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Outcome Measures for the Evaluation of Treatment Response in Hidradenitis Suppurativa for Clinical Practice
A HiSTORIC Consensus Statement

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IMPORTANCE Although several clinician- and patient-reported outcome measures have been developed for trials in hidradenitis suppurativa (HS), there is currently no consensus on which measures are best suited for use in clinical practice. Identifying validated and feasible measures applicable to the practice setting has the potential to optimize treatment strategies and generate generalizable evidence that may inform treatment guidelines.

OBJECTIVE To establish consensus on a core set of clinician- and patient-reported outcome measures recommended for use in clinical practice and to establish the appropriate interval within which these measures should be applied.

EVIDENCE REVIEW Clinician- and patient-reported HS measures and studies describing their psychometric properties were identified through literature reviews. Identified measures comprised an item reduction survey and subsequent electronic Delphi (e-Delphi) consensus rounds. In each consensus round, a summary of outcome measure components and scoring methods was provided to participants. Experts were provided with feasibility characteristics of clinician measures to aid selection. Consensus was achieved if at least 67% of respondents agreed with use of a measure in clinical practice.

FINDINGS Among HS experts, response rates for item reduction, e-Delphi round 1, and e-Delphi round 2 surveys were 76.4% (42 of 55), 90.5% (38 of 42), and 92.9% (39 of 42), respectively; among patient research partners (PRPs), response rates were 70.8% (17 of 24), 100% (17 of 17), and 82.4% (14 of 17), respectively. The majority of experts across rounds were practicing dermatologists with 18 to 19 years of clinical experience. In the final e-Delphi round, most PRPs were female (12 [85.7%] vs 2 males [11.8%]) and aged 30 to 49 years. In the final e-Delphi round, HS experts and PRPs agreed with the use of the HS Investigator Global Assessment (28 [71.8%]) and HS Quality of Life score (13 [92.9%]), respectively. The most expert-preferred assessment interval in which to apply these measures was 3 months (27 [69.2%]).

CONCLUSIONS AND RELEVANCE An international group of HS experts and PRPs achieved consensus on a core set of HS measures suitable for use in clinical practice. Consistent use of these measures may lead to more accurate assessments of HS disease activity and life outcomes, facilitating shared treatment decision-making in the practice setting.

Supplemental content

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Among inflammatory skin diseases, hidradenitis suppurativa (HS) may be the most heterogeneous in its presentation and disease course. There are several distinct morphologic lesions in HS, including nodules, abscesses, and tunnels. Patients experience a broad range of symptoms, including fatigue, drainage, odor, itch, and, most notably, pain. Disease course is rather unpredictable, as patients experience flares in addition to chronic activity. Response to treatment is also highly variable, and few therapies demonstrate consistently high and sustained efficacy.[1] Nearly one-half of patients with HS express dissatisfaction with their medical treatments.[2,3]

In this context, assessment of disease activity and treatment response is also complex. Standardized and regular application of outcome measures in clinical practice may facilitate bidirectional discussion between the dermatologist and patient on whether treatment goals are being met and whether timely adjustments to the overall therapeutic strategy may be warranted.[4] This approach has led to improved outcomes for patients with a number of chronic inflammatory diseases, including rheumatoid arthritis and psoriatic arthritis.[5-7] Longitudinal recording of clinical outcomes may also support analyses of treatment effectiveness, which offers insight into treatment effect in the broader HS population that clinical trial data cannot provide.[8] Further integration of patient-reported measures allows capture of treatment effect on symptoms and life quality, which patients may hesitate to discuss due to fear of stigmatization[9] and which may otherwise be underestimated by clinicians.[10-12] The objective of this study was to provide expert and patient consensus-based recommendations on the application of validated, HS-specific outcome measures that are feasible for clinical practice.

Methods

This consensus statement was developed by the Hidradenitis Suppurativa Core Outcomes Set International Collaboration (HiSTORIC), an international multistakeholder group comprising experts, patient research partners (PRPs), methodologists, and industry partners with a background in health outcomes whose objective is to develop a core outcome set (COS) for interventional trials in HS and for clinical practice.[13] Along with approximately 20 COS groups, HiSTORIC operates under the Consortium for Harmonizing Outcomes Research in Dermatology and Core Outcome Set Initiative Collaboration, an umbrella research organization whose mission is to develop, disseminate, and implement COSs for clinical trials and routine practice for dermatologic conditions with the goals of standardizing valid and reliable measurement of disease activity and treatment response and of comparing effectiveness.[14] In 2018, HiSTORIC established consensus on the core domain set (ie, what to measure) for interventional clinical trials in HS, which included the following: (1) pain, (2) physical signs, (3) HS-specific quality of life, (4) global assessment, (5) progression of course (flare and recurrence after surgery), and (6) symptoms.[15] To date, HiSTORIC has developed and validated a number of clinician-reported outcome measures (ClinROMs) and patient-reported outcome measures (PROMs) mapped to these core domains.[16-22]

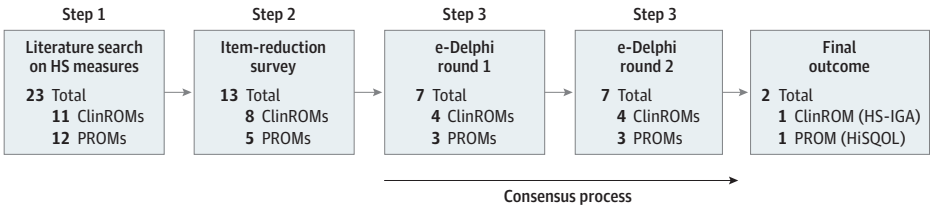
A total of 55 HS experts (comprising dermatologists, internists, surgeons, and nurses) and 24 PRPs from the HiSTORIC group were invited to participate in this study, which consisted of the following 3 phases: (1) a literature search to identify candidate outcome measures in HS, (2) an online item reduction survey, and (3) an electronic Delphi (e-Delphi) survey to establish consensus on a set of HS measures that should be applied to clinical practice (**Figure 1**). Consensus surveys pertaining to the most suitable ClinROMs and PROMs for practice were completed separately by HS experts and PRPs, respectively, between September 2022 and February 2023. To prioritize feasibility for application to clinical practice, it was determined a priori that no more than 1 ClinROM and 1 PROM could be recommended at the conclusion of the consensus process.

This study was approved by the human participants research committee of the Feinstein Institutes for Medical Research at Northwell Health. Informed consent was obtained through an introductory information sheet in which participants were informed of the purpose of the survey and asked whether they wished to proceed to answer questions. Potential respondents were informed that participation was voluntary and that all responses were anonymous. This project was conducted in compliance with the Conducting and Reporting Delphi Studies (CREDES) standards[23] and the Standards for Quality Improvement Reporting Excellence (SQUIRE) reporting guideline.[24]

Identification of Candidate Treat-to-Target Measures

A literature search was performed to identify HS outcome measures that have been evaluated for psychometric properties, including convergent validity, interrater reliability, intrarater reliability, and responsiveness. This search resulted in 11 ClinROMs and 12 PROMs. Following initial review, 3 ClinROMs and 7 PROMs were removed from consideration due to lack of specificity for HS, insufficient psychometric properties, or inadequate feasibility for the practice setting (eTable 1 in the Supplement). We restricted outcome measurement instruments to those that were disease specific, as these measures capture disease effect with depth and tend to be more sensitive in detecting changes in the patient's condition compared with general measures.[25]

Figure 1. Methods Overview



ClinROM indicates clinician-reported outcome measure; e-Delphi, electronic Delphi; HiSQOL, Hidradenitis Suppurativa Quality of Life score; HS, hidradenitis suppurativa; HS-IGA, Hidradenitis Suppurativa Investigator Global Assessment; and PROM, patient-reported outcome measure.

Item Reduction Survey

A single-round item reduction survey was conducted among HS experts and among PRPs separately to eliminate measures that were unlikely to achieve consensus due to low feasibility or limited relevance to patients' perception of treatment response. Information provided to participants included the following: (1) rationale for the application of HS measures to clinical practice, (2) summary of the components and scoring methodology of candidate measures,[16,18,19,26-33] and (3) feasibility characteristics of measures for clinical practice (eTables 2 and 3 in the Supplement).

Experts were asked to select 4 of 8 candidate ClinROMs that were most feasible for use in clinical practice. In addition, experts were asked to select the most appropriate assessment interval within which to apply the measures. The PRPs were asked to rank each of the 5 PROMs according to their ability to capture information most relevant to determining whether a treatment is working adequately. The 4 ClinROMs with the highest number of votes and the 3 PROMs receiving the highest aggregate ratings (based on a weighted scale) were selected for consideration in consensus rounds.

Consensus on HS Measures for Clinical Practice

Consensus rounds were conducted separately among HS experts and PRPs on the most preferred ClinROMs and PROMs applicable to practice. Participants who completed the item reduction survey were eligible to participate in e-Delphi consensus rounds. Information provided to participants included the following: (1) summary of the components and scoring methodology of candidate measures, (2) feasibility characteristics of measures for routine practice, and (3) psychometric properties of the measures.[16-18,26-28,34-42] Background materials provided to participants are provided in eTables 2, 3, and 4 in the Supplement.

Experts were asked to rate their level of agreement with the following standardized statement for ClinROMs included in the consensus exercise: "[Measure name] is a feasible measure that I am willing to utilize in my routine clinical practice to assess treatment response." We used the term "treatment response" to refer to a change in the value of a particular outcome measure after the initiation of a treatment. In addition, experts were asked to select the most appropriate assessment interval within which to apply the measure. The PRPs were asked to rate their level of agreement with the following standardized statement for PROMs included in the consensus exercise: "[Measure name] captures aspects of HS impact that are relevant to me, and it should be used routinely to evaluate response to treatment."

Experts and PRPs were asked to score each standardized statement using a 5-point Likert scale, which allowed participants to specify their level of agreement (strongly agree to strongly disagree). In accordance with the Delphi method, experts and PRPs were provided with aggregate data and anonymized comments from the previous Delphi round prior to making selections in the subsequent round.

Thresholds and definitions of consensus were based on previously cited values and were designated a priori.[43] Consensus-in was defined as at least 67% of total participants agreeing or strongly agreeing with use of the measure in clinical practice. Consensus-out was defined as at least 67% of total participants disagreeing or strongly disagreeing with use of the measure. Instruments that did not meet either of these definitions were deemed to have no consensus. Prior to survey distribution, we specified that if multiple measures reached consensus, the measure with the highest percent agreement would be recommended.

Statistical Analysis

Descriptive statistics were calculated to evaluate the practice and experience characteristics of experts (geographic region, primary specialty, years in practice, and practice setting) and demographic characteristics of patients (geographic region, age category, sex, self-identified race and ethnicity [to understand participant diversity relative to the broader population of patients with HS], time since HS symptom onset, and HS disease severity) responding to each survey round. All statistical analyses were performed using Excel, version 16.70 software (Microsoft Corporation).

Results

Demographic characteristics of HS experts and PRPs participating in item reduction and e-Delphi consensus rounds are shown in **Table 1** and **Table 2**, respectively. Among experts, response rates were 42 of 55 (76.4%), 38 of 42 (90.5%), and 39 of 42 (92.9%) in the item reduction, e-Delphi round 1, and e-Delphi round 2 surveys, respectively; among PRPs, response rates were 17 of 24 (70.8%), 17 of 17 (100%), and 14 of 17 (82.4%), respectively. Across the rounds, the majority of experts were practicing dermatologists (item reduction survey, 39 of 42 [92.9%]; e-Delphi round 1, 35 of 38 [92.1%]; e-Delphi round 2, 36 of 39 [92.3%]), with a median of 18.00 years (IQR, 10.25-29.50 years) to 19.00 years (IQR, 9.25-25.75 years) of clinical experience following training. Most PRPs were female (item reduction survey, 15 [88.2%] vs 2 male [11.8%]; e-Delphi round 1, 15 [88.2%] vs 2 male [11.8%]; e-Delphi round 2, 12 [85.7%] vs 2 male [14.3%]), all were White, most were between the ages of 30 and 49 years (ranging from 76.5% [13 of 17] in the item reduction survey and e-Delphi round 1 to 78.6% [11 of 14] in e-Delphi round 2), and most had moderate disease (ranging from 52.9% [9 of 17] in the item reduction survey and e-Delphi round 1 to 57.1% [8 of 14] in e-Delphi round 2). The majority of experts and all PRPs were from North America or Europe.

Item Reduction Survey

The 4 ClinROMs that received the highest number of votes among experts were the following: HS Investigator Global Assessment (HS-IGA) (29 of 46 [63.0%]), HS Physician Global Assessment (29 of 46 [63.0%]), International HS Severity Score System (26 of 46 [56.5%]), and HS Clinical Response (HiSCR) (25 of 46 [54.3%]). Among PROMs, the HS Quality of Life score (HiSQOL) (weighted ranks, 60), HS Impact Assessment (weighted ranks, 51), and HS Severity Assessment (weighted ranks, 50) were scored by PRPs as most relevant to capturing therapeutic response. The remaining ClinROMs and PROMs were not selected for consideration in consensus rounds due to low agreement among experts and PRPs, respectively. Results of the item reduction survey round are shown in eTable 5 in the Supplement.

Consensus on Outcome Measures and Assessment Interval

Results for expert consensus rounds are shown in **Figure 2**. After the second round, the HS-IGA met criteria for consensus-in, with 28 experts (71.8%) agreeing to its utility in clinical practice. None of the

Table 1. Characteristics of Experts in Hidradenitis Suppurativa

Characteristic	No. (%)		
	Item reduction survey	e-Delphi round 1	e-Delphi round 2
No. of experts surveyed	55	42	42
Response rate	42 (76.4)	38 (90.5)	39 (92.9)
Geographic region			
US	17 (40.5)	15 (39.5)	15 (38.4)
Europe	16 (38.1)	15 (39.5)	16 (41.0)
Canada	3 (7.1)	3 (7.9)	3 (7.7)
Southeast Asia	3 (7.1)	2 (5.3)	2 (5.1)
Australia	2 (4.8)	2 (5.3)	2 (5.1)
South America	1 (2.4)	1 (2.6)	1 (2.6)
Primary specialty			
Dermatology	39 (92.9)	35 (92.1)	36 (92.3)
Surgery	1 (2.4)	1 (2.6)	1 (2.6)
Other (eg, internal medicine)	2 (4.8)	2 (5.3)	2 (5.1)
Time in practice (after training completion), median (IQR), y	18.50 (10.00-28.75)	19.00 (9.25-25.75)	18.00 (10.25-29.50)
Practice setting			
Academic or university	34 (81.0)	29 (76.3)	32 (82.1)
Community based[a]	7 (16.7)	8 (21.1)	7 (17.9)
Research	1 (2.4)	1 (2.6)	0

Abbreviation: e-Delphi, electronic Delphi.

[a] Refers to physicians who work in private practice and private hospitals.

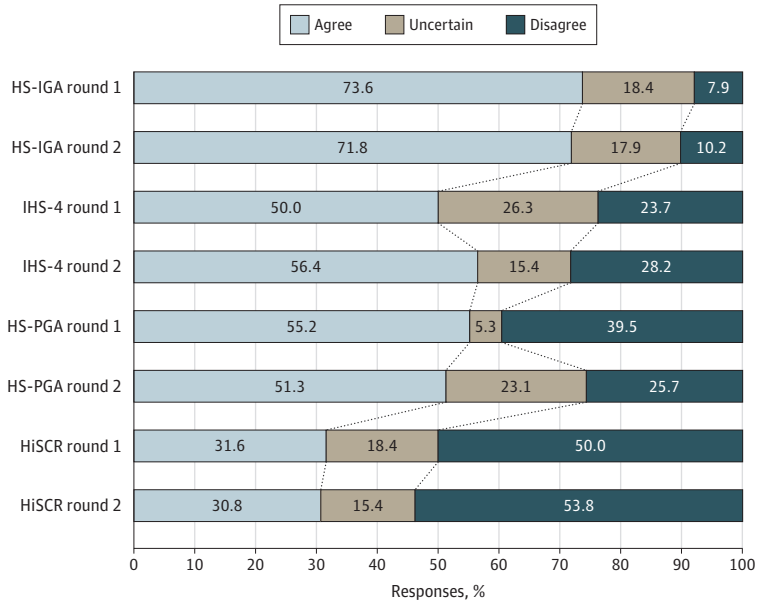
Table 2. Characteristics of Patient Research Participants With HS

Characteristic	No. (%)		
	Item reduction survey	e-Delphi round 1	e-Delphi round 2
No. of patients surveyed	24	17	17
Response rate	17 (70.8)	17 (100)	14 (82.4)
Geographic region			
US	6 (35.3)	6 (35.3)	6 (42.9)
Europe	9 (52.9)	9 (52.9)	6 (42.9)
Canada	2 (11.8)	2 (11.8)	2 (14.3)
Age category, y			
18-29	0	0	0
30-39	4 (23.5)	4 (23.5)	3 (21.4)
40-49	9 (52.9)	9 (52.9)	8 (57.1)
50-59	2 (11.8)	2 (11.8)	2 (14.3)
≥60	2 (11.8)	2 (11.8)	1 (7.1)
Sex			
Female	15 (88.2)	15 (88.2)	12 (85.7)
Male	2 (11.8)	2 (11.8)	2 (14.3)
White race	17 (100)	17 (100)	14 (100)
Time since HS symptom onset, median (IQR), y	28.0 (24.0-34.0)	27.0 (23.0-33.0)	27.5 (22.5-33.5)
Time since HS diagnosis, median (IQR), y	16.0 (10.0-23.0)	17.0 (11.0-23.0)	14.5 (10.25-22.25)
HS disease severity			
Mild	3 (17.6)	3 (17.6)	4 (28.6)
Moderate	9 (52.9)	9 (52.9)	8 (57.1)
Severe	5 (29.4)	5 (29.4)	2 (14.3)

Abbreviations: e-Delphi, electronic Delphi; HS, hidradenitis suppurativa.

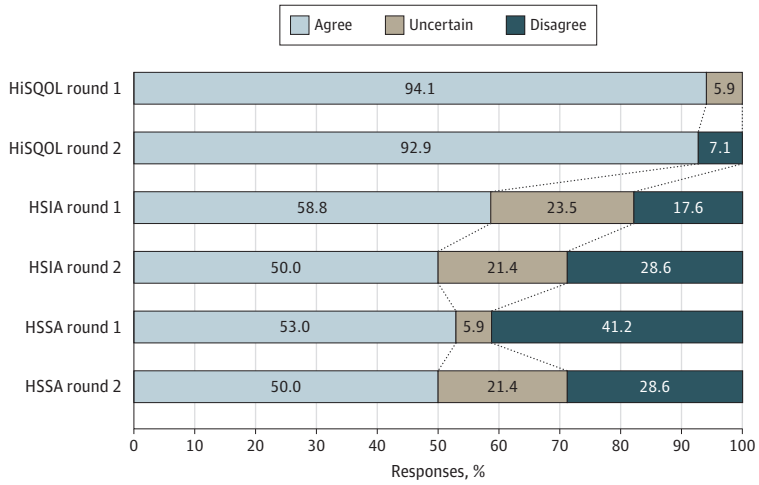
remaining ClinROMs achieved 67% or higher agreement after e-Delphi round 2. Use of the International HS Severity Score System, HS Physician Global Assessment, and HiSCR in clinical practice was supported by 22 (56.4%), 20 (51.3%), and 12 (30.8%) experts, respectively, after e-Delphi round 2. More than one-half (21 [53.8%]) of experts disagreed with the use of HiSCR in clinical practice. Most

Figure 2. Electronic Delphi Results for Clinician-Reported Outcome Measures



HiSCR indicates Hidradenitis Suppurativa Clinical Response; HS-IGA, Hidradenitis Suppurativa Investigator Global Assessment; HS-PGA, Hidradenitis Suppurativa Physician Global Assessment; and IHS-4, International Hidradenitis Suppurativa Severity Score System.

Figure 3. Electronic Delphi Results for Patient-Reported Outcome Measures



HiSQOL indicates Hidradenitis Suppurativa Quality of Life score; HSIA, Hidradenitis Suppurativa Impact Assessment; and HSSA, Hidradenitis Suppurativa Symptom Assessment.

experts agreed to apply the selected measures at 3-month (27 [69.2%]) or 4-month (7 [17.9%]) intervals.

Results for PRP consensus rounds are shown in **Figure 3**. After the second round, the HiSQOL met criteria for consensus-in, with 13 PRPs (92.9%) agreeing to its application in clinical practice. No other PROMs achieved 67% or higher agreement. Use of the Hidradenitis Suppurativa Symptom Assessment and HS Impact Assessment in clinical practice was agreed on by an equal percentage (7 [50.0%]) of PRPs.

Discussion

An objective framework within which to evaluate disease status and response to treatment, both medical and procedural, is a necessary component to determining whether timely changes to the treatment strategy during the window of opportunity in HS may be warranted.[44] In this study, HiSTORIC achieved consensus on outcome measures in HS that are recommended to be applied in clinical practice. These measures include the HS-IGA, a ClinROM selected by HS experts, and the HiSQOL, a PROM selected by patients. Most experts endorsed a 3-month assessment interval. The HS-IGA was developed using a phase III clinical trial data set (Efficacy and Safety Study of Adalimumab in Treatment of Hidradenitis Suppurativa [PIONEER I], NCT01468207) with input from experts, PRPs, and methodologists within HiSTORIC.[16] The measure was validated using a replicate phase III clinical trial data set (PIONEER II, NCT01468233), as well as a separate more recent phase II clinical trial data set (UCB HS0001).[16,17] As a global assessment, the HS-IGA is a simple-to-use measure that demon-

strates very strong test-retest reliability, good convergent validity with known disease activity anchors, and responsiveness to change[16,17] (eTable 6 in the Supplement). The HS-IGA uses the familiar construct of a 6-point ordinal scale with response defined as 2-point improvement from baseline (eTable 7 in the Supplement). The HS-IGA is scored as a number between 0 and 5 based on the sum of abscess, nodule (inflammatory and noninflammatory), and tunnel (draining and nondraining) in either the upper- or lower-body regions. Specification of qualifying lesion types and distinction among difficult-to-discern lesion types (ie, inflammatory nodule vs abscess, draining abscess vs draining tunnel) are not required by the clinician, which may support measurement accuracy. Papules, plaques, pustules, comedones, and scars are not counted in the score. The score limits counting to 21 qualifying lesions. These features of the HS-IGA may allow for feasibility and ease of use in clinical practice.

The HiSQOL, a disease-specific quality-of-life measure for adults with HS, captures the unique features of HS that are not directly measured with general skin quality-of-life measures. The measure consists of 17 items, each with a 7-day recall period, that assesses a wide range of HS symptoms, including pain, itch, odor, and drainage, as well as psychosocial outcomes and activities that may be affected by HS.[19] Each item is scored using an ordinal scale, ranging from 0 (not at all) to 4 (extremely). Some items have a response option of "unable to do, due to HS" that is scored with the highest number of points (4), indicating greater effect on quality of life. The total score ranges from 0 to 68, with higher scores indicating worse quality of life (eFigure in the Supplement). The HiSQOL has been translated into approximately 20 languages, which will support its broader application.[45,46] The HiSQOL has also been converted into an electronic version, which has shown acceptability and usability regardless of age, sex, or device familiarity, as well as ease of use.[47] The HiSQOL was developed by an international steering group that included patients, thereby enhancing its content validity and ability to comprehensively capture the influence of HS on quality of life. As a result, the HiSQOL may be more sensitive to changes in the status of a patient with HS with treatment.[10] Previous studies on the HiSQOL have shown excellent reliability, including test-retest and internal consistency, and very strong convergent and known-groups validity.[19,21] Analysis from a recent phase II trial defined the minimum important difference on the HiSQOL as an 18-point, or 58%, reduction in total score from baseline.[48] Additional studies with the HiSQOL are under way to evaluate responsiveness and application to adolescents with HS, as well as to create a reduced, or mini, set of items.

It is important to underscore that recommendations on the use of disease measures for HS in practice represent 1 component of a comprehensive evaluation strategy. Adherence to recommendations also does not ensure an improved outcome for every patient. Ultimate judgment on assessment and treatment should be made by the physician in partnership with the patient. The intent of these recommendations is to provide an objective framework with both clinician and patient input that can facilitate bidirectional discussion, trust building, and decision-making on the current treatment strategy and the need to adjust or escalate treatment in an appropriate time frame. Defining feasible HS measures that can be used in routine practice provides the foundation on which targets of treatment may be established and treatment outcomes may be assessed. While HiSTORIC has achieved consensus on the HS measures that should be applied in practice, the thresholds that should be achieved on each as an indication of treatment adequacy is not yet defined. For this reason, payers should not require use of this framework for access or continuation of treatments. As additional and more effective treatment options become available, the treat-to-target benchmark will have more meaningful application in practice. Indeed, similar treat-to-target frameworks that guide treatment decisions through shared decision-making have improved outcomes for patients with other chronic diseases, including diabetes mellitus, hypertension, rheumatoid arthritis, and psoriatic arthritis.[49-53]

Strengths and Limitations

This study has several strengths. Experts were primarily dermatologists with approximately 20 years of clinical experience and expertise in medical treatment of patients with HS. In addition, the e-Delphi method had several benefits, including (1) asynchronous survey distribution, (2) anonymity of survey responses, and (3) presentation of anonymized comments to aid decision-making. The PROM was selected by patients with HS and experience in participating in consensus processes on HS measures. We also used an iterative process of consultation and feedback to ensure development of a high-quality survey instrument for each round.

This study also has some limitations that merit consideration. While we aimed to optimize global participation, most experts and patients with HS represented countries in North America and Europe, where historically, HS has been a significant research focus. The HS expert consensus results may have been influenced by differing regional practices in HS management. Neither the HS-IGA nor the HiSQOL has been studied in the practice setting. However, experts and patients have agreed that both validated measures are simple to use and evaluate concepts relevant to the practical care of patients with HS. Furthermore, while we encourage application of the proposed HS disease activity and outcome measures in practice, we recognize the inherent variability in individual practice time, staffing, and workflows that may limit implementation. Potential implementation challenges include the need to train clinicians in outcome measure scoring and interpretation and to train other clinical staff in routine administration and collection of data. Given some challenges to practice implementation, outcome measurement may need to be prioritized for patients with diseases, such as HS, for which treatment outcomes are frequently suboptimal.

Conclusions

With this study, HiSTORIC has achieved consensus on the application of HS-IGA and HiSQOL measures to evaluate clinical practice outcomes in patients with HS. The measures are recommended to be applied at 3- to 4-month intervals during treatment. Application of HS outcome measures in practice may facilitate shared decision-making on treatments with the goal of optimizing treatment strategies, controlling symptoms, and slowing disease progression. Use of these measures in practice may also generate clinical evidence that may inform HS treatment guidelines. Future consensus studies will establish targets of treatment in practice, as well as a definition of minimal disease activity that may be applied in clinical trials and in practice as more efficacious treatments of HS are developed.

ARTICLE INFORMATION

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