

The Hidradenitis Suppurativa Symptom and Impact Diary: Development and psychometric evaluation of a novel set of patient-reported outcomes for hidradenitis suppurativa

John R Ingram¹, Magdalena B Wozniak², Anna Passera³, Lorenz Uhlmann³, Angela Llobet Martinez³, Falk G Bechara^{4,5}, Randall H Bender⁶, Lori D McLeod⁶, Susan Martin⁶, Santiago G Moreno^{6,3}, Jessica Marvel⁷, Shoba Ravichandran⁷ and Alexa B Kimball⁸

¹Division of Infection and Immunity, Cardiff University, Cardiff, UK

²Novartis Ireland Limited, Dublin, Ireland

³Novartis Pharma AG, Basel, Switzerland

⁴Department of Dermatology, Venereology and Allergology, Ruhr-University Bochum, Bochum, Germany

⁵International Center for Hidradenitis Suppurativa/Acne Inversa (ICH), Ruhr-University Bochum, Germany

⁶RTI Health Solutions, Research Triangle Park, NC, USA

⁷Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA

⁸Harvard Medical School and Clinical Laboratory for Epidemiology and Applied Research in Skin (CLEARS), Department of Dermatology, Beth Israel Deaconess Medical Center, Boston, MA, USA

Correspondence: John R. Ingram. Email: ingramjr@cardiff.ac.uk

Abstract

Background Hidradenitis suppurativa (HS) is associated with a substantial disease burden. Given the complex nature of HS-related symptoms, patient-reported outcome (PRO) measures are important to ensure that the patient experience is captured when evaluating the efficacy of treatments in clinical trials.

Objectives To develop the Hidradenitis Suppurativa Symptom and Impact Diary (HSSID®), a novel PRO measure for use in clinical trials to assess the symptoms and impacts of HS in adult patients, and to validate its psychometric properties.

Methods The development phase involved patients with HS and clinicians with HS expertise and included three sequential stages: (i) concept elicitation interviews ($n=8$); (ii) item development; and (iii) cognitive debriefing interviews ($n=12$). The psychometric properties of the HSSID were evaluated using data from a subset of patients participating in the SUNSHINE (NCT03713619) and SUNRISE (NCT03713632) trials, and included assessments of reliability, validity and ability to detect change. Anchor-based methods to estimate meaningful change thresholds were explored.

Results The HSSID comprises 11 items; 5 relate to HS symptoms (lesion-related pain, lesion-related itching, lesion drainage, odour and physical fatigue) and 6 to HS impacts (ability to walk, ability to move [other than walking], sleep disturbance, time spent with other people, negative impact on emotions and ability to complete work). Patients found the HSSID items easy to understand and reported no difficulties recalling symptoms/impacts experienced in the previous 24 h. Overall, 478 patients from SUNSHINE and SUNRISE were included in the psychometric evaluation phase. Good association with low redundancy was observed among HSSID items with moderate (> 0.30) to strong (> 0.50) inter-diary item correlations among symptoms and impact items, and across groups. Test–retest reliability estimates in stable subsets were high across SUNSHINE and SUNRISE, ranging from 0.78 to 0.96. Construct validity analysis confirmed that each HSSID item correlated with ≥ 1 targeted support variable. HSSID item scores demonstrated satisfactory responsiveness to detect change; however, anchor-based meaningful change thresholds could be established for the worst lesion-related pain item only.

Conclusions The HSSID appropriately assesses the symptoms and impacts of HS in adults. HSSID items demonstrated generally robust psychometric properties.

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Lay summary

Hidradenitis suppurativa is a skin disease that can cause painful boils. These boils sometimes drain and can smell bad. People with the disease can sometimes feel embarrassed or depressed because of their symptoms. Past studies have looked at whether certain medications can improve the symptoms of the disease.

The aim of this study was to develop the 'Hidradenitis Suppurativa Symptom and Impact Diary' ('HSSID' for short). This is a new tool that can be used in clinical trials to assess the symptoms (for example, pain) and impact (for example, the ability to walk) of the disease. It will allow adults living with the disease to report how these symptoms change over time. We also tested whether each of the questions asked by the tool (also called 'items') measures what they were designed to.

To develop the new tool, interviews were carried out with people living with hidradenitis suppurativa. They were asked which symptoms and impacts of the disease were most important to them. Based on this, an early version of the HSSID tool was developed. This early version was then reviewed by different people living with HS and updated based on their feedback. Doctors caring for people with the disease were also involved in developing the tool. The tool includes 11 questions. Five of the items are related to the disease symptoms. Six of the items are related to the impacts of the disease. Two previous studies called 'SUNSHINE' and 'SUNRISE' looked at whether an injectable drug called 'secukinumab' could improve the disease symptoms. Some people taking part in the SUNSHINE and SUNRISE studies used the HSSID. We found that the HSSID items measured what they were designed to measure based on information collected as part of the SUNSHINE and SUNRISE studies.

Our findings suggest that the HSSID can appropriately assess symptoms and impact in adults with hidradenitis suppurativa.

What is already known about this topic?

- Hidradenitis suppurativa (HS) is a difficult-to-treat chronic, recurring, inflammatory skin disease associated with a high burden of disease and a substantial negative impact on patients' quality of life.
- Patient-reported outcome (PRO) measures are important to ensure that the patient experience is captured when evaluating the efficacy of treatments in clinical trials

What does this study add?

- The Hidradenitis Suppurativa Symptom and Impact Diary (HSSID®) is a novel PRO measure that has demonstrated strong cross-sectional psychometric measurement properties for all its items.

What are the clinical implications of this work?

- The HSSID can be used in clinical trials to assess the symptoms and impacts of HS in adult patients.

Hidradenitis suppurativa (HS) is a chronic, recurrent, inflammatory, follicular skin disease characterized by deep dermal inflammatory nodules, abscesses and tunnels.^{1–4} HS is associated with a substantial disease and comorbidity burden.^{5,6} It can have a profound psychosocial impact on patients' lives, driven by pain – reported to be the most disturbing symptom^{7–10} – depression, anxiety, self-consciousness and sexual dysfunction.^{11–14} The impact on quality of life (QoL) is reportedly worse in HS than other dermatological conditions, such as atopic dermatitis, and other major non-dermatological conditions.^{15,16} Difficult-to-treat cutaneous complications of HS are often accompanied by malodorous and purulent drainage, which further contribute to the negative impact on QoL experienced by patients.^{17,18}

Given the complex nature of HS-related symptoms, patient-reported outcome (PRO) measures are important to ensure that the patient experience is captured when evaluating treatment effect in clinical trials. The Hidradenitis Suppurativa cORe outcomes set International Collaboration

(HISTORIC) identified pain, HS-specific QoL and the symptoms of drainage and fatigue as core domains relevant to stakeholders, including patients, for use in HS clinical trials.¹⁹

The SUNSHINE and SUNRISE phase III trials demonstrated sustained efficacy of secukinumab, alongside a favourable safety profile, in patients with moderate-to-severe HS.²⁰ When the SUNSHINE and SUNRISE trials were initiated, HS-specific PRO measures were in development, but none were fully validated, readily available or recommended for use in clinical trials.²¹ Therefore, Novartis, supported by RTI Health Solutions (RTI-HS), developed the Hidradenitis Suppurativa Symptom and Impact Diary (HSSID®) to assess the symptoms and impacts of HS in adult patients, for use in the SUNSHINE and SUNRISE trials. The HSSID was developed to capture concepts of interest for treatment efficacy (e.g. worst lesion-related pain) and concepts important to other aspects of the patient experience (e.g. drainage and odour). Here, we report on the development and psychometric evaluation of the HSSID.

Materials and methods

Study design

SUNSHINE (NCT03713619) and SUNRISE (NCT03713632) were identical double-blind randomized multicentre placebo-controlled clinical trials that assessed the clinical efficacy and safety of secukinumab in patients with moderate-to-severe HS.²⁰ The study design and results of SUNSHINE and SUNRISE have been published previously.²⁰

The development and evaluation of the psychometric properties of the HSSID were conducted in two phases. The first phase included development of the HSSID with the objective of creating a tool that could be used in SUNSHINE and SUNRISE; the second phase included evaluation of the psychometric properties of the HSSID, which was conducted using data from a subset of patients participating in SUNSHINE ($n=233$) and SUNRISE ($n=245$).

Development phase of the Hidradenitis Suppurativa Symptom and Impact Diary

The HSSID was developed in accordance with the US Food and Drug Administration PRO Guidance for Industry 2009.²² The HSSID development process included three stages: (i) concept elicitation; (ii) item development; (iii) qualitative evaluation (cognitive debriefing interviews).

Concept elicitation

Interviews were conducted with four clinical dermatologists with expertise in HS to gain their perspective on treating patients with HS to inform development of the interview guide for the concept elicitation patient interviews. Telephone interviews were then conducted with eight patients to elicit information on important symptoms and impacts of HS. Patients were identified via the Hidradenitis Suppurativa Foundation, an advocacy group in the USA. Participant criteria were developed to identify patients with moderate-to-severe HS, the target population for future Novartis clinical trials. Included patients were aged 18–65 years, diagnosed with HS for at least 1 year prior to the study, had HS symptoms consistent with Hurley stage II/III, had a prior history of surgical or laser procedures related to HS, were currently on or had been treated with systemic medications, but still experiencing HS symptoms, and had ≥ 3 current lesions (defined as lesions causing pain and/or drainage). Patients were excluded if they were taking biologics or had used them within the last year. Interviews were conducted by two experienced RTI-HS team members, including S.M., with training in qualitative methodology and more than two decades of qualitative experience. Each interview lasted approximately 60 min and was audio recorded and transcribed verbatim. The interview guide is provided in Appendix S1 (see [Supporting Information](#)).

Conceptual model

A conceptual model was developed based on input from clinicians and patients with HS (based on the results of the concept elicitation interviews) and further refined based on feedback from two dermatologists in the USA who had extensive clinical and research experience in dermatological diseases, including HS (Figure S1; see [Supporting Information](#)).

Item development

Based on the results of the clinician interviews and the concept elicitation interviews, a draft item pool was developed using standard survey methodology. The items were developed to incorporate the terminology used by the participants, and alternative item wording and response options [i.e. numerical rating scales (NRS) and verbal rating scales] were developed for further evaluation with participants. In addition, the draft item pool was reviewed by two clinical experts prior to finalizing the items for the cognitive debriefing interviews.

Qualitative evaluation

Cognitive debriefing interviews were conducted with 12 adults with HS (different individuals from those who participated in the concept elicitation interviews) in two iterative rounds to refine the items. All cognitive debriefing interviews were conducted via telephone by two experienced members of the RTI-HS team, following an interview guide. Patients were identified via the Hidradenitis Suppurativa Foundation; eligibility criteria were the same as the concept elicitation interviews, except that the exclusion criteria regarding biologic use was omitted. Interviews began with open-ended concept elicitation of symptoms and impacts of HS experienced by patients. Participants were then asked to engage in cognitive debriefing of the draft measure. A 'think aloud' format was used to gather information about patients' interpretation of each item. Interviewers also asked probing questions to gain further information on interpretation of the questions and response options, to identify any need for modifications to improve comprehension and ease of response. After discussing each item individually, participants were asked to identify which items were most and least relevant to their experience with HS, whether any item(s) could be omitted, and if any concepts were missing. The results of the first round of interviews ($n=6$) were analysed to identify any patterns in how patients interpreted each item and determine how well the items captured relevant concepts; the revised instructions and items were evaluated in a second round of interviews ($n=6$). Each interview lasted approximately 60 min and was audio recorded and transcribed. Transcripts were verified through an iterative process of technical and editorial review. The recordings were destroyed once the transcripts were finalized. The interview guide is provided in Appendix S2 (see [Supporting Information](#)).

Psychometric evaluation phase of the Hidradenitis Suppurativa Symptom and Impact Diary

Data source

The psychometric evaluation analysis used data from the SUNSHINE and SUNRISE phase III clinical trials. Patients included in the psychometric analysis were aged ≥ 18 years, had received ≥ 1 dose of the study treatment and had a baseline HSSID item score. In addition, as part of the inclusion criteria for SUNSHINE and SUNRISE, patients had moderate-to-severe HS (defined as ≥ 5 inflammatory lesions affecting ≥ 2 distinct anatomical areas) for ≥ 1 year and agreed to daily use of topical over-the-counter antiseptics on the areas affected by HS lesions while on the study treatment.

Measures

Patient instruments to support the evaluation of the HSSID included the Dermatology Life Quality Index (DLQI); European Quality of Life 5-dimension 3-levels (EQ-5D-3L); Work Productivity and Activity Impairment: Specific Health Problem (WPAI-SHP); pain NRS; Patient Global Impression of Change (PGI-C); and Patient Global Impression of Severity (PGI-S) questionnaires.

Clinical measures to support the evaluation of the HSSID were HS Clinical Response [HiSCR; $\geq 50\%$ reduction in abscess and inflammatory nodule (AN) count with no increase in the number of abscesses and/or draining tunnels relative to baseline], AN50 (50% reduction in AN count relative to baseline), modified Hidradenitis Suppurativa Score (mHSS) and the Hidradenitis Suppurativa Physician Global Assessment (HS-PGA).

Analytical methods

Table 1 provides an overview of the analytical methods used to evaluate the psychometric properties of the HSSID.

Results

Development phase

Concept elicitation

Of the eight patients who completed the concept elicitation interviews, seven were women and the mean (range) age was 33.9 (25.0–41.0) years (Table 2). The mean (range) time since diagnosis was 9.9 (0.5–19.0) years, and six patients had Hurley stage III HS. Pain and a lack of general knowledge/awareness about HS were the most frequently reported difficult aspects of having HS (each 38%; $n=3$), followed by impact on life and daily activities (25%; $n=2$), and feeling of hopelessness, scarring, discoloration of skin and passing the disease on to offspring (each 13%; $n=1$). All patients spontaneously reported pain and redness as one of their HS symptoms. Other commonly reported HS symptoms were draining (spontaneous report, $n=7$; probed report, $n=1$), fatigue (spontaneous report, $n=3$; probed report, $n=4$), scarring (spontaneous report, $n=2$; probed report, $n=5$), swelling/inflammation (spontaneous report, $n=1$; probed report, $n=5$), warmth around lesions (spontaneous report, $n=1$; probed report, $n=7$) and odour (spontaneous report, $n=4$; probed report, $n=2$). Patients most frequently reported pain as the most bothersome symptom (Figure 1); a summary of the most representative patient quotes related to the most bothersome symptoms of HS is provided in Table 3. In terms of impacts of HS, all patients spontaneously reported limitations on the ability to walk due to pain. Other commonly reported physical impacts included difficulty with moving (besides walking) and difficulty with other physical activities.

Draft item pool

The most frequently reported concepts by patients (reported by three or more patients) were included in the draft item pool, along with those that were reported as bothersome and that had the potential to improve with treatment. The draft item pool included 29 items for further evaluation.

Cognitive debriefing interviews

The initial item pool was evaluated and refined through 2 iterative rounds of interviews conducted with 12 patients (Table 2), who provided feedback on their understanding of instructions, questions, response options and the recall period. Participants found the items easy to understand and simple to answer. They reported no difficulty recalling HS symptoms and impacts experienced in the previous 24 h. In relation to the impact items, participants were probed on the appropriateness of a 24-h recall period to assess whether a longer time period, such as a week, could be implemented. When probed, each participant stated that they experienced day-to-day variation in the impact concepts included and therefore the use of a longer recall period was not recommended.

The Hidradenitis Suppurativa Symptom and Impact Diary

The final HSSID is a self-administered eDiary that measures HS symptoms and impacts during the previous 24 h. The HSSID comprises 11 items; 5 relating to symptoms of HS (lesion-related pain, lesion-related itching, lesion drainage, odour and physical fatigue) and 6 to impacts [ability to walk, ability to move (other than walking), sleep disturbance, time spent with other people, negative impact on emotions and ability to complete work] (Appendix S3; see [Supporting Information](#)).

Psychometric evaluation of the Hidradenitis Suppurativa Symptom and Impact Diary

Baseline patient characteristics

Overall, 233 patients in SUNSHINE and 245 patients in SUNRISE were included in the psychometric analysis of the HSSID (Table 4). Most patients were women (SUNSHINE 62.7%; SUNRISE 59.2%); mean age was 36.1 and 37.2 years, and mean time since diagnosis was 8.6 and 9.2 years in SUNSHINE and SUNRISE, respectively.

Descriptive statistics

Daily responses (which were incorporated into a weekly score calculated as the average of the seven daily scores; requiring at least four daily scores or the weekly score was recorded as missing) showed a general trend toward lower scores (improvement) from baseline to week 2 and week 2 to week 16 in SUNSHINE and SUNRISE. The greatest mean (SD) changes for weekly HSSID item scores from baseline to week 16 were for the items 'worst pain' [SUNSHINE -1.2 (2.2); SUNRISE -1.1 (2.3)] and 'worst itching' [SUNSHINE -1.2 (2.1); SUNRISE -1.1 (2.3)] (Table S1; see [Supporting Information](#)).

Distributions of weekly mean scores did not show floor or ceiling effects across any of the HSSID items. This provided evidence that the proposed weekly scores had sufficient ranges to show detriment and improvement, given that a ceiling effect occurs when a large proportion of the sample provides responses using the highest/best score category, leaving limited room for score increase/improvement, and a floor effect occurs when a large proportion of the sample provides responses using the lowest/worst score category, leaving limited room for score decrease/deterioration.

Table 1 Analytical methods used to evaluate the psychometric properties of the Hidradenitis Suppurativa Symptom and Impact Diary (HSSID®)

Analysis	Purpose	Brief description of key methods
Descriptive statistics	<ul style="list-style-type: none"> Summarize sample characteristics Assess the use and appropriateness of response scales and identify possible floor and ceiling effects (defined as observed endorsements at twice the expected probability in an extreme category than would be expected under a uniform distribution (i.e. $\geq 18\%$ in an extreme category for an 11-point, 0–10 rating item and $\geq 40\%$ or $\geq 50\%$ for 5-item or 4-item ordinal response items, respectively) Assess missing data Evaluate the correlations among the HSSID items 	<ul style="list-style-type: none"> Key daily HSSID response frequencies Key weekly item score statistics (HSSID items) Key support variable statistics
Structure		<ul style="list-style-type: none"> Daily and weekly inter-item correlations^a Thresholds: <ul style="list-style-type: none"> moderate correlation ≥ 0.30 to < 0.50 large correlation ≥ 0.50 to < 0.80 very large correlation ≥ 0.80
Test–retest reliability	<ul style="list-style-type: none"> Assess agreement of scores to ensure that HSSID scores are consistent across time when no change has occurred 	<ul style="list-style-type: none"> Two-way mixed-effects ANOVAS with absolute agreement for single measures were used to compute ICC estimates of test–retest reliability using data for baseline and week 2 for each item: <ul style="list-style-type: none"> estimated using the full sample and stable subsamples ICC values of ≥ 0.70 indicated adequate reliability
Construct validity	<ul style="list-style-type: none"> Assess whether HSSID scores measure what each item is expected (hypothesized) to measure 	<ul style="list-style-type: none"> Correlations (Pearson/polychoric) between HSSID scores and other study measures (e.g. DLQI domainscores, WPAI-SHP activity domain scores and mHSS) The a priori hypothesis regarding the directions and magnitudes of correlations was that positive correlations are predicted between the HSSID scores and the DLQI, EQ-5D-3L, WPAI-SHP, HS-PGA and mHSS scores Moderate-to-strong correlations hypothesized between HSSID item scores and support measures are presented in Table S8 The test of construct validity for the HSSID scores was dependent on meeting levels of prespecified correlation: <ul style="list-style-type: none"> ≥ 0.50 = strong 0.30–0.49 = moderate 0.10–0.29 = small
Known groups validity	<ul style="list-style-type: none"> Evaluate whether HSSID scores can distinguish between groups that are hypothesized to differ 	<ul style="list-style-type: none"> ANOVA by groups defined using other study measures [e.g. HiSCR, HS-PGA, PGI-S and EQ-5D-3L (mobility, usual activities and anxiety/depression domains)]
Ability to detect change (sensitivity to change)	<ul style="list-style-type: none"> Evaluate whether HSSID scores can detect change where change is expected (hypothesized) 	<ul style="list-style-type: none"> ANOVA by groups of known change: <ul style="list-style-type: none"> patients reporting more improvement based on the grouping variable were hypothesized to have more negative (i.e. improved) HSSID change scores Correlation between change in HSSID scores and other study change measures (e.g. those related to DLQI symptoms domain and HS-PGA change score groups, and HiSCR and PGI-C week 16 score groups)
Meaningful within-patient change (meaningful improvement, threshold for improvement)	<ul style="list-style-type: none"> Develop thresholds of meaningful within-patient change of HSSID scores 	<ul style="list-style-type: none"> Anchor-based method using other study measures as anchors (descriptive statistics; CDF and PDF plots with 95% CIs) Candidate anchors: PGI-S, PGI-C, HiSCR, AN50 ROC analysis estimates Distribution-based methods: half-SD and standard error of measurement

The clinical trial study design did not incorporate a test–retest time period. Baseline and week 2 were selected and stable subsamples were identified to provide data for the test–retest evaluation. In addition, the evaluation of internal consistency and factor analysis was not pursued given that the scales were formative. AN50, $\geq 50\%$ reduction in abscess and inflammatory nodule count; CDF, cumulative distribution function; CI, confidence interval; DLQI, Dermatology Life Quality Index; EQ-5D-3L, European Quality of Life 5-dimension 3-levels; HiSCR, Hidradenitis Suppurativa Clinical Response; HS-PGA, Hidradenitis Suppurativa Physician Global Assessment; ICC, intraclass correlation coefficient; mHSS, modified Hidradenitis Suppurativa Score; PDF, probability density function; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity; ROC, receiver operating characteristic; SD, standard deviation; WPAI-SHP, Work Productivity and Activity Impairment: Specific Health Problem. ^aSuggested minimum correlation value = 0.30; specified correlation value to identify redundancy = 0.80.

Structure

Inter-item correlations among daily HSSID items at baseline (week 0), week 2, and week 16 were generally similar across timepoints in SUNSHINE and SUNRISE (Tables S2, S3; see

Supporting Information). The correlations among the symptom items all exceeded 0.30. A small number of correlations exceeded 0.80, which could indicate redundancy; lesion drainage and odour from drainage were highly associated,

Table 2 Demographic and clinical characteristics of patients in the concept elicitation and cognitive debriefing stages of the development of the Hidradenitis Suppurativa Symptom and Impact Diary (HSSID®)^a

Characteristic	Concept elicitation (n=8)	Cognitive debrief interviews		
		Round 1 (n=6)	Round 2 (n=6)	Total (n=12)
Age (years), mean (range)	33.9 (25–41)	34.7 (22–49)	36.2 (21–59)	35.5 (21–59)
Sex				
Male	1 (12.5)	0 (0)	1 (16.7)	1 (8.3)
Female	7 (87.5)	6 (100)	5 (83.3)	11 (91.7)
Race/ethnicity				
White	5 (62.5)	5 (83.3)	4 (66.7)	9 (75.0)
Black	2 (25.0)	1 (16.7)	1 (16.7)	2 (16.7)
Indian	1 (12.5)	0 (0)	0 (0)	0 (0)
Hispanic	0 (0)	0 (0)	1 (16.7)	1 (8.3)
Highest level of education				
High school or lower	1 (12.5)	2 (33.3)	1 (16.7)	3 (25.0)
Some college	2 (25.0)	1 (16.7)	3 (50.0)	4 (33.3)
College	3 (37.5)	1 (16.7)	0 (0)	1 (8.3)
Postgraduate	2 (25.0)	2 (33.3)	2 (33.3)	4 (33.3)
Employment				
Full-time	5 (62.5)	4 (66.7)	1 (16.7)	5 (41.7)
Part-time	0 (0)	1 (16.7)	3 (50.0)	4 (33.3)
Not employed	3 (37.5)	1 (16.7)	2 (33.3)	3 (25.0)
Time since diagnosis (years), mean (range)	9.9 (0.5–19)	11.2 (5–22)	11.3 (4–20)	11.3 (4–22)
Hurley stage				
II	2 (25.0)	1 (16.7)	1 (16.7)	2 (16.7)
III	6 (75.0)	5 (83.3)	5 (83.3)	10 (83.3)
Currently using biologics				
Yes	2 (25.0)	3 (50.0)	2 (33.3)	5 (41.7)
No	6 (75.0)	3 (50.0)	4 (66.7)	7 (58.3)

Data are presented as *n* (%) unless otherwise stated. ^aDifferent participants undertook the concept elicitation and cognitive debriefing interviews.

although not exactly redundant. Correlations among the impact items ranged from large to very large (using the criteria outlined in Table 1) and correlations between symptoms and impacts items were moderate to large. The analysis did not identify any items that needed to be removed due to redundancy. Correlations among the weekly item scores were generally similar to the daily item scores.

Test–retest reliability

Test–retest reliability was conducted both in the overall sample and in two separate stable subsamples identified by (i) stable (equivalent) PGI-S scores at baseline and week 2, and (ii) by a ‘No change’ PGI-C week 2 response. Test–retest statistics all exceeded the criterion of 0.70, indicating adequate reliability in both the overall sample and stable subsamples. The greatest intraclass correlation coefficients (ICCs) were for worst fatigue item across SUNSHINE and SUNRISE and across the overall and stable subsamples (ICC range 0.90–0.96) (Table S4; see [Supporting Information](#)).

Construct validity

The HSSID items and supporting measures describing similar symptoms or impacts were anticipated to be more strongly associated vs. items describing less similar symptoms or impacts; all hypotheses predicted at least moderate ($r \geq 0.30$) correlations between HSSID items and supporting measures. Hypotheses were met, except for two assessments; in these cases, the failures were both in SUNSHINE and the misses were not large ($r = 0.28$ for symptom item on worst lesion-related itching; $r = 0.29$ for impact item on ability to complete work) (Table S5; see [Supporting Information](#)).

Known group validity

The known group analysis demonstrated that the hypothesis of statistically significant group mean differences was met, except in one case (HS-PGA group; worst fatigue item in SUNRISE). The analysis showed that group means were appropriately ordered among the known groups, except for three cases (HS-PGA group; HSSID worst lesion-related pain, worst lesion-related itching and worst fatigue items in SUNRISE).

Ability to detect change

A priori hypotheses were defined based on change from baseline to week 16 according to external support variables (PGI-S, PGI-C, HiSCR, AN50, DLQI and HS-PGA). In SUNSHINE, all HSSID item scores were responsive to change when change groups were defined by PRO measure scores [PGI-S ($P < 0.0001$ to 0.0002), PGI-C ($P < 0.0001$ to 0.0028) and DLQI symptoms and feelings ($P < 0.0001$ to 0.0015)] and the primary clinical endpoint [HiSCR ($P < 0.0001$ to 0.0270)] (Table S6; see [Supporting Information](#)). In SUNRISE, all HSSID scores detected change identified by PGI-C score ($P < 0.0001$ to 0.0261) and change in DLQI symptoms and feelings score ($P < 0.0001$ to 0.0099). HiSCR score-related changes were identified by 9 of the 11 HSSID item scores (exceptions were lesion drainage and drainage odour) (Table S7; see [Supporting Information](#)).

Meaningful change threshold estimations

The anchor method is often used to establish meaningful within-patient change thresholds. In this type of analysis, an external reference is used to examine the relationship between scores. In this study, the analysis to confirm

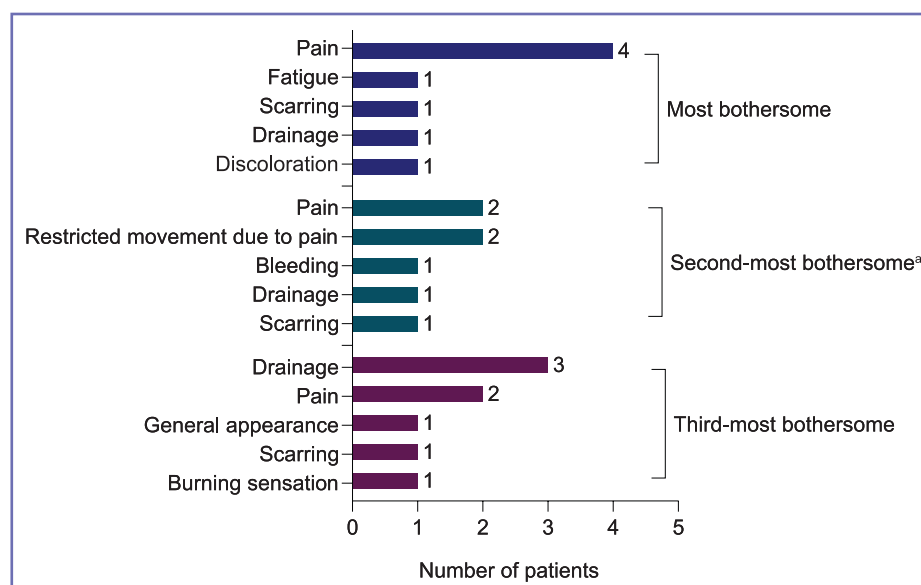


Figure 1 Findings from the patient concept elicitation interviews on the most bothersome symptoms of hidradenitis suppurativa ($n=8$). ^aThe total for this category is seven because one patient reported an issue that was not a sign or symptom (costs associated with purchasing bandages).

adequate association between target scores and candidate clinical anchors [including PGI-S changes (between baseline and week 16), week 16 PGI-C scores, patients achieving HiSCR and AN50 at week 16] and to confirm alignment between mean change group scores and candidate anchor change group definitions to support their appropriateness for serving as anchors, detected deficiencies with

the functioning of key candidate anchor measures. These included insufficient item change score correlations (HiSCR and AN50); in addition, some HSSID items did not exhibit ordered means/medians across the anchor change groups. Following review of the correlations, descriptive statistics, empirical cumulative distribution functions and probability density functions, the evidence fully supported estimating

Table 3 Selected verbatim patient quotes from the concept elicitation interviews related to the most bothersome symptoms of hidradenitis suppurativa

Symptom	Verbatim patient quotes
Pain	<p>'Because it affected my everyday living. If I was in too much pain, I would have to not participate in things. It affected me emotionally. Um...I wasn't as social as I was when I wasn't flaring.'</p> <p>'Just because I can't get away from it. It's just something that...I'm in pain every single day of my life.'</p> <p>'It's difficult to find, first of all, physicians that understand how significant the pain is. And then when nobody really understands the disease, then nobody really understands what's going on. It seems to me like the pain is atrocious, but then it's also downplayed by everyone else, like you're making too big of a deal out of it. It's just a form of acne, when it's not. And so, the pain first of all, it limits movement or any activities I can be a part of, I have to cancel plans often due to the pain.'</p>
Draining	<p>'You have this pus and blood and all that. You have to cover it. It takes a lot of time. Changing the bandages. It's not like you...it's just all of it. It's time consuming.'</p> <p>'Because it's something your body is exiting out and you have to take care of it. And it's not something like sweat. It's, yeah, you just take a shower and you feel clean. But this, it's natural substance on your skin. You can feel when it dries up, its foul smell.'</p> <p>'If that [drainage] wasn't there, this disease [could] be a lot [more] controllable. Because now you're not worried about going into public and your shirt getting wet from the pus and you're looking at your shirt. You sat down and you're not constantly checking out your buttocks to see if there's a blood stain or anything, and you're walking around because it's embarrassing.'</p>
General appearance (discoloration, pigmentation, scarring)	<p>'So, the discoloration, you can have a cyst or a boil, and it's over and done with 7 days tops. Then it leaves a discoloration and it leaves scarring that lasts for years.'</p> <p>'It's because...like, if I want to wear a bathing suit. I'm not comfortable in a bathing suit because I have scars all on my thighs and on my underarms.'</p>
Restriction due to pain	<p>'If the soreness and the tenderness wasn't there, it'd be a lot easier because then you can sit down. You can go to sleep. You can play sports.'</p>
Fatigue	<p>'I would say that the fatigue affects me the most just because I've got two kids, and they notice that I'm tired all the time.'</p>
Bleeding	<p>'Because I bleed everywhere. When I go to the bathroom, I bleed all over the toilet. I stain my clothes. My friend [laughter], my best friend was worried that I was going to bleed on her new couch. I can't wear coloured leggings because I'm going to bleed on them and they're going to see it.'</p>
Burning sensation	<p>'For me it would be the burning. That deep burning sensation when it's starting to form.'</p>

Table 4 Baseline patient characteristics of the psychometric analysis population in the SUNSHINE and SUNRISE trials

Characteristic	SUNSHINE (n = 233)	SUNRISE (n = 245)
Age (years), mean (SD)	36.1 (11.9)	37.2 (11.5)
Sex		
Male	87 (37.3)	100 (40.8)
Female	146 (62.7)	145 (59.2)
Race		
American Indian or Alaska Native	1 (0.4)	0 (0.0)
Asian	2 (0.9)	3 (1.2)
Black or African American	30 (12.9)	32 (13.1)
Native Hawaiian or Other Pacific Islander	0 (0.0)	1 (0.4)
White	198 (85.0)	207 (84.5)
Multiple	2 (0.9)	2 (0.8)
Country		
Germany	62 (26.6)	67 (27.3)
Spain	26 (11.2)	26 (10.6)
France	56 (24.0)	69 (28.2)
Italy	9 (3.9)	10 (4.1)
USA	80 (34.3)	73 (29.8)
Time since diagnosis of HS (years), mean (SD)	8.6 (8.4)	9.2 (8.3)
Hurley stage		
I	16 (6.9)	5 (2.0)
II	136 (58.4)	142 (58.0)
III	81 (34.8)	98 (40.0)
Weight (kg), mean (SD)	99.0 (25.1)	96.3 (23.8)

Data are *n* (%) unless otherwise stated. HS, hidradenitis suppurativa.

anchor-based meaningful change thresholds for the worst lesion-related pain item only.

Discussion

Patients with HS experience a substantial negative impact on their lives.^{13,14} HS-specific PRO measures capture the patient experience of living with HS when evaluating treatment effects in clinical trials. No suitable measures were validated or readily available for use when the SUNSHINE and SUNRISE trials were planned and initiated; therefore, the HSSID was developed for use in these trials.

Recognition of the need for HS-specific PRO measures has resulted in the recent development of a number of HS-specific tools, for which the limitations and strengths have been described.^{21,23} Additional measures include the Hidradenitis Suppurativa Patient Global Assessment of QoL (HS PtGA),²⁴ a single-item PRO for HS-specific health-related QoL; the 9-item Hidradenitis Suppurativa Symptom Assessment (HSSA); the 17-item Hidradenitis Suppurativa Impact Assessment (HSIA);²⁵ the 17-item HiSQOL,²⁶ which includes 3 subdomains; and the 23-item QoL in HS (QoL-HS) questionnaire.²⁷ The HiSQOL instrument has a 7-day recall period and includes 17 items that are grouped into symptom, psychosocial and functional domains.²⁶ In contrast, the HSSID has a 24-h recall period and includes 11 items categorized according to symptoms and impacts. Both instruments share several core items, such as those addressing HS symptoms and the impact on walking, sleep and work/study – underscoring the relevance of these concepts to people living with HS. However, they also differ in scope: the HiSQOL includes items on sexual activity/desire, while the HSSID uniquely captures fatigue and social interaction. The HSSID was purpose-built to assess HS symptoms and patient-perceived impact of secukinumab treatment in the context of the SUNSHINE and SUNRISE trials, and its

development preceded the publication of the HiSQOL. The findings of the psychometric evaluation in the current study provided support for test–retest reliability, construct validity, discriminate validity (known groups) and the ability to detect change (responsiveness) in the HSSID.

A strength of the study was the robust development process and psychometric analysis conducted with the rigour described in regulatory guidance. A limitation of the study was the performance of the anchors in the anchor-based threshold estimation. The distal relationship between these anchors and the target scores made estimation of the meaningful change thresholds in this study challenging. The proposed global anchors, which were clinical measures, were not aligned well enough with the individual constructs underlying the target scores to be used to define meaningful change in the different symptom items. In other words, the most suitable available candidate anchors invoked general constructs such as the patient's HS 'symptoms' or 'overall status', but a strong association between these more general measures with specific individual HS symptom items did not materialize in this study. Change in pain appeared to drive the more general assessments of change but did not always align closely with other specific symptom changes. Consideration of the related qualitative results revealed that most patients considered worst lesion-related pain to be the most important symptom when considering their overall HS severity, a finding that is consistent with previous literature and the limitations observed for the meaningful change analyses.^{7,9,19} It should be noted that the HSSID was developed and evaluated in a population of adult patients with moderate-to-severe HS; the concepts of importance may be different for patients who have mild HS. Further, the HSSID was developed for use in clinical trials; while it is relevant for use in clinical practice, its performance was not evaluated outside of the clinical trial setting.

In conclusion, the HSSID adequately and appropriately assesses the symptoms and impacts of HS in adult patients.

The HSSID demonstrated strong cross-sectional psychometric measurement properties for all HSSID items. The HSSID can be used by patients with moderate-to-severe HS in a clinical trial setting. Further research is warranted using more specific anchors to better define meaningful change for the different symptom and impact items.

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Conflicts of interest

J.R.I. received a stipend as immediate past-Editor-in-Chief of the *British Journal of Dermatology* and an authorship honorarium from UpToDate. He is a consultant for Abbvie, Boehringer Ingelheim, Cantargia, ChemoCentryx, Citryll, Elasmogen, Engitix, Incyte, Indero, Insmmed, Kymera Therapeutics, MoonLake, Novartis, UCB Pharma, UNION Therapeutics and Viela Bio. He is co-copyright holder of HiSQOL, HIDE, Investigator Global Assessment and Patient Global Assessment instruments for HS and his department receives income from copyright of the Dermatology Life Quality Index (DLQI) and related instruments. M.B.W., A.P., A.L.M. and J.M. are employees of Novartis and hold company stock. L.U., S.R. and S.G.M. were employees of Novartis at the time of the study. F.G.B. has received honoraria for participation in advisory boards, in clinical trials and/or as a speaker from AbbVie Inc., AbbVie Deutschland GmbH & Co. KG, Acelyrin, Avalo, Beiersdorf, Boehringer Ingelheim Pharma GmbH & Co. KG, Celltrion, Dr. Wolff, Incyte Corporation, JanssenCilag GmbH, Johnson & Johnson, Lilly, Merck, Mölnlycke, MoonLake, Novartis Pharma GmbH, Sanofi, Sitala and UCB Pharma. R.H.B. was a full-time employee of RTI Health Solutions, which provides clinical outcome assessment development and psychometric evaluation support to pharmaceutical companies, at the time of the study. L.D.M. and S.M. are full-time employees of RTI Health Solutions, which provides clinical outcome assessment development and psychometric evaluation support to pharmaceutical companies. A.B.K. declares the following: Institution received grants: Acelyrin, AnaptysBio, Avalo, Bristol Myers Squibb, Eli Lilly, Incyte, Janssen, Moonlake, Novartis, Pfizer, Prometheus, Regeneron, Sanofi, Sonoma Bio, UCB. Consulting or Honoraria: Abbvie, Avalo, Boehringer Ingelheim, Cellarity, Citryll, Eli Lilly, Evoimmune, Janssen, Merck, Moonlake, Novartis, Nurix, Pfizer, Sanofi, Sonoma Bio, Takeda, Target RWE, UCB, Union Therapeutics, Ventyx, Zura Bio. Other: Member, Board of Directors, Almirall.

Data availability

Novartis is committed to sharing with qualified external researchers access to patient-level data and supporting clinical documents from eligible trials. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided are anonymized to respect the privacy of patients who have participated in the trials in line with applicable laws and regulations. For any enquiries relating to use of the Hidradenitis Suppurativa Symptom and Impact Diary, please contact novartisprerequest@rws.com

Ethics statement

Study data were acquired as part of two phase III randomized controlled trials that received standard Institutional Review Board (IRB) approval. The study protocol for the phase III trials and all amendments were reviewed by the Independent Ethics Committee or IRB for each centre. The phase III studies were performed according to The International Conference on Harmonisation Guidelines for Good Clinical Practice that have their origin in the Declaration of Helsinki. All materials for the development study were reviewed and approved by an RTI International IRB committee (ID 14089).

Patient consent

Written informed consent was obtained from each patient during the screening visit and before any study-specific procedure was carried out. Written patient consent for publication was obtained.

Supporting Information

Additional [Supporting Information](#) may be found in the online version of this article at the publisher’s website.

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