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The development and preliminary validation of the CTCL-PRO-20: a novel quality of life survey for patients with cutaneous T-cell lymphoma

Neha Akkad[1,2], Donna B. Jeffe[3], Anastasia Krause[4], Noor Al-Hammadi[5], Marcus Watkins[4], Amy Musiek[6], Neha Mehta-Shah[4]

[1]Department of Medicine, Internal Medicine Residency Program, Washington University in St. Louis School of Medicine, St. Louis, MO, USA

[2]Division of Cancer Medicine, Hematology and Oncology Fellowship Program, MD Anderson Cancer Center, Houston, TX, USA

[3]Department of Medicine, Division of General Medicine, Geriatrics, and Hospital Medicine Washington University in St. Louis School of Medicine, St. Louis, MO,
USA https://orcid.org/0000-0002-7642-3777

[4]Department of Medicine, Division of Oncology, Washington University in St. Louis School of Medicine, St. Louis, MO, USA

[5]Department of Health and Clinical Outcomes Research, Saint Louis University School of Medicine, St. Louis, MO, USA

[6]Department of Medicine, Division of Dermatology, Washington University in St. Louis School of Medicine, St. Louis, MO, USA

Corresponding Author:
Neha Mehta-Shah, MD, MSCI
Division of Oncology
Mail Stop 8056-0029-11
Washington University
660 South Euclid Avenue
St. Louis, MO 63110
Mehta-n@wustl.edu
https://orcid.org/0000-0001-5744-0670

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ABSTRACT:

Cutaneous T-cell lymphoma (CTCL) is a rare disease with a high symptom burden, negatively impacting patients' quality of life (QoL). There is no agreed-upon CTCL-specific metric to measure QoL in CTCL. Thus, we created a novel questionnaire to fill this gap. Eighty CTCL-patients participated in this cross-sectional survey study. An iterative process of principal components analysis (PCA) yielded a 5-component solution with 20 items; this patient-reported outcomes (PRO) questionnaire, the CTCL-PRO-20, had high internal-consistency reliability (Cronbach's α=0.93). Components measured self-consciousness (α =.94), treatment burden (α=.92), lack of CTCL resources (α=.74), sleep/fatigue (α=.87), and skin concerns (α=.88). High Pearson correlations were observed between the CTCL-PRO-20 and QoL measures more relevant to patients' experiences (e.g., MF/SS-CTCL QoL and Skindex-29); lower correlations were observed with the generic-QoL (SF-36) and single-focused (e.g., sleep-disturbance) measures. Patients with stable/no active disease (vs. progressive disease) reported significantly lower treatment-burden scores (better QoL). Patients who received systemic and topical treatments (vs. no treatment) reported significantly higher CTCL-PRO-20 scores (poorer QoL). This single-center study provides preliminary evidence of construct and convergent validity of the CTCL-PRO-20 and its components, warranting further validation in a well-powered study to examine its sensitivity to change after treatment intervention.

INTRODUCTION:

Cutaneous T-Cell Lymphoma (CTCL) is a rare form of T-cell non-Hodgkin lymphoma that presents in the skin; mycosis fungoides (MF) and its leukemic variant Sézary syndrome (SS) are the most common CTCL subtypes.[1] CTCL is treatable but not curable without an allogeneic transplant, and therefore therapy is largely palliative and symptom directed. Patients with advanced-stage disease (stage IIB-IVB) have a poor prognosis, and a median survival of <5 years.[2, 3] In addition, CTCL carries unique disease-specific challenges, which have a significant negative impact on patient quality of life (QoL), partially due to the particularly debilitating symptom burden even when compared to other malignancies and skin diseases.[4, 5] A prior study[4] evaluating QoL in patients with CTCL showed significantly worse scores than patients with general dermatologic diseases on several QoL measures, including the Health Utilities Index-3 (HUI3)[6], RAND 36-item Health Survey 1.0 (SF-36),[7] Skindex-29,[8] Visual Analog Scale (VAS) Itch over the past 24 hours,[9] and 5-D Itch Scale.[10] This study[4] also showed that CTCL patients with advanced-stage disease had greater QoL impairment than patients with early-stage disease (stage IA-IIA).

While clinical trials in CTCL have incorporated tools to evaluate QoL, they have relied largely on measures used for other dermatologic conditions or more general oncology QoL metrics, as robust CTCL-specific measures that show sensitivity to change in disease status were not available at the time these trials were conducted. In addition, several measures used to evaluate QoL in patients with CTCL are lacking critical information about CTCL-specific concerns important to this patient population. Using inductive thematic analysis of interviews with CTCL patients, Bhat et al.[11] identified several issues important to patients' QoL including itch, pain, fatigue, sleep, skin breaks, skin flaking, concerns about appearance, isolation, "otherness", depression, hopelessness, uncertainty, treatment burden, and a lack of resources about CTCL in the community; some of these particular patient concerns have not been captured in existing QoL measures. To our knowledge, there is no existing QoL measure that was made using all of these concerns affecting QoL in CTCL patients.[11]

We therefore sought to develop a comprehensive, CTCL-specific PRO measure based on analysis of patient interview data, incorporating patient feedback on item development, and validating this new measure in patients with early- and advanced-stage disease in a single-center, pilot study.

METHODS

Patient Population

A single-center, cross-sectional survey study was conducted at Washington University in St. Louis from 3/15/2023- 8/10/2023. Eligibility criteria included patients who had a biopsy-confirmed diagnosis of CTCL, were ≥ 18 years old, able to read and speak English, and able to independently complete surveys. This study was carried out in accordance with the declaration of Helsinki and was approved by the Washington University School of Medicine Institutional Review Board (IRB). All patients enrolled provided informed consent.

Questionnaire Item Development

Based on inductive thematic analysis of semi-structured interview data from 18 patients with early- and late-stage CTCL,[11] 54 items were developed for a new CTCL-focused QoL questionnaire. These items were reviewed for clinical relevance by a multidisciplinary panel including oncologists, dermatologists, and an expert in instrument development, after which 46 items remained. Next, one-on-one cognitive interviews were conducted with nine CTCL patients

(5 early-stage, 4 late-stage) to elicit feedback about the clarity of item wording, interpretation, response options, and survey length.[12, 13] Participant feedback was examined by the multidisciplinary panel, who then revised or removed items identified as problematic, (e.g., compound sentence construction or redundancy) leaving 41 items for pilot testing (Supplemental Figure 1).

Response options for each new CTCL-PRO item used a 5-point Likert scale ranging from Strongly disagree (1) to Strongly agree (5). Four CTCL-PRO items focused on treatment burden that patients experienced in the past month; for these four items, a sixth response option was offered for patients not receiving treatment: “Not applicable – I have not been on treatment in the last month.” This option was given a score of 0, which would not adversely affect the total score a patient received. Lower total scores due to “not applicable” responses to these items (scored 0) should not be interpreted differently than a score of 1 on these items.[14] Item responses were summed, and higher total scores indicate greater CTCL-specific concerns (i.e., poorer QoL).

Data Collection

In addition to the 41 newly developed items, participants completed six previously validated questionnaires, including the eight SF-36 subscales,[7] Mycosis Fungoides/Sézary Syndrome (MF/SS)-CTCL QoL,[14] VAS-Itch (past 24 hours),[9] Skindex-29,[15] Center for Epidemiologic Studies Depression (CES-D) Scale,[16] and the Patient Reported Outcomes Measurement Information System (PROMIS™) Sleep Disturbance.[17] Scoring of each measure followed the developer’s published scoring guidelines. Patients could complete the survey either electronically using REDCap or on paper. Clinical data were collected from the electronic medical record and included initial stage at diagnosis and current stage and disease status at time of survey completion (stable/no active disease, active disease responding to current therapy, and progressive disease), type(s) of treatment received (light, topical, radiation, and systemic therapies), and lines of treatment received (0-4).

Statistical Analysis

An iterative process of principal components analysis (PCA)[18] with the 41 newly developed, CTCL-focused PRO items was run for data reduction. PCA is a commonly used, efficient statistical process for data reduction to empirically identify multi-item components for analysis from item responses.[19, 20] After dropping items that lacked variance in response, we ran the PCA using an oblique (oblimin) rotation to examine correlations among individual items and item loadings on specific components, and to determine if components were intercorrelated.[21] Component loadings are the regression coefficients of each item on each component extracted. We retained items loading ≥.600 on a single component and dropped items loading ≥.400 on more than one component after rotation.[18, 22] Cross-loading on more than one component indicates an item does not discriminate between different constructs.[23] At this early stage of instrument development, we also considered retaining items that loaded ≥.500 on a component, if the item was especially relevant to CTCL topics identified during patient interviews,[11] without loading ≥.400 on another component. We thus retained components using commonly accepted criteria: each component should have at least three items with moderate-to-high component loadings on one factor after rotation,[18] and an eigenvalue >1.000.[18] Cronbach’s α was used to measure the internal-consistency reliability of items that loaded highly on each component and on the overall CTCL-PRO; Cronbach’s α ≥.70 was considered acceptable.[24, 25] We examined the construct and convergent validity of the new measure using Pearson correlations between our new CTCL-PRO measure and each of the other questionnaires. We examined differences in each of the QoL continuous measures by patient demographics, disease status, stage, and treatments received using analyses of variance (ANOVAs). We used chi-square tests to measure associations among the categorical demographic and clinical variables. Two-tailed statistical significance was set at $p<.05$; statistical tests were performed using IBM SPSS version 28.0.0.0 (IBM Corp, Armonk, NY).

RESULTS

Patient Characteristics

Ninety-three patients consented to participate in this study, of whom 80 (88%) were included in the PCA. Seventy-four (80%) patients completed >75% of items on each measure and were included in the subsequent analyses to examine the construct and convergent validity of the new CTCL-PRO questionnaire following the PCA. There were no significant differences in demographic or clinical variables between participants and non-participants (Table 1). Among the 74 participants with complete data, 42 (57%) were men and 63 (85%) self-identified as white. Forty-seven (64%) participants were early-stage and 27 (36%) were advanced-stage CTCL at diagnosis. At time of survey completion**,** 19 of the 27 patients with initial advanced-stage disease were re-staged as early-stage disease due to response to treatment, all patients with initial early-stage disease remained early-stage. Thirty-five (47%) patients had stable/no active disease, 28 (38%) had active disease responding to current therapy, and 11 (15%) had progressive disease. Most patients received 1-2 types of treatment (84%). Specific systemic therapies patients received most recently prior to survey completion are described are described in a footnote to Table 1.

Principal Component Analysis

An iterative process of PCA was run using (oblique) oblimin rotation, yielding a 5-component solution with 20 items. The 20 items comprising this novel measure, the CTCL-PRO-20, are shown in Supplemental Figure 2. We report the pattern matrix loadings after rotation (Table 2). Items with loadings ≥.600 on one component were retained[22], as were two items loading ≥.500 on their respective component measuring sleep problems and concern about sores, which were identified in patient interviews as being especially relevant to CTCL-related QoL.[11] Items with moderate-to-high loadings on each of the five CTCL-PRO-20 components demonstrated acceptably high internal-consistency reliabilities: Component 1) 6-item self-consciousness (Cronbach's α =.94); Component 2) 4-item treatment burden (Cronbach's α =.92); Component 3) 3-item lack of CTCL resources (Cronbach's α =.74); Component 4) 4-item sleep/fatigue (Cronbach's α =.87); and Component 5) 3-item concern about sores (Cronbach's α =.88). Cronbach's α for the overall 20-item CTCL-PRO-20 measure was .93. We computed total scores for the overall CTCL-PRO-20 and each of the five subscales; higher total scores on the CTCL-PRO-20 and subscales indicate greater CTCL-related concerns and poorer QoL. In the component correlation matrix after oblimin rotation, the self-consciousness component and sleep/fatigue component were moderately correlated ($r=.543$); however, correlations among other pairs of components were low (ranging from $r=.095$ to $r=.363$).

Construct and Convergent Validity

We assessed the construct and convergent validity of the overall CTCL-PRO-20 and its components using Pearson correlations between each of these CTCL-PRO-20 components and other previously validated metrics (Table 3).

Overall CTCL-PRO-20. Low-to-moderate correlations were observed between the overall CTCL-PRO-20 and each of the measures less specific to CTCL. Low-to-moderate negative correlations were observed between the overall CTCL-PRO-20 and the SF-36 scales (higher scores on the SF-36 indicate better QoL and higher scores on the CTCL-PRO-20 indicate poorer QoL). The lowest significant correlation was between the overall CTCL-PRO-20 and SF-36 Physical functioning scale ($r=-.314$). Correlations were moderate between the overall

CTCL-PRO-20 and each of the VAS-Itch (r=.665), CES-D Scale (r=.617), and PROMIS™ Sleep Disturbance Scale (r=.465). Correlations were highest between the overall CTCL-PRO-20 and the MF/SS-CTCL QoL (r=.803) and Skindex-29 overall (r=.809).

CTCL-PRO-20 self-consciousness component. The self-consciousness component showed moderate-to-high correlations with each of the other QoL measures except for the SF-36 Physical functioning (r=-.205) and Role limitations due to physical health subscales (r=-.366); this component also showed a low but significant correlation with patient age (r=-.244).

CTCL-PRO-20 treatment-burden component. Moderate correlations were observed between the CTCL-PRO-20 treatment-burden component and the VAS Itch (r=.434) and Skindex-29 Symptoms subscale (r=.408). Overall, low correlations were observed between the CTCL-PRO-20 treatment-burden component and other variables. Low but significant correlations were seen between the treatment-burden component and the Skindex-29 Overall (r=.342) measure, the Skindex-29 Emotional (r=.284) and Functioning (r=.296) subscales, the SF-36 Social functioning subscale (r=-.272), and the MF/SS-CTCL QoL (r=.322). The remaining six variables were not significantly correlated with this component.

CTCL-PRO-20 lack of CTCL resources component. Moderate correlations were observed between the CTCL-PRO-20 lack-of-CTCL-resources component and the MF/SS-CTCL QoL, seven of eight SF-36 subscales, Skindex-29 Overall and subscales, and CES-D. Although low, correlations between this lack-of-CTCL-resources component and the VAS Itch, PROMIS sleep disturbance, and SF-36 Physical functioning subscale were statistically significant.

CTCL-PRO-20 sleep/fatigue component. The CTCL-PRO-20 sleep/fatigue component demonstrated moderate-to-high correlations with each of the other measures, except the SF-36 Role limitations due to emotional problems subscale (r=-.320). Of note, the sleep/fatigue component was only moderately correlated with PROMIS sleep disturbance, but highly correlated with VAS Itch, MF/SS CTCL QoL, and Skindex-29 Overall and Symptoms and Functioning subscales.

CTCL-PRO-20 concerns about sores component. There were low correlations between the CTCL-PRO-20 concerns-about-sores component and each of the VAS-Itch (r=.319) and eight SF-36 subscales, but moderate correlations were observed between this component and the other QoL measures.

Correlations among CTCL-PRO-20 overall and five component scores. The self-consciousness (r=.872) and sleep/fatigue (r=.820) components correlated more highly with the overall CTCL-PRO-20 than the other three components, which nevertheless showed moderate-to-high correlations (ranging from .601 to .765) with the overall CTCL-PRO-20 (Table 4). Each component also correlated more highly with the overall CTCL-PRO-20 than they correlated with each of the other CTCL-PRO-20 components.

Between-Group Differences in the Overall CTCL-PRO-20 and Components

Using ANOVAs, we observed no significant differences by sex or race/ethnicity in the CTCL-PRO-20 overall or its components (data not shown). Differences based on disease status, initial stage, and current stage are summarized in Table 5. The CTCL-PRO-20 treatment-burden component differed significantly by disease status (p=.02); in Bonferroni post-hoc pairwise comparisons, patients with stable/no active disease reported significantly lower treatment-burden scores (i.e., better QoL) than patients with progressive disease (6.9 [4.9] vs. 11.1 [5.1]; p=.03). Patients with active disease responding to current therapy scored between these two groups. The other CTCL-PRO-20 components and overall score did not differ significantly by disease status. There were no significant differences observed in the CTCL-PRO-20 overall or its component scores by initial or current stage.

In ANOVAs of the CTCL-PRO-20 overall or component scores by receipt of types of treatment at time of survey (Table 6), patients receiving (vs. not receiving) systemic therapies reported significantly higher scores indicating greater agreement with self-consciousness and concern about sores. Patients receiving topical treatments reported higher scores for the CTCL-PRO-20 overall measure, self-consciousness, and a lack of CTCL resources. CTCL-PRO-20 overall and component scores did not differ significantly between patients receiving and not receiving light or radiation therapy, though sample sizes were small for these groups, especially radiation, received by four patients.

DISCUSSION:

The CTCL-PRO-20 is a novel 20-item CTCL-specific questionnaire reflecting concerns affecting CTCL patient QoL. It is one of very few CTCL-specific QoL surveys created with input from both early-and advanced-stage patients, and was developed for use in clinical practice and clinical research studies. The MF/SS-CTCL-QoL questionnaire[14] and Functional Assessment of Cancer (FACT)-CTCL[26] were also developed to measure QoL in CTCL patients, however these two measures use different item wording and have a single factor structure. The FACT-CTCL, which includes both the well-validated, 27-item FACT-General (FACT-G)[27] and the newer CTCL-S asks patients to indicate their responses "as it applies to the past 7 days"[26] without mention of MF/SS, whereas the MF/SS-CTCL-QoL[14] and CTCL-PRO-20 ask patients to consider their response over the "past 4 weeks" or "past month," respectively, with explicit mention of MF/SS. Although we compute a CTCL-PRO-20 total score, the five, distinct, multi-item subscales can each be used as separate CTCL-specific QoL measures, setting this measure apart from the MF/SS-CTCL-QoL and CTCL-S, which are both single-score measures of QoL. Moreover, the CTCL-PRO-20 component addressing the lack of knowledge and resources about CTCL is unique to this measure. Importantly, all three of these CTCL-specific QoL questionnaires require further validation to show sensitivity to change in response to treatment in clinical trials. None of these CTCL-specific measures have been adequately validated for use in clinical practice thus far.

In this preliminary assessment of the psychometric properties of the CTCL-PRO-20, items on each of the five components and the overall CTCL-PRO-20 demonstrated high internal-consistency reliability.[25] The MF/SS-CTCL-QoL and overall Skindex-29, which predominantly measure issues that affect CTCL patient QoL, were highly correlated with the overall CTCL-PRO-20, supporting its convergent validity. The significant low-to-moderate correlations between the CTCL-PRO-20 and other QoL questionnaires indicate the CTCL-PRO-20 measures constructs that may be related to but are different from the other questionnaires, supporting discriminant validity. Additionally, each of the CTCL-PRO-20 components correlated more highly with the overall measure than with each other, indicating that each component contributes differentially to this measure. The CTCL-PRO-20 treatment-burden component scores were significantly higher in patients with progressive disease and patients receiving systemic therapy scored significantly higher on the self-consciousness and concern about sores components, providing preliminary evidence that the CTCL-PRO-20 captures treatment effects on QoL. To our knowledge, the association between lack of CTCL resources and QoL is a novel finding, indicating a need for more patient-directed resources and information to better prepare them for living with this rare disease. Inconsistent with our previous findings using other QoL measures,[4] we observed no significant differences in CTCL-PRO-20 scores based on stage. Our finding may be due to the small sample of patients with advanced-stage CTCL or the efficacy of some well-tolerated modern therapies, which warrants further study.

Other studies reported that women with CTCL have worse QoL than men[27-29] and Black patients are more likely to develop CTCL and have worse overall survival compared to white patients.[30,

[31] However, CTCL-PRO-20 scores did not differ significantly by sex or race/ethnicity. This could be due to the CTCL-specific focus of this measure, suggesting that among patients in our sample, the effects of CTCL on QoL may not be differentially experienced by sex or race/ethnicity. Similar results were reported using the MF/SS CTCL QoL.[14]

As noted, there are two existing, however only preliminarily validated, surveys intended to measure QoL in CTCL patients, the MF/SS-CTCL-QoL and FACT-CTCL. The MF/SS-CTCL-QoL study included mostly patients with early stage disease, and stage was self-reported[14], introducing potential inaccuracies, as staging CTCL can be complex. While the CTCL-PRO-20 overall was highly correlated with the MF/SS-CTCL-QoL, some CTCL-PRO-20 components had low or moderate correlations with the MF/SS-CTCL-QoL, indicating that these components are measuring different constructs. A subscale of the FACT-CTCL questionnaire, the CTCL-S,[26] was published after our study was initiated, and therefore not included in our preliminary validity assessments. The CTCL-PRO-20 provides unique insights into PROs that are either not captured, or not captured in as much depth, by these existing questionnaires as they are in the multi-item self-consciousness and lack of CTCL resources components of the CTCL-PRO-20. The extent to which the CTCL-PRO-20 and CTCL-S are correlated will be examined in future validation studies using both measures. Importantly, further research is needed to examine each of these new CTCL-specific measures' sensitivity to change in response to therapy.[14, 26]

The CTCL-PRO-20 covers additional CTCL-specific domains compared to other validated measures used in clinical trials including FACT-G and Skindex-29. Skindex-29 measures skin-related symptoms, which is only one component of the many important domains affecting CTCL patient QoL, importantly it lacks questions about skin breaks/sores and lack of understanding in the community which we found to be important components of CTCL patient QoL. FACT-G, developed to measure health-related QoL in patients with cancer lacks questions about itch, skin breaks/flaking, concern about appearance/self-consciousness, and lack of understanding in the community. The items developed for the CTCL-PRO-20 initially included all domains we found important to CTCL patient QoL specifically, and the domains retained after the PCA included nearly all of these important domains, representing a unique combination compared to existing measures. (Supplemental Table 1) Items regarding pain, depression, hopelessness, and uncertainty, while noted as important to CTCL patient QoL[11] and therefore included in the initial PCA, either cross-loaded on two or more components with loadings >.400 or did not load highly (≥.600) on a single component measuring affect as intended.[22] Such items were either complex or otherwise unable to distinguish between constructs; therefore, they were dropped from further analysis.[23]

QoL metrics have become an important endpoint in registrational trials in CTCL. The phase III ALCANZA[32] and MAVORIC trials[33] evaluating the efficacy of brentuximab vedotin and mogamulizumab respectively, used Skindex-29, FACT-G, and EQ-5D (ALCANZA only) to measure QoL and showed improved QoL in the experimental arms.[32, 34] However, none of these trials included a CTCL-specific measure of PROs. After additional validation, we hope the CTCL-PRO-20 can be used to measure PROs for patients with CTCL in clinical trials and could also be applied to disease assessment in clinic. In other rare diseases, such as myelofibrosis, disease-specific QoL tools have become a primary endpoint of registrational trials[35], and such PRO measures are needed in CTCL. Development of the CTCL-PRO-20 was driven by the need for a CTCL-focused measure of QoL, which continues to be a critical focus of our future work to assess this new measure's sensitivity to change after intervention.

Limitations include that this study was carried out at a single center with a relatively small sample size. Based on prior work, larger samples of 150-200 and moderate component saturation (i.e., loadings≥.600) provide more stable estimates and can approximate a good fit to the population pattern across varying conditions.[22] We purposefully retained items with moderate-to-high component loadings that did not load >.400 on any other component; thus, the component saturation was adequate for each of the five components and the overall measure. Few patients had advanced-stage disease at time of survey completion, limiting our ability to observe significant differences by stage, and while representative of our patient population, few non-white patients participated, limiting the generalizability of our findings. Validation studies with larger samples are needed to further substantiate the stability of the component structure,[22] the convergent and discriminant validity of the CTCL-PRO-20, and establish the external validity of the new measure in a more diverse population. Thus, we are carrying out a large multicenter study (n=250) to evaluate the CTCL-PRO-20 measure's test-re-test reliability and sensitivity to change in response to treatment. We will then plan to carry out a prospective assessment of CTCL-PRO-20 scores in a cohort undergoing a therapeutic intervention in a clinical trial with uniform response assessment, which will allow for evaluation of the survey's sensitivity to change in response to treatment. The CTCL-PRO-20 is already incorporated into an ongoing investigator-initiated CTCL clinical trial. If validated in multi-center studies, we expect the CTCL-PRO-20 will have utility as a CTCL-specific QoL tool that can be used as an endpoint for clinical trials and a simple tool to aid clinical decision-making.

References

1. Willemze R, Jaffe ES, Burg G, et al. WHO-EORTC classification for cutaneous lymphomas. Blood. 2005;105(10):3768-3785.
2. Scarisbrick JJ. The PROCLIPI international registry, an important tool to evaluate the prognosis of cutaneous T cell lymphomas. Presse Med. 2022;51(1):104123.
3. Scarisbrick JJ, Quaglino P, Whittaker S, et al. A new prognostic index (CLIPI) for advanced cutaneous lymphoma enables precise patient risk stratification. Blood. 2025;146(14):1687-1692.
4. Herbosa CM, Semenov YR, Rosenberg AR, et al. Clinical severity measures and quality-of-life burden in patients with mycosis fungoides and Sézary syndrome: comparison of generic and dermatology-specific instruments. J Eur Acad Dermatol Venereol. 2020;34(5):995-1003.
5. Ottevanger R, van Beugen S, Evers AWM, et al. Quality of life in patients with Mycosis Fungoides and Sézary Syndrome: a systematic review of the literature. J Eur Acad Dermatol Venereol. 2021;35(12):2377-2387.
6. Horsman J, Furlong W, Feeny D, Torrance G. The Health Utilities Index (HUI®): concepts, measurement properties and applications. Health Qual Life Outcomes. 2003;1(1):54.
7. Hays RD, Sherbourne CD, Mazel RM. The RAND 36-item health survey 1.0. Health Econ. 1993;2(3):217-227.
8. Chren MM, Lasek RJ, Quinn LM, et al. Skindex, a quality-of-life measure for patients with skin disease: reliability, validity, and responsiveness. J Invest Dermatol. 1996;107(5):707-713.
9. Reich A, Heisig M, Phan NQ, et al. Visual analogue scale: evaluation of the instrument for the assessment of pruritus. Acta Derm Venereol. 2012;92(5):497-501.
10. Elman S, Hynan LS, Gabriel V, et al. The 5-D itch scale: a new measure of pruritus. Br J Dermatol. 2010;162(3):587-593.
11. Bhat TS, Herbosa CM, Rosenberg AR, et al. Current measures are not sufficient: an interview-based qualitative assessment of quality of life in cutaneous T-cell lymphoma*. Br J Dermatol. 2021;184(2):310-318.
12. Beatty PC, Willis GB. Research synthesis: the practice of cognitive interviewing. Public Opin Q. 2007;71(2):287-311.
13. Willis GB, Artino AR Jr. What Do Our Respondents Think we're asking? Using cognitive interviewing to improve medical education surveys. J Grad Med Educ. 2013;5(3):353-356.
14. McCaffrey S, Black RA, Nagao M, et al. Measurement of quality of life in patients with mycosis fungoides/sézary syndrome cutaneous t-cell lymphoma: development of an electronic instrument. J Med Internet Res. 2019;21(1):e11302.
15. Chren MM, Lasek RJ, Flocke SA, et al. Improved discriminative and evaluative capability of a refined version of Skindex, a quality-of-life instrument for patients with skin diseases. Arch Dermatol. 1997;133(11):1433-1440.
16. Radloff LS. The CES-D Scale:A self-report depression scale for research in the general population. applied psychological measurement. Appl Psychol Meas. 1977;1(3):385-401.
17. Yu L, Buysse DJ, Germain A, et al. Development of short forms from the PROMIS™ sleep disturbance and sleep-related impairment item banks. Behav Sleep Med. 2011;10(1):6-24.
18. Zwick WR, Velicer WF. Comparison of five rules for determining the number of components to retain. Psychol Bull. 1986;99(3):432-442.
19. Velicer WF, Jackson DN. Component analysis versus common factor analysis: some further observations. Multivariate Behav Res. 1990;25(1):97-114.

20. de Winter J, Dodou D. Common factor analysis versus principal component analysis: a comparison of loadings by means of simulations. Commun Stat Simul Comput. 2016;45:299-321.
21. Brown JD. Choosing the Right Type of Rotation in PCA and EFA. Shiken: JALT Testing & Evaluation SIG Newsletter. 2009;13(3):20-25.
22. Guadagnoli E, Velicer WF. Relation of sample size to the stability of component patterns. Psychol Bull. 1988;103(2):265-275.
23. Brooks GP, Pokoo JS, Adjanin N, Johanson GA. Cross-loadings in scale development: monte carlo study of structural item-total correlation analysis with small samples. GLMJ. 2023;47(2):1-15.
24. Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika. 1951;16(3):297-334.
25. Bland JM, Altman DG. Cronbach's alpha. BMJ. 1997;314(7080):572.
26. Raymundo C, Cella D, Wagner LI, et al. Development and psychometric properties of the functional assessment of cancer therapy-cutaneous t-cell lymphoma (FACT-CTCL) instrument. Br J Dermatol. 2024;192(1):78-84.
27. Cella DF, Tulsky DS, Gray G, et al. The functional assessment of cancer therapy scale: development and validation of the general measure. J Clin Oncol. 1993;11(3):570-579.
28. Chalaka CW, Mahurin HM, Tarabadkar E, et al. Gender disparities in health-related quality of life (HRQoL) in patients with cutaneous T-cell lymphoma. Int J Womens Dermatol. 2023;9(2):e085.
29. Molloy K, Jonak C, Woei AJF, et al. Characteristics associated with significantly worse quality of life in mycosis fungoides/Sézary syndrome from the Prospective Cutaneous Lymphoma International Prognostic Index (PROCLIPI) study. Br J Dermatol. 2020;182(3):770-779.
30. Su C, Nguyen KA, Bai HX, et al. Racial disparity in mycosis fungoides: an analysis of 4495 cases from the US National Cancer Database. J Am Acad Dermatol. 2017;77(3):497-502.e2.
31. Weinstock MA, Horm JW. Mycosis fungoides in the United States. Increasing incidence and descriptive epidemiology. JAMA. 1988;260(1):42-46.
32. Horwitz SM, Scarisbrick JJ, Dummer R, et al. Randomized phase 3 ALCANZA study of brentuximab vedotin vs physician's choice in cutaneous T-cell lymphoma: final data. Blood Adv. 2021;5(23):5098-5106.
33. Kim YH, Bagot M, Pinter-Brown L, et al. Mogamulizumab versus vorinostat in previously treated cutaneous T-cell lymphoma (MAVORIC): an international, open-label, randomised, controlled phase 3 trial. Lancet Oncol. 2018;19(9):1192-1204.
34. Dummer R, Prince HM, Whittaker S, et al. Patient-reported quality of life in patients with relapsed/refractory cutaneous T-cell lymphoma: Results from the randomised phase III ALCANZA study. Eur J Cancer. 2020;133:120-130.
35. Verstovsek S, Gerds AT, Vannucchi AM, et al. Momelotinib versus danazol in symptomatic patients with anaemia and myelofibrosis (MOMENTUM): results from an international, double-blind, randomised, controlled, phase 3 study. Lancet. 2023;401(10373):269-280.

Table 1. Characteristics of patients who consented to participate (N=93)

	Participants with complete data N=74 (%)	Non-participants N=19 (%)	P value[a]
Age, mean (SD), yrs	64.1 (15.0)	64.6 (13.6)	.90
Sex			.20
Male	42 (56.8)	14 (73.7)	
Female	32 (43.2)	5 (26.3)	
Race/ethnicity			.72
White	63 (85.1)	16 (84.2)	
Black	9 (12.2)	3 (15.8)	
Hispanic	2 (2.7)	0 (0.0)	
Initial stage			.40
Early stage (IA, IB, IIA)	47 (63.5)	14 (73.7)	
Advanced stage (IIB-IVB)	27 (36.5)	5 (26.3)	
Current[b] stage			.99
Early stage (IA, IB, IIA)	66 (89.2)	17 (89.5)	
Advanced stage (IIB-IVB)	8 (10.8)	2 (10.5)	
Current[b] disease status			.86
Stable/no active disease	35 (47.3)	10 (52.6)	
Active disease responding to current therapy	28 (37.8)	7 (36.8)	
Progressive disease	11 (14.9)	2 (10.5)	
Current[b] receipt of treatment			
Systemic treatment[c]			.41
Yes	39 (52.7)	12 (63.2)	
No	35 (47.3)	7 (36.8)	
Light treatment			.59
Yes	26 (35.1)	5 (26.3)	
No	48 64.9()	14 (73.7)	
Topical treatment			.80
Yes	31 (41.9)	9 (47.4)	
No	43 (58.1)	10 (52.6)	
Radiation therapy			.58
Yes	4 (5.4)	0 (0.0)	
No	70 (94.6)	19 (100.0)	
Combinations of treatment received			.39
Untreated	6 (8.1)	0 (0.0)	
Only other types of treatment	29 (39.2)	7 (36.8)	
Systemic with or without other treatment	39 (52.7)	12 (63.2)	
Total types of treatment received			.86
0	8 (10.8)	1 (5.3)	

1	40 (54.1)	12 (63.2)	
2	22 (29.7)	5 (26.3)	
3	4 (5.4)	1 (5.3)	

[a] Chi-square tests reported or Fisher's exact tests when cells for 2 x 2 tests included <10 cases.

[b] "Current" refers to the time of survey completion (participants) or consent (non-participants).

[C] Systemic treatment includes any CTCL-directed therapy that was given via an oral or intravenous route, including the following: Bexarotene (n=19), Mogamulizumab (n=5), Lacutamab (n=3), Brentuximab vedotin (n=3), Methotrexate (n=1), Gemcitabine (n=1), Pembrolizumab (n=1), Upadacitinib (n=1), liposomal doxorubicin (n=1), and Mogamulizumab-CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone; n=1). One patient had most recently received an allogeneic stem cell transplant as their CTCL-directed therapy.

Table 2. Descriptive statistics for each item and pattern matrix from principal components analysis after oblimin rotation showing item loadings on each component of the CTCL-PRO-20 Questionnaire (N=80).

	Mean (SD)[a]	Component Coefficients[b]				
		CTCL-PRO-20 Self-consciousness	CTCL-PRO-20 Treatment burden	CTCL-PRO-20 Lack of CTCL resources	CTCL-PRO-20 Sleep/fatigue problems	CTCL-PRO-20 Concern about sores
Item 2. I refrain from going out in public because of my appearance.	1.9 (1.2)	**.890**	.085	-.068	.078	-.169
Item 6. I am embarrassed to be with other people due to skin flaking.	2.1 (1.2)	**.842**	.015	-.117	.023	.076
Item 23. I am concerned about my appearance due to MF/SS.	2.8 (1.3)	**.746**	-.081	.158	.009	.172
Item 24. I feel self-conscious about my appearance due to MF/SS.	2.9 (1.4)	**.822**	-.037	.106	-.051	.163
Item 35. I feel socially isolated because of my MF/SS.	2.2 (1.2)	**.758**	.137	.102	.026	.009
Item 37. I am embarrassed about the way I look.	2.6 (1.3)	**.809**	.014	.082	.017	.110
Item 38. The frequency of my treatment(s) interferes with my daily activities.	2.1 (1.4)	-.029	**.968**	.031	.009	-.100
Item 39. The frequency of my treatment(s) interferes with my social life.	1.9 (1.3)	.026	**.897**	.012	.097	-.034
Item 40. The time I have spent receiving treatment for MF/SS has been a burden.	2.0 (1.3)	.061	**.942**	-.035	-.127	.042
Item 41. The side effects of MF/SS treatments have been burdensome.	2.1 (1.3)	-.040	**.693**	.013	.088	.273
Item 17. In the general population, there is a lack of understanding about MF/SS.	4.1 (0.9)	-.111	-.009	**.876**	-.077	.060
Item 21. It is frustrating that more people do not know about MF/SS.	3.2 (1.1)	.225	.085	**.643**	.123	-.034
Item 22. There is a lack of available resources for me to share with friends and family to help them better understand MF/SS.	3.1 (1.0)	.073	-.012	**.752**	.105	-.073

Item 1. Worrying about MF/SS prevents me from falling asleep.	2.1 (1.2)	.397	.000	.098	**.548**	-.201
Item 7. Symptoms of MF/SS, including itch, impact my ability to fall asleep.	2.7 (1.4)	.087	.097	.042	**.837**	-.072
Item 20. Fatigue due to MF/SS or its treatment prevents me from completing daily tasks.	2.5 (1.2)	.140	.024	.093	**.646**	.086
Item 31. My MF/SS symptoms, including itch, cause me to wake up during the night.	2.8 (1.4)	-.183	-.007	-.006	**.943**	.190
Item 8. I have experienced broken skin (sores or cuts) due to MF/SS or its treatment.	3.2 (1.4)	.057	.119	-.029	.025	**.853**
Item 10. I am concerned about the sores and/or cuts on my skin.	3.0 (1.3)	.124	.092	.115	.105	**.767**
Item 19. Skin flaking due to MF/SS is bothersome.	3.1 (1.4)	.330	-.081	-.079	.266	**.586**

[a] Response options for each item used a 5-point Likert scale ranging from 1=Strongly disagree to 5=Strongly agree, with higher scores indicating poorer quality of life.

[b] Coefficients in bold font indicate items with moderate-to-high correlations on each component.

CTCL-PRO-20, Cutaneous T-cell Lymphoma Patient-reported Outcomes 20-item Questionnaire; MFSS/CTCL, Mycosis Fungoides/Sézary Syndrome.

Table 3. Pearson correlations among each of the CTCL-PRO-20 overall and component scores and other variables of interest (N=74)

	CTCL-PRO-20 Overall	CTCL-PRO-20 Self-consciousness	CTCL-PRO-20 Treatment burden	CTCL-PRO-20 Lack of CTCL resources	CTCL-PRO-20 Sleep/fatigue problems	CTCL-PRO-20 Concern about sores
Age	-.182	-.244[c]	-.016	-.092	-.216	-.054
VAS Itch	.665[a]	.538[a]	.434[a]	.315[b]	.638[a]	.535[a]
MFSS/CTCL QoL	.803[a]	.777[a]	.322[b]	.507[a]	.766[a]	.603[a]
PROMIS Sleep disturbance	.465[a]	.440[a]	.079	.361[b]	.564[a]	.319[b]
SF36 Physical functioning	-.314[b]	-.205	-.138	-.364[b]	-.407[a]	-.159
SF36 Role limitations-physical health	-.504[a]	-.366[b]	-.300[b]	-.437[a]	-.491[a]	-.371[b]
SF36 Role limitations-emotional problems	-.439[a]	-.478[a]	-.186	-.384[a]	-.320[b]	-.265[c]
SF36 Vitality	-.521[a]	-.464[a]	-.175	-.499[a]	-.552[a]	-.326[b]
SF36 Emotional well-being	-.587[a]	-.642[a]	-.141	-.429[a]	-.555[a]	-.397[a]
SF36 Social functioning	-.611[a]	-.556[a]	-.272[c]	-.518[a]	-.616[a]	-.359[b]
SF36 Pain	-.505[a]	-.428[a]	-.194	-.438[a]	-.579[a]	-.302[b]
SF36 General health	-.531[a]	-.425[a]	-.291[c]	-.464[a]	-.520[a]	-.351[b]
Skindex-29 Symptoms	.760[a]	.574[a]	.408[a]	.406[a]	.743[a]	.748[a]
Skindex-29 Emotional	.756[a]	.767[a]	.284[c]	.499[a]	.677[a]	.567[a]
Skindex-29 Functioning	.754[a]	.736[a]	.296[c]	.486[a]	.716[a]	.556[a]
Skindex-29 Overall	.809[a]	.757[a]	.342[b]	.504[a]	.758[a]	.649[a]
CES-D	.617[a]	.632[a]	.184	.503[a]	.552[a]	.450[a]

CTCL-PRO-20, Cutaneous T-Cell Lymphoma Patient-reported Outcomes 20-item; VAS, Visual Analog Scale; MFSS/CTCL QoL, Mycosis Fungoides/Sézary Syndrome Cutaneous T-Cell Lymphoma Quality of Life; PROMIS, Patient Reported Outcomes Measurement Information System; SF-36, RAND 36-Item Health Survey (Short Form); CES-D, Center for Epidemiologic Studies-Depression

[a] p<.001. [b] p<.01. [c] p<.05.

Table 4. Pearson correlations among each of the CTCL-PRO-20 overall and component scores (N=74)

	CTCL-PRO-20 Overall	CTCL-PRO-20 Self-consciousness	CTCL-PRO-20 Treatment burden	CTCL-PRO-20 Lack of CTCL resources	CTCL-PRO-20 Sleep/fatigue problems	CTCL-PRO-20 Concern about sores
CTCL-PRO-20: Self-consciousness	.872[a]	1.00				
CTCL-PRO-20: Treatment burden	.657[a]	.384[a]	1.00			
CTCL-PRO-20: Lack of CTCL resources	.601[a]	.467[a]	.258[c]	1.00		
CTCL-PRO-20: Sleep/fatigue problems	.820[a]	.632[a]	.396[a]	.486[a]	1.00	
CTCL-PRO-20: Concern about sores	.765[a]	.623[a]	.363[b]	.313[b]	.577[a]	1.00

CTCL-PRO-20, Cutaneous T-Cell Lymphoma Patient-reported Outcomes 20-item Questionnaire.

[a] p<.001. [b] p<.01. [c] p<.05.

Table 5. Analysis of variance of CTCL-PRO-20 overall and component mean (SD) total scores, by current disease status and initial and current stage (N=74).

	Current disease status				Initial stage			Current stage		
CTCL-PRO-20 components	Stable/ no active disease n=35	Active disease responding to therapy n=28	Progressive disease n=11	P	Early n=47	Advanced n=27	P	Early n=66	Advanced n=8	P
Overall	49.5 (17.3)	52.3 (16.0)	61.2 (14.9)	.13	50.2 (16.3)	55.9 (17.2)	.16	51.6 (16.7)	58.0 (17.6)	.31
Self-consciousness	13.6 (7.2)	14.0 (5.7)	17.4 (5.9)	.24	13.6 (6.2)	15.6 (7.0)	.20	14.0 (6.5)	16.9 (6.8)	.24
Treatment burden	6.9 (4.9)	8.8 (4.0)	11.1 (5.1)	.02	8.0 (5.4)	8.6 (3.6)	.59	8.2 (5.0)	8.3 (3.0)	.98
Lack of CTCL resources	10.2 (2.7)	10.1 (2.5)	10.5 (2.0)	.94	10.0 (2.6)	10.7 (2.3)	.22	10.2 (2.5)	10.4 (2.3)	.86
Sleep/fatigue	9.9 (4.8)	9.9 (4.1)	11.0 (3.9)	.76	9.6 (4.4)	10.9 (4.2)	.25	9.8 (4.4)	12.0 (4.0)	.19
Concern about sores	8.9 (3.7)	9.4 (3.9)	11.3 (3.2)	.18	9.0 (3.4)	10.1 (4.2)	.20	9.3 (3.7)	10.5 (4.1)	.39

CTCL-PRO-20, Cutaneous T-Cell Lymphoma Patient-reported Outcomes 20-item Questionnaire.

Table 6. Analysis of variance of CTCL-PRO-20 overall and component mean (SD) total scores, by each type of treatment received. (N=74).

CTCL-PRO-20 components	**Systemic therapy**		P	**Light therapy**		P	**Topical therapy**		P	**Radiation therapy**		P
	No n=35	Yes n=39		No n=48	Yes n=26		No n=43	Yes n=31		No n=70	Yes n=4	
Overall	48.5 (15.0)	55.7 (17.7)	.06	54.6 (17.0)	48.0 (15.9)	.11	56.5 (17.5)	46.4 (14.0)	.009	52.0 (16.7)	57.8 (19.1)	.50
Self-consciousness	12.7 (5.4)	15.8 (7.2)	.04	15.4 (6.7)	12.3 (5.9)	.06	16.3 (7.0)	11.5 (4.6)	.002	14.3 (6.5)	14.8 (7.9)	.89
Burden of treatment	7.6 (5.3)	8.8 (4.3)	.26	8.0 (4.5)	8.5 (5.4)	.69	8.9 (4.7)	7.4 (4.8)	.18	8.2 (4.8)	9.5 (4.4)	.59
Lack of CTCL resources	10.2 (2.3)	10.2 (2.7)	.99	10.4 (2.6)	9.8 (2.2)	.34	10.9 (2.3)	9.3 (2.5)	.007	10.2 (2.5)	11.0 (2.2)	.53
Sleep/fatigue	9.5 (4.3)	10.6 (4.4)	.27	10.7 (4.5)	8.9 (3.9)	.08	10.7 (4.4)	9.2 (4.1)	.12	10.1 (4.4)	10.2 (4.4)	.94
Concern about sores	8.5 (3.5)	10.2 (3.8)	.047	10.0 (3.8)	8.4 (3.5)	.08	9.7 (3.8)	9.0 (3.6)	.42	9.3 (3.7)	12.2 (2.5)	.12

CTCL-PRO-20, Cutaneous T-Cell Lymphoma Patient-reported Outcomes 20-item Questionnaire.

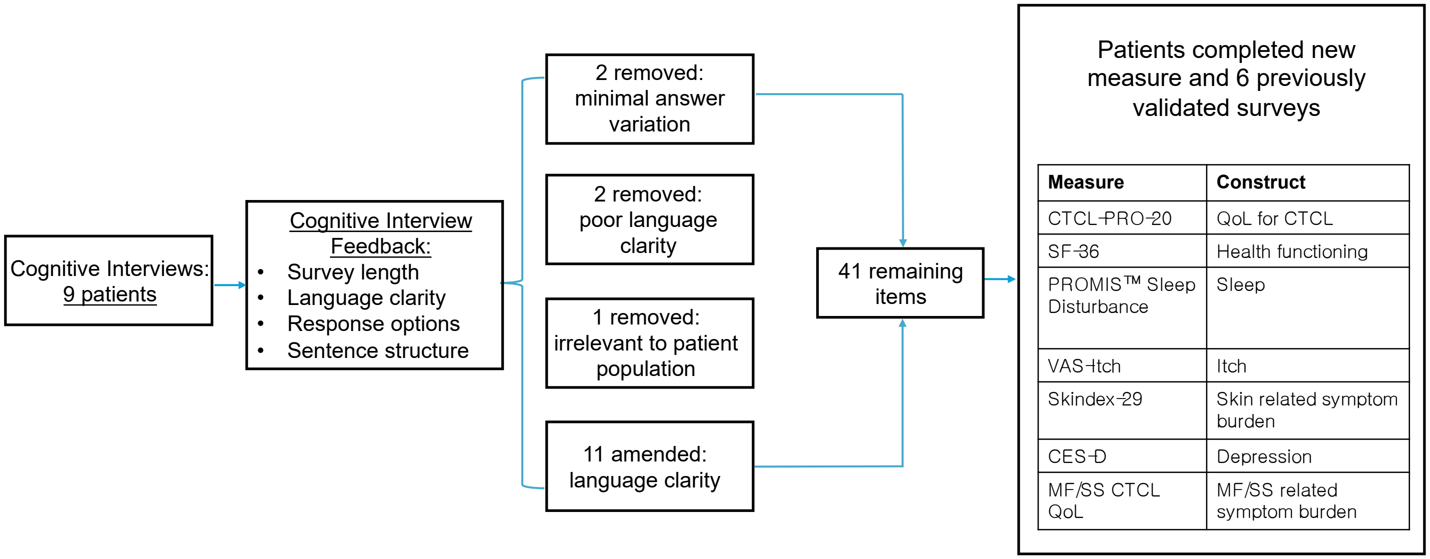
Supplemental Table 1. Domains Important to CTCL Patient Quality of Life[1] and Coverage by Existing Patient Reported Outcome (PRO) Measures.

	Skindex-29	**MF/SS-CTCL**	**FACT-G**	**FACT-CTCL**	**CTCL-PRO-20**
Itch	x			x	x
Pain	x		x	x	
Fatigue	x	x			x
Sleep	x		x	x	x
Skin breaks	x			x	x
Skin flaking				x	x
Lack of CTCL resources					x
Concern about appearance	x			x	x
Isolation	x	x			x
Otherness					x
Depression	x	x	x	x	
Hopelessness		x	x	x	
Uncertainty	x	x	x	x	
Treatment Burden	x	x	x	x	x

[1] T.S. Bhat, C.M. Herbosa, A.R. Rosenberg, O. Sogade, D.B. Jeffe, N. Mehta-Shah, Y.R. Semenov, A.C. Musiek, Current measures are not sufficient: an interview-based qualitative assessment of quality of life in cutaneous T-cell lymphoma, *British Journal of Dermatology*, Volume 184, Issue 2, 1 February 2021, Pages 310–318, https://doi.org/10.1111/bjd.19298

CTCL, Cutaneous T-cell Lymphoma; MF/SS, mycosis fungoides/Sezary syndrome, FACT-G, Functional Assessment of Cancer Therapy General

Supplemental Figure 1: Process of CTCL-PRO-20 Questionnaire Development



Measure	**Construct**
CTCL-PRO-20	QoL for CTCL
SF-36	Health functioning
PROMIS™ Sleep Disturbance	Sleep
VAS-Itch	Itch
Skindex-29	Skin related symptom burden
CES-D	Depression
MF/SS CTCL QoL	MF/SS related symptom burden

Supplemental Figure 2: CTCL-PRO-20

Clinical Symptoms, Side Effects, and Associated Concerns about Cutaneous T Cell Lymphoma (CTCL).

The following statements reflect concerns about how symptoms and side effects of treatment for Mycosis Fungoides or Sézary syndrome (MF/SS) might have affected aspects of your quality of life over the past month. Please indicate your response by circling your level of agreement with each statement as it relates to your experience living with MF/SS.

1. **Worrying about MF/SS prevents me from falling asleep.**

Strongly Disagree Disagree Neutral Agree Strongly Agree

2. **I refrain from going out in public because of my appearance.**

Strongly Disagree Disagree Neutral Agree Strongly Agree

3. **I am embarrassed to be with other people due to skin flaking.**

Strongly Disagree Disagree Neutral Agree Strongly Agree

4. **Symptoms of MF/SS, including itch, impact my ability to fall asleep.**

Strongly Disagree Disagree Neutral Agree Strongly Agree

5. **I have experienced broken skin (sores or cuts) due to MF/SS or its treatment.**

Strongly Disagree Disagree Neutral Agree Strongly Agree

6. **I am concerned about the sores and/or cuts on my skin.**

Strongly Disagree Disagree Neutral Agree Strongly Agree

7. **In the general population, there is a lack of understanding about MF/SS.**

Strongly Disagree Disagree Neutral Agree Strongly Agree

8. **Skin flaking due to MF/SS is bothersome.**

Strongly Disagree Disagree Neutral Agree Strongly Agree

9. **Fatigue due to MF/SS or its treatment prevents me from completing daily tasks.**

Strongly Disagree Disagree Neutral Agree Strongly Agree

10. **It is frustrating that more people do not know about MF/SS.**

Strongly Disagree Disagree Neutral Agree Strongly Agree

11. There is a lack of available resources for me to share with friends and family to help them better understand MF/SS.

Strongly Disagree Disagree Neutral Agree Strongly Agree

12. I am concerned about my appearance due to MF/SS.

Strongly Disagree Disagree Neutral Agree Strongly Agree

13. I feel self-conscious about my appearance due to MF/SS.

Strongly Disagree Disagree Neutral Agree Strongly Agree

14. My MF/SS symptoms, including itch, cause me to wake up during the night.

Strongly Disagree Disagree Neutral Agree Strongly Agree

15. I feel socially isolated because of my MF/SS.

Strongly Disagree Disagree Neutral Agree Strongly Agree

16. I am embarrassed about the way I look.

Strongly Disagree Disagree Neutral Agree Strongly Agree

17. The frequency of my treatment(s) interferes with my daily activities.

Strongly Disagree Disagree Neutral Agree Strongly Agree

Not applicable – I have not been on treatment in the last month

18. The frequency of my treatment(s) interferes with my social life.

Strongly Disagree Disagree Neutral Agree Strongly Agree

Not applicable – I have not been on treatment in the last month

19. The time I have spent receiving treatment for MF/SS has been a burden.

Strongly Disagree Disagree Neutral Agree Strongly Agree

Not applicable – I have not been on treatment in the last month

20. The side effects of MF/SS treatments have been burdensome.

Strongly Disagree Disagree Neutral Agree Strongly Agree

Not applicable – I have not been on treatment in the last month