.D., F.A.A.S.M.¹; Birgit Frauscher, M.D.²; Richard Allen, Ph.D., F.A.A.S.M.³; Heike Benes, M.D.⁴; K. Ray Chaudhuri, M.D.⁵; Diego Garcia-Borreguero, M.D.⁶; Hochang B. Lee, M.D.⁷; Daniel L. Picchietti, M.D., F.A.A.S.M.⁸; Claudia Trenkwalder, M.D.⁹; Pablo Martinez-Martin, M.D., Ph.D.¹⁰; Glenn T. Stebbins, Ph.D.¹¹; Anette Schrag, M.D.¹²; and members of the MDS Committee on Rating Scales¹³

¹Department of Neurology, Vanderbilt University School of Medicine, Nashville, TN; ²Department of Neurology Medical University of Innsbruck, Austria; ³Johns Hopkins University, Baltimore, MD; ⁴Institute for Medical Research and Sleep Medicine, Schwerin, Germany and University of Rostock, Department of Neurology, Rostock, Germany; ⁵National Parkinson Foundation Center of Excellence, Kings College, London, UK; ⁶Sleep Research Institute, Madrid, Spain; ⁷Department of Psychiatry, Yale University, New Haven, CT; ⁸University of Illinois School of Medicine and Carle Foundation Hospital, Urbana, IL; ⁹Department of Neurology, Georg-August University, Goettingen, Germany; ¹⁰National Center of Epidemiology and CIBERNED, Carlos III Institute of Health, Madrid, Spain; ¹¹Department Neurological Sciences, Rush University Medical Center, Chicago, IL; ¹²UCL Institute of Neurology, University College, London, UK; ¹³See Appendix

Objectives: Over the last decade therapeutic, pathogenetic, epidemiological and genetic research in restless legs syndrome/Willis-Ekbom Disease (RLS/WED) has required the development of specific quality of life scales and sleep scales. A Movement Disorder Society Task Force formally evaluated the quality of these scales.

Methods: A literature search retrieved 5 quality of life instruments specific to RLS. As per MDS protocol, each scale was evaluated by 3 criteria which included (a) use in RLS, (b) use by research or clinical groups other than the group that developed the scale, and (c) formal validation and adequate clinimetric properties. Scales were categorized as "Recommended" when all 3 criteria were met, "Suggested" when used for RLS but only one of the other criteria was met, and "Listed" when used in RLS but there was absence of the other two criteria. Details regarding the development, use and clinimetric properties of each instrument are summarized along with the recommendations of the Task Force.

Results and Conclusion: The Restless Legs Syndrome Quality of Life Scale-Abetz (RLS-QOL-Abetz) is the only scale designated as Recommended for use in cross-sectional assessments and treatment-related changes in RLS quality of life. Daily diaries hold future promise for the evaluation of RLS symptoms without the need for retrospective recall. An important need is the development of pediatric RLS quality of life instruments.

Keywords: restless legs syndrome, Willis-Ekbom Disease, quality of life, sleep scales

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Restless legs syndrome (RLS) can significantly impact quality of life in patients with moderate to severe intensity of symptoms on a level par with type 2 diabetes mellitus, depression, hypertension, and osteoarthritis combined.¹ Therefore, RLS Quality of Life (RLS-QOL) scales and scales specific to sleep disturbance in RLS were developed to facilitate clinical research on RLS. This review summarizes the quality of the extant instruments for evaluating the quality of life in RLS/Willis-Ekbom Disease (WED) and makes recommendations as to the usefulness of these scales. *Diagnostic instruments and rating scales for the severity of adult RLS, pediatric RLS, and augmentation are addressed in separate publications.*

It is to be pointed out that none of the quality of life scales reviewed here are diagnostic instruments and a proper diagnosis of RLS must be made prior to the use of the scales. Therefore, the integrity of these scales is directly proportional to the integrity of the RLS diagnosis itself. An important article appeared in 2009,²

pointing out that if one asks about the 4 criteria for RLS to a general population without doing a proper differential diagnosis, 16% of subjects who do not have RLS will be misclassified as having RLS. This knowledge inspired the International RLS Study Group to add a fifth criterion to the previous diagnostic criteria requiring a differential diagnosis for RLS and listing examples of some of the disorders in the differential diagnosis of RLS.³ It is emphasized that even though some of the scales evaluated here were validated prior to the formalization of the need to perform an adequate differential diagnosis of RLS, this differential diagnosis has always been performed by RLS experts. To the extent that scales were validated in cohorts by RLS experts, these cohorts were found to be acceptable to the task force.

The challenges to the development of a good quality of life scale are many.⁴⁻¹² One of the principal challenges is for the developers of the scale to determine which quality of life measures are actually important to the patient. One way to handle

this is to have preliminary questions screened by patient focus groups for meaningfulness. Even after this process is done, a post hoc analysis of the questions is important. As in one example, the actual recipients of the final questionnaire were largely no longer working and questions regarding impact on work life became less relevant. In addition, recipients of the final questionnaire were more sensitive to questions regarding sex life than was previously anticipated.⁴

It is also to be emphasized that the quality of life instruments reviewed here have only been validated in adult populations. Children would probably require the development of separate quality of life instruments pertinent to the home and school setting in language appropriate for age. To our knowledge there are no quality of life instruments that have been developed or validated for the pediatric RLS population. This therefore represents an important unfulfilled need.

METHODS

Administrative Organization and Critique Process

This project was organized under the leadership and guidance of the Movement Disorder Society (MDS). The senior author of the project (AW) was asked to head and form the

working group of a Movement Disorder Society Task Force (MDS-TF) to evaluate quality of life and sleep scales specific to RLS.

Literature Search and Selection of Scales

A PubMed literature search was conducted to identify scales used to assess quality of life or sleep in RLS. The terms “restless legs syndrome quality of life” or “RLS quality of life” identified 329 articles, of which only 8 evaluated RLS quality of life scales. When the terms “restless legs syndrome” or “RLS” was crossed with the term “sleep scale,” 106 articles were identified, of which only 2 were found that evaluated RLS sleep scales. If an RLS instrument not captured by the literature review was mentioned in an article, the paper or abstract evaluating the instrument was also obtained and reviewed. A total of 5 RLS instruments were obtained and reviewed. In some cases there was more than one article evaluating a single scale.

Review Criteria

Table 1 lists the criteria used to designate scales as “Recommended,” “Suggested,” or “Listed” for use in RLS: (1) if an RLS quality of life or sleep scale has been applied to RLS-related populations, has been employed by investigators other than the group that originally developed it, and has satisfactory clinimetric properties that instrument is “recommended”; (2) if it has been applied to RLS but meets only one of the other two requirements it is “suggested”; and (3) if it has only been applied to RLS but does not meet either of the other two criteria it is “listed.” When the validation of an instrument is available only in the format of an abstract without a full publication, the scale is discussed, but its clinimetric properties cannot be properly rated. **Table 2** denotes the criteria fulfilled by each scale, including the final level of recommendation using the MDS criteria. **Table 3** summarizes the clinimetric properties of each scale.

RESULTS

A total of 5 instruments pertinent for review were identified, 3 to evaluate quality of life (QOL) in RLS patients and 2

Table 1—Definition of the categories for evaluation of RLS instruments.

Recommended:

1. Instrument has been applied to RLS populations;
2. Other groups beyond the original developing group have published data on the clinical utility of the scale;
3. Psychometrical studies are available that conclude that the scale is valid and reliable.

Suggested:

Instrument has been applied to RLS populations but only one other criterion (2) or (3) from the above recommended category applies.

Listed:

Instrument has been applied to RLS populations, but no further criterion met.

Table 2—Evaluation of different quality of life and sleep instruments for RLS.

Instruments for RLS	Use in RLS	Use by other investigators	Adequate clinimetrics	Appropriate population	Conclusions
RLS quality of life					
RLS-QOL-Abetz	Yes	Yes	Yes	Clinic and community RLS	Recommended cross-sectional conditions & change with Rx
RLS-QLI	Yes	Yes	No	Clinic and community RLS	Suggested cross-sectional conditions
RLS-QOL-Kohnen	Yes	In treatment trials under non-validated conditions	No	Clinic and community RLS	Suggested cross-sectional conditions
Sleep questionnaires specific for RLS					
Post sleep questionnaire for RLS	Yes	No	No	Clinic	Listed cross-sectional conditions & change with Rx with caveats
The Restless Legs Syndrome-next day impact questionnaire	Yes	No	No	Clinic	Listed

Table 3—Detailed analysis of quality of life and sleep instruments.

Instruments for RLS	Miscellaneous	IRR by Kappa or ICC or other, Test-Retest	CA, FA	CRIT, CONV, DIV, KG	Response ES
RLS quality of life					
RLS-QOL-Abetz		Test-Retest ICC = 0.79	CA = 0.92. 3 factors with 72% variance.	CONV $r = 0.5$ with MCS of SF-36. Item-scale correlations 0.5 to 0.9. KG $p < 0.0001$.	$r = -0.51$, $p < 0.0001$ (see text). ES 0.54 to 1.51.
RLS-QLI		Test-Retest subscales 0.81 to 0.93	4 factors with 73.3% of variance. CA of subscales 0.85 to 0.91.	CRIT subscales to IRLS $r = -0.43$ to -0.77 . Correlation between subscales 0.48 to 0.63. CONV subscales $r = 0.26$ to 0.62.	
RLS-QOL-Kohnen			1 factor with 66.8% of variance. CA = 0.95.	CRIT to IRLS = 0.93. Inter-item correlation $r = 0.64$ to 0.91. CONV to RLS-6 = 0.60	
Sleep questionnaires specific for RLS					
Post sleep questionnaire for RLS				CONV items to IRLS 0.25 to 0.49. CONV to POMS (0.04 to 0.48). CONV to MOS (0.04 to 0.49). CONV to RLS-QOL-Abetz (-0.12 to -0.57). KG $p < 0.0001$	Guyatt's statistic 0.38 to 3.46
The Restless Legs Syndrome-next day impact questionnaire	Strong face and content validity for RLS patients who do not have daytime symptoms and are on no soporific medication. Not yet validated.				

IRR, interrater reliability as measured by Cohen κ or intraclass correlation (ICC) or other; CA, Cronbach α , which is a measure of the internal consistency of the instrument; FA, factor analysis which is a method applied to inform about the dimensionality of the instrument (construct validity); CRIT, criterion validity which means comparison of the instrument to a gold standard; CONV, convergent validity which refers to the correlation of the instrument with another measure of RLS or its comorbidities; DIV, divergent or discriminant validity which refers to the correlation of the instrument with another measure not related to RLS; KG, Known-groups (discriminative) validity which refers to the ability of the instrument to detect differences between groups at a point in time; Response, responsiveness which is a measure of change of an instrument over time with or without treatment; ES, effect size; POMS, Profile of Mood States; MOS, MOS sleep scale; MCS, a component of the SF-36 quality of life scale that is a measure of mental health.

instruments to assess the sleep disturbance commonly found in RLS patients. All of these were self-evaluative scales. Because of its distinctive character, a post-sleep diary for RLS is not given full review in this article.

RLS Quality of Life

Restless Legs Syndrome Quality of Life Questionnaire-Abetz (RLS-QOL-Abetz)

DESCRIPTION OF THE SCALE

This scale includes 18 self-administered questions on the impact of RLS on daily life, emotional well-being, social life, and work life.⁴ Lower scores indicate lower quality of life. The authors developed and revised the scale in consultation with clinician experts and RLS patients themselves, producing a final version after field testing a preliminary version of the scale. Scale properties were evaluated by sending the RLS-QOLs by mail to 200 RLS clinic patients for completion upon receipt. It is to be emphasized that all these patients had the diagnosis of RLS performed in the clinic by clinicians with expertise in RLS. The scale was then mailed again, and the patients were asked

to return it after 2 weeks from the first assessment. Eighty-five patients returned the initial assessment, and, of those, 62 returned the second assessment. The scale has been translated in to many languages including Dutch, Finnish, French, German, Greek, Hungarian, Italian, and Japanese. A separate validation of the scale has been done in Hindi.

KEY CRITERIA

This instrument has been utilized in RLS patients (Criterion 1) and has been used by multiple research groups (Criterion 2). In regards to clinimetric testing (Criterion 3), construct validity as determined by a factor analysis showed that there were 3 possible factors. The first unrotated factor had an eigenvalue of 6.1 with a cumulative variance of 51%, and the eigenvalues and cumulative variances of the second and third factors were small. Since the first factor was so large and some clinically relevant items loaded on the other factors, a decision was made to focus on a summary score. Some items were dropped from the summary score, e.g., work-related items, since a large number of patients were not working. Questions on impact on sexual activity were also dropped from the summary score since many patients preferred not to answer these questions. However, despite

the fact that these questions were dropped from the summary score, the questions regarding work and sexual activity were maintained as part of the questionnaire since the information collected was thought to be of possible future relevance. The final summary score included 10 of the original 18 questions, with lower scores indicating lower quality of life. All items in the summary score met or exceeded the threshold for acceptable item convergent validity, and item scale correlations ranged from 0.50 to 0.90. Floor and ceiling effects were minimal. The scale summary score showed good internal consistency with a Cronbach α of 0.92. The ICCs were above the minimum standard of 0.70 for test-retest reliability for the RLS-QOL summary scale (ICC = 0.79) in the total sample and for patients with stable symptoms (ICC = 0.84). Convergent validity was moderate between the scale summary score and the Mental Component Score of the SF-36 ($r = 0.50$, $p < 0.0001$) and nonsignificant with the Physical Component Score of the SF-36. For known-groups validity there was a significant difference between the mean scores on the RLS-QOL summary scale stratified by the severity levels of RLS as determined by the International Restless Legs Scale-patient version. Responsiveness was assessed by looking at the difference between summary scale scores for the two administrations of the scale and then comparing the results to those obtained by the co-administration of a health status questionnaire, where patients rated themselves as worse, stable, or improved. There was a good correlation with acceptable effect sizes.⁴ The RLS-QOL was also evaluated in a second study that was done in a trial population of 547 subjects who underwent treatment with ropinirole for RLS in one of two placebo-controlled, multinational studies. Again, the diagnosis of RLS was made in the clinic by clinicians with expertise in RLS. Results were similar.⁵ Responsiveness was demonstrated by looking at the summary score (renamed the overall life impact score) of the RLS-QOL from baseline to week 12 of treatment and determining the correlation of change in scores with the Clinical Global Impression-Improvement ([CGI-I] $r = -0.51$, $p < 0.001$). A sub-analysis showed that there was a parallel between the improvement in the RLS-QOL life impact score and the level of improvement seen in the CGI-I.⁵ The effect size was large (1.51) in both the ropinirole studies for patients declaring themselves “very much improved” on the CGI and also large in the first (1.15) and second (1.00) ropinirole studies for patients declaring themselves “much improved” on the CGI. The effect size was moderate for patients declaring themselves “minimally improved” on the CGI (ES = 0.74 and 0.54, respectively).

STRENGTHS AND WEAKNESSES

The RLS-QOL-Abetz has excellent clinimetric properties and has been validated under cross-sectional conditions and responsiveness has been shown with treatment. The diagnosis of RLS was made in the clinic by clinicians with expertise in RLS.

CONCLUSIONS

The RLS-QOL-Abetz was designed for RLS, has been used in RLS research, including therapeutic trials by groups other than the original authors, and shows excellent clinimetric properties. It has been validated in a clinical setting and shows sensitivity to change with treatment in a clinical trial setting. Therefore, the RLS-QOL-Abetz is “Recommended.”

The Restless Legs Syndrome Quality of Life Instrument (RLS-QLI)

DESCRIPTION OF THE SCALE

For this self-administered scale, items were generated from a literature review, consultation with M.D. and Ph.D. specialists and input from two patient focus groups.⁶ An initial screening of 392 subjects with self-reported RLS resulted in an item reduction and the final scale, consisting of 17 questions, was validated in a sample of 574 persons from the RLS Foundation’s Interest Group Listserv who also reported having RLS. Lower scores indicate lower quality of life.

KEY CRITERIA

This instrument has been utilized in RLS patients (Criterion 1) and has been used by multiple research groups (Criterion 2). In regards to clinimetric testing (Criterion 3), factor analysis revealed 4 factors that explained 73.3% of the total variance: Daily Function, Social Function, Sleep Quality, and Emotional Well-Being. Each subscale demonstrated good internal consistency (Cronbach α coefficients range: 0.85-0.91). There was a moderate to high correlation between the subscales (range: 0.48-0.63). Test-Retest stability at a 2-week interval in 30 subjects showed Pearson correlation coefficients ranging from 0.81 to 0.93. Convergent validity showed, as a whole, moderate correlations between the RLS-QLI subscale scores and the corresponding SF-36 Subscales ($r = 0.26$ -0.62). Criterion-related validity was shown by satisfactory correlations of the RLS-QLI subscale scores with the IRLS total score, subscales and individual IRLS items ($r = -0.43$ to -0.77).⁶

STRENGTHS AND WEAKNESSES

The RLS-QLI has excellent clinimetric properties, but it has been only evaluated under cross-sectional conditions. Thus, response to change with treatment has yet to be investigated. Because the scale was administered to subjects who were from the RLS foundation Interest Group’s electronic mailing list, the accuracy of the RLS diagnosis in the previous office visit, if there was one, cannot be guaranteed. Therefore we cannot enthusiastically support the clinimetric properties of this scale.

CONCLUSIONS

The RLS-QLI, designed for use in RLS, has been used by groups beyond its designers, and demonstrates adequate reliability and validity. However, the accuracy of the RLS clinical diagnosis cannot be guaranteed and the clinimetric analysis is therefore weakened. There is no information about responsiveness. According to MDS criteria, the scale is “Suggested” for evaluating quality of life at any single point in time.

Restless Legs Syndrome Quality of Life Questionnaire-Kohnen (RLS-QOL-Kohnen)

DESCRIPTION OF THE SCALE

Kohnen et al. developed a separate self-administered RLS quality of life instrument named identically to the one developed by Abetz et al.^{4,5,7} To avoid confusion and for purposes of the current evaluation we will use the term RLS-QOL-Kohnen.⁷ The questions were developed from a survey of 721 patients

of North-German RLS self-help groups (64% females, median age 65 years) and later an additional survey of 69 other RLS patients from self-help groups. Six-point Likert-type scales were used to determine severity for each question.

KEY CRITERIA

This instrument has been utilized in RLS patients (Criterion 1) and has been used by multiple research groups (Criterion 2). In regards to clinimetric testing (Criterion 3), the validation has only been published in abstract form and thus cannot be fully evaluated. In the validation presented in abstract form, the final version has 12 items that explore 4 areas: (1) consequences of RLS symptoms on sleep, activities of daily living, mood, and social interactions; (2) everyday life, tiredness, and mood; (3) pain and side effects of RLS medications; and (4) coping behavior. All the 12 items loaded on a single factor that explained 66.8% of the variance. The inter-item correlation ranged from 0.64 to 0.91. Cronbach α was 0.95, indicating good internal consistency. Convergent validity with a severity scale for RLS, the RLS-6 was about 0.60.^{7,8} Correlation of the RLS-QOL-Kohnen total score to the total score of the IRLS is very high ($r = 0.93$) (Criterion validity).⁷

STRENGTHS AND WEAKNESSES

Reported clinometric properties of the scale are excellent. However, the validation data are published in abstract form only, limiting interpretation of the scale properties. In addition, because RLS subjects were chosen from a self-help group, the accuracy of the RLS diagnosis cannot be guaranteed and enthusiasm for the clinimetric properties of this scale is dampened. Stability and sensitivity to change with treatment have not yet been investigated.

CONCLUSIONS

The RLS-QOL-Kohnen scale, developed for and used in RLS, has been used by authors beyond the designers. The scale showed satisfactory clinimetric properties, although stability and responsiveness have not been examined. In addition, validation data, to our knowledge, have been published in abstract form only and therefore cannot be fully evaluated. In addition the diagnosis of RLS cannot be guaranteed based upon the data presented. Therefore, this scale is classified as “Suggested” (Table 2).

Sleep Questionnaires Specific for RLS

Post-Sleep Questionnaire for RLS (PSQ)

DESCRIPTION OF THE SCALE

In the development of this self-completed scale, pooled data of 540 adult patients from two 12-week, randomized, placebo-controlled trials of gabapentin enacarbil in RLS were employed.⁹ The RLS diagnosis was verified in the clinic by clinicians with expertise in the diagnosis of RLS.

Scale ratings are based on subjective experiences over the last week and assess 5 domains: overall quality of sleep, ability to function during the day, frequency of RLS symptoms, awakening at night due to RLS symptoms, and length of awakening in the night due to RLS symptoms. The scale employs 4

Likert-type scale questions and one open ended question on the number of nights per week with RLS symptoms. Higher PSQ scores indicate worse sleep.

KEY CRITERIA

This instrument has been utilized in RLS patients (Criterion 1) but has not been used by multiple research groups (Criterion 2). In regards to clinimetric testing (Criterion 3), the PSQ showed small to moderate criterion validity as all correlations between each PSQ item and the total IRLS score ranged from 0.25 to 0.49. It is well known that sleep disturbance, in general, is highly associated with anxiety and depression. The 5 PSQ questions had weak to moderate correlations (0.04 to 0.48) with the Profile of Mood States (POMS) total score. In addition, weak to moderate convergent validity was found between the PSQ questions and Medical Outcomes Study (MOS)-Sleep Scale domains ($r = 0.04$ to 0.49). Each item of the PSQ showed small to large convergent validity with the RLS-QOL-Abetz score ($r = -0.12$ to -0.57). Satisfactory known-groups validity was demonstrated by significant correlations between the baseline severity of each of the 5 PSQ items and the severity levels of RLS based on the IRLS (all, $p < 0.001$). The scale was shown to be very responsive to treatment with improvement in the 5 PSQ questions, paralleling the improvement in different levels of the CGI as rated by both the patient (Guyatt responsiveness index 0.38 to 3.46) and the examiner (Guyatt responsiveness index 0.44 to 2.87) separately. An instrument with a Guyatt responsiveness index > 0.2 has acceptable responsiveness, and an instrument with > 1.00 has high responsiveness to change. Furthermore this improvement was seen independent of treatment assignment since all the subjects, both placebo and drug treated, were analyzed as a group for purposes of the validation.⁹

STRENGTHS AND WEAKNESSES

The PSQ showed weak to strong correlations with other measures of RLS severity, but demonstrated excellent sensitivity to change under treatment conditions.

CONCLUSIONS

The PSQ was designed for RLS, but it has not been used by investigators beyond its designers. In addition, its internal consistency and stability have not been explored. The convergent validity with RLS severity measures is variable, but the responsiveness is satisfactory. One strength is that the diagnosis of RLS was made in the clinic by clinicians with expertise in RLS. However, overall the clinimetric properties are not thought to be strong. Accordingly, the PSQ is classified as “Listed,” with the mentioned limitations, for use in the evaluation of the sleep disturbance severity in RLS.

The Restless Legs Syndrome-Next Day Impact Questionnaire

DESCRIPTION OF THE SCALE

The items for this scale were developed using interviews with patients and evaluation of the patient responses by clinical and measurement experts.¹⁰ The final scale consists of 14 items assessing the impact of sleep loss from RLS on daily functioning. The scale is rated based upon function for a single day “today” and is self-administered by patients at night with

a 12-hour recall. Each item is rated on an 11-point Likert-type scale with higher numbers indicating increasing impact of RLS sleep loss on daytime functioning. The scale probes daytime functioning focusing on possible impairments in alertness, concentration, and mood. The patients for the development of the scale were carefully selected to not have any significant daytime symptoms of RLS or be on any RLS medications.¹⁰

KEY CRITERIA

This instrument has been utilized in RLS patients (Criterion 1) but has not been used by multiple research groups (Criterion 2). In regards to clinimetric testing (Criterion 3), the scale shows good content validity but no further validation of this scale has been carried out at this point in time so no statement can be made about how the cohort chosen for the future validation will be done.

STRENGTHS AND WEAKNESSES

This scale was developed by a very rigorous process but has not been validated under cross-sectional conditions nor has responsiveness to change been shown with treatment. If responsiveness can be shown under treatment conditions, the scale would be useful primarily in clinical trials where patients do not have any daytime RLS symptoms and are not on any medications that could also cause the symptoms of sleepiness, tiredness, and lack of concentration or impaired mood. For patients who have significant daytime RLS or are on daytime RLS medications, we could see that it would be difficult to separate out the impact of sleep disturbance due to RLS from the direct impact of daytime RLS symptoms on mood or the soporific effect of RLS medications if taken during the day.

CONCLUSIONS

The scale has been developed and used for RLS, but to our knowledge it has not been used by any group beyond the original developers and has not been validated. Therefore, this scale is classified as “Listed” (Table 2).

DISCUSSION

The Movement Disorder Society Task Force commissioned to evaluate the Quality of Life and sleep scales for RLS identified five relevant scales, summarized in Table 2. None of the scales has been evaluated or used in settings or populations beyond those in which they were validated. With that limitation considered, only the RLS-QOL-Abetz, however, is “Recommended” for use both as a cross-sectional measure and as a tool for assessing change with treatment. The RLS-QLI and the RLS-QOL-Kohnen are “Suggested.” The Restless legs Syndrome-Next Day Impact Questionnaire and the Post Sleep Questionnaire for RLS are “Listed.” Enthusiasm for the otherwise good clinimetric properties of the RLS-QLI, the RLS-QOL-Kohnen, and the Subjective Post Sleep Diary for RLS (SPSD) is dampened, since the patients selected for the studies were drawn from patient support groups where the diagnosis of RLS cannot be guaranteed as it was not done by known experts. However, we would not discourage the use of these scales altogether, as the specificity of the original 4 diagnostic criteria is 84%, which is reasonably good.

Although there are limitations to the available RLS-specific QOL and sleep scales, development of a new adult scale is not currently recommended. The Task Force recommends that future endeavors include validation of daily diaries as a measure of the sleep disturbance and other symptoms of RLS in response to treatment.^{11,12} An additional important unfilled need is the development of a Pediatric RLS quality of life instrument.

APPENDIX

MDS Committee on Rating Scales Development

Pablo Martinez-Martin, Chair

Glenn Stebbins, Co-Chair

Esther Cubo

Christopher G. Goetz

Deborah Hall

Sheng Luo

Laura Marsh

Bart Post

Cristina Sampaio

Anette Schrag

Daniel Weintraub

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many of the scales and evaluative instruments we employ in RLS/WED research today including the widely used RLS-6 and the RLS Quality of Life scales. For the RLS/WED community he was the principal person to whom we all turned for advice and help in the development and validation of these instruments. He will be much missed.

Author Roles: Drs. Walters, Frauscher, Martinez-Martin, Stebbins, and Schrag were involved in the conception, organization, execution, review, and critique of the project and manuscript. Dr. Walters wrote the first and all subsequent drafts of the manuscript. Drs. Allen, Benes, Chaudhuri, Garcia-Borreguero, Lee, Picchetti, and Trenkwalder were involved in the conception, review, and critique of the project and manuscript.

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Address correspondence to: Arthur S. Walters, M.D., Department of Neurology, Vanderbilt University School of Medicine, MCN A-0118 1161 21st Ave South, Nashville, Tennessee 37232; Tel: (615) 322-0283; Fax: (615) 936-0223; E-mail: Arthur.Walters@Vanderbilt.edu

DISCLOSURE STATEMENT

This was not an industry supported study. Dr. Walters served as a consultant for and has received research funding from UCB Pharma and Mundi Pharma. He has also received funding from the USA National Institutes of Health. He has also served as an expert witness in a single legal case involving restless legs syndrome. Dr. Frauscher has received research funding from the Austrian Science Fund, a Schroedinger Fellowship Abroad, and the National Bank of Austria Anniversary Fund. Dr. Allen served as a consultant for Luitpold Pharmaceuticals, Pfizer, Phar-

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