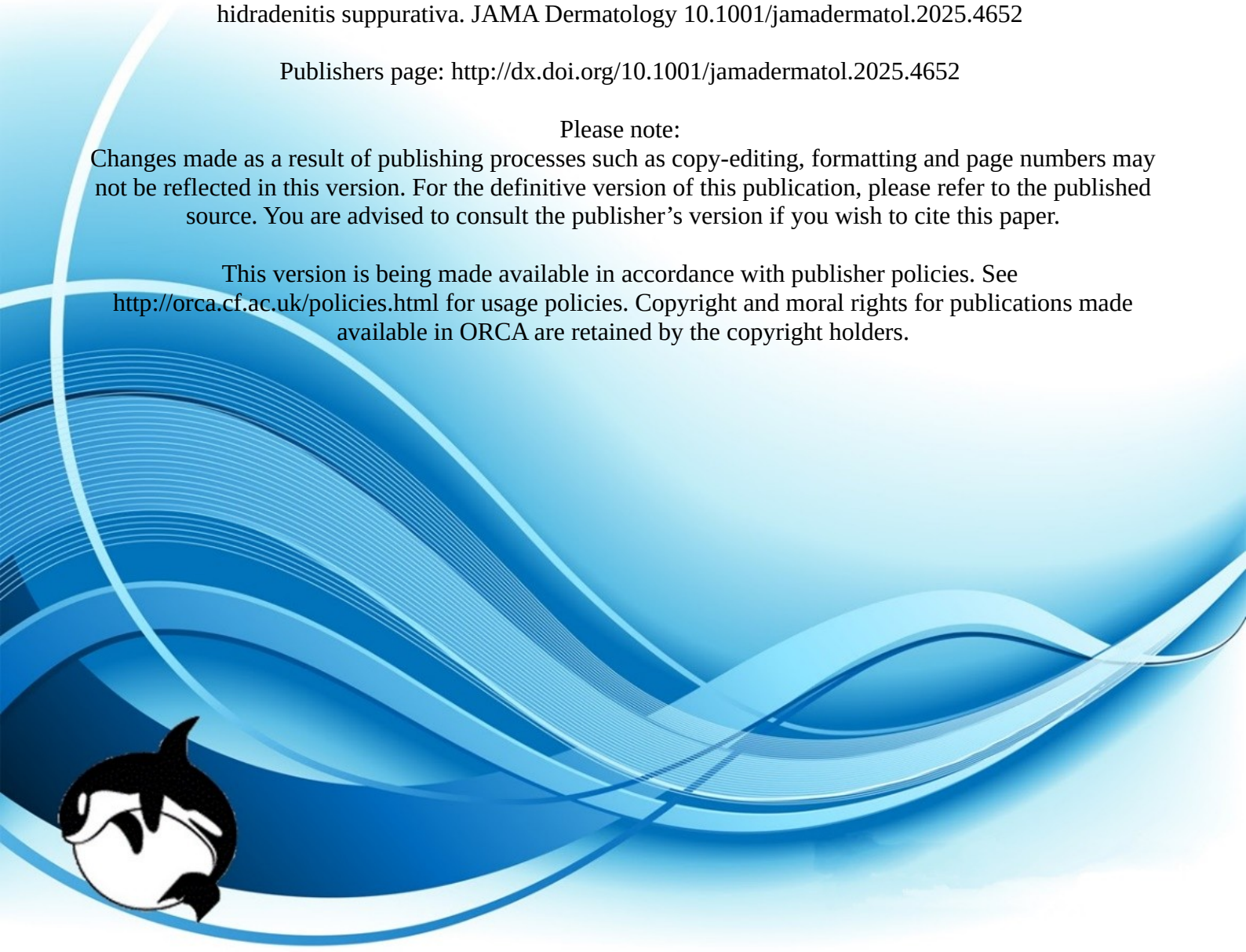

Article type: Consensus Statement

Title: Standardization of Lesion Classification and Assessment by Investigators in Clinical Trials for Hidradenitis Suppurativa: A Consensus Exercise Using a Modified Delphi Approach

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Keywords: hidradenitis suppurativa; investigator; clinical trial; lesion; morphology; nodule; abscess; fistula; tunnel; HiSCR; classification; accuracy; standardization; training; intra-rater; inter-rater; reliability; assessment; consensus.

Abbreviations:
AN: Abscess-Nodule
C3, CHORD Cousin Collaboration
COS: Core Outcome Set
DLQI: Dermatology Life Quality Index
e-Delphi: electronic Delphi
FDA: U.S. Food and Drug Administration
HiSCR – Hidradenitis Suppurativa Clinical Response
HiSQOL: Hidradenitis Suppurativa Quality of Life
HiSTORIC: Hidradenitis Suppurativa Core Outcomes Set International Collaboration
HS: Hidradenitis Suppurativa
HS-IGA: Hidradenitis Suppurativa Investigator Global Assessment
HASI-R: Hidradenitis Suppurativa Activity and Severity Index-Revised
IGA: Investigator Global Assessment
IRB: Institutional Review Board
IQR: Interquartile Range
PRP: Patient Research Partner
PtGA: Patient Global Assessment
REDCap: Research Electronic Data Capture
RCT: Randomized Controlled Trial
SEM: Standard Error of Measurement
US: Ultrasound
VAS: Visual Analog Scale

Key Points

Question: Is there agreement among trial investigators on morphological definitions and methods of lesion assessment in clinical trials for hidradenitis suppurativa.

Finding: Through a modified Delphi process involving expert dermatologists, consensus was achieved on 11 morphologic lesion definitions and on 15 of 17 statements guiding standardized HS lesion assessments.

Meaning: Detailed morphologic definitions to support classification of HS lesions and guidance that standardize assessment of these lesions achieving consensus can be implemented in study protocols and investigator trainings with the goal of improving accuracy and reliability of investigator ratings in clinical trials for moderate to severe HS.

Abstract

Importance: Accuracy in lesion classification and reliability of lesion assessments by investigators in clinical trials for hidradenitis suppurativa (HS) may be limited.

Objective: To establish consensus-based morphological definitions of HS lesions and guidance statements that standardize lesion assessments for implementation in clinical trials for HS.

Evidence Review: Health professionals (primarily dermatologists) with expertise in the measurement of HS disease activity as well as novice raters completed a preliminary questionnaire in which participants were asked to assess images of HS lesions and provide qualitative feedback on their decision making. Based on this feedback, detailed morphologic definitions for lesions and guidance statements that standardize lesion assessments were formulated and presented for consensus voting in two electronic Delphi (e-Delphi) surveys. A virtual group discussion after round 1 supported participants in round 2 voting.

Findings: Response rates were 50 of 59 (84.7%), 43 of 50 (86.0%), and 40 of 44 (90.9%) in the preliminary, e-Delphi round 1, and e-Delphi round 2 surveys, respectively. Morphological definitions for 11 lesion types in HS achieved the pre-specified 70% consensus threshold, with 9 definitions reaching at least 90% agreement. After two e-Delphi rounds, 15 of 17 guidance statements achieved the pre-specified consensus threshold, with 13 statements receiving endorsement from over 80% of participants. Two guidance statements related to assessment of a fistulous plaque with multiple openings and assessment of scalp lesions failed to reach consensus.

Conclusions and Relevance: Morphologic definitions for HS lesions and guidance that standardizes assessment of HS lesions can be implemented in clinical trial protocols and investigator trainings with the goals of improving accuracy and reliability of investigator ratings.

Introduction

Hidradenitis suppurativa (HS) is a debilitating inflammatory disease linked to significant comorbidity burden[1] and overall mortality[2] that has substantial impact on general health-related and skin-specific quality of life.[3] Treatment represents the greatest unmet need for patients with HS.[4,5,6] With at least 20 unique mechanisms of action under evaluation in phase 2 or 3 drug development programs, the therapeutic pipeline for moderate to severe HS is robust.[7] To date however, more drug development programs having good translational and clinical premise have failed than have succeeded. High placebo responses for patients in trials for patients with moderate to severe HS has resulted in abandonment of drug development in several programs.[7]

Poor separation from placebo may be at least partially explained by low accuracy and non-standard investigator lesion assessments in HS, a disease with complex and heterogeneous physical findings. Indeed, both intra- and inter-rater reliability of HS lesion assessments have been demonstrated to be problematic, in particular for high stakes lesions including abscess and draining tunnel on the Hidradenitis Suppurativa Clinical Response (HiSCR).[8,9,10]

The Hidradenitis Suppurativa Core Outcomes Set International Collaboration (HiSTORIC) group is addressing challenges in drug development programs in HS through development of a core measures set that may overcome important limitations to measuring treatment response.[11,12] For example, HiSTORIC has developed and validated the HS investigator global assessment (HS-IGA) which obviates the need to distinguish lesion types and limits lesion counting.[13,14] HiSTORIC is also testing a measure which assesses color change, induration, skin openings, extent of tunnels, and surface area, without having to distinguish and count lesions.[15] The objective of this study was to provide expert consensus on detailed morphologic definitions of HS lesions and guidance statements that standardize assessment of HS lesions within and across the investigator pool in clinical trials.

Methods

This consensus statement included participants from HiSTORIC, an international multistakeholder group comprising HS experts, patient research partners (PRPs), and methodologists 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.[12]Along with approximately 20 COS groups, HiSTORIC operates under the CHORD Cousin Collaboration (C3), an umbrella research organization whose mission is to develop, disseminate, and implement COSs for dermatologic conditions with the goals of standardizing valid and reliable measurement of disease activity and treatment response and of comparing effectiveness.[16]

In order to reach consensus on lesion assessment standards, we carried out an e-Delphi study between July, 2024 and April, 2025 comprising the following five steps: 1) nomination of ambiguous HS lesions and lesion assessment scenarios; 2) preliminary survey to elicit qualitative feedback; 3) e-Delphi survey round 1 evaluating consensus on morphological definitions and guidance statements for lesion assessments; 4) inter-round virtual discussion meeting; 5) e-Delphi survey round 2. The consensus exercise was not prospectively registered, and it was reported in compliance with the Accurate Consensus Reporting Document (ACCORD) guidelines.[17] Anonymity was planned in the study design and applied to all Delphi participants and image sources. Survey responses were collected using anonymized identifiers through a secure electronic platform. The inter-round discussion meeting was not anonymous. Participation was voluntary, and reminders were sent via email to encourage survey completion and continued engagement throughout the consensus process. This study was approved by the human participants research committee of the Feinstein Institutes for Medical Research at Northwell.

Preliminary Survey

Prior to e-Delphi rounds, a preliminary survey was administered to 59 expert and 23 novice participants to elicit qualitative feedback that would inform development of morphologic definitions and guidance statements. The expert group included physician members of HiSTORIC while the novice group included physicians and other allied health professionals who would be eligible for the role of primary or sub-investigators, some of whom may not have participated in an HS clinical trial. The preliminary survey comprised 3 sets of questions based on ambiguous HS lesions and lesion assessment scenarios, which included the following: 1) 16 questions in which participants classified a lesion depicted by an

image based on a list of options; 2) 10 open-ended questions requesting specific history and/or physical features which best distinguish between similar appearing lesion types; 3) 17 multiple-choice questions relating to methods of assessment for specific lesion types (e.g., method of assessment of drainage from a fistula/tunnel). Participants were asked to provide a rationale for all answers to inform where morphologic definitions and guidance statements may be necessary.

Based on responses and qualitative feedback from the preliminary survey, morphologic definitions were developed for the following 11 HS lesions: nodule (inflammatory and non-inflammatory), papule (inflammatory and non-inflammatory), granulating growth, pustule, abscess, fistula/tunnel (draining and non-draining), rope-like scar, and plaque (inflammatory and non-inflammatory), cyst (inflammatory and non-inflammatory), ulcer, and comedone. Also based on feedback, guidance statements recommending a standardized assessment approach for HS lesions were developed for 17 scenarios. Survey pilot testing was not conducted.

e-Delphi Rounds and Virtual Discussion

Experts responding to the preliminary survey were invited to participate in e-Delphi round 1. For each morphologic definition and guidance statement, a priori consensus was defined as at least 70% of respondents selecting “Agree”/”Agree with minor modification” or selecting a single answer choice for questions with multiple choice options. Responses were collected individually via online survey tools (REDCap). Items reaching consensus in e-Delphi round 1 were not included in the subsequent consensus round. Each consensus step’s objective was to establish consensus on morphologic definitions and guidance statements through iterative feedback.

A virtual group discussion meeting was held to review aggregate results from round 1 and to discuss guidance statements that did not reach consensus. Following this meeting, a second e-Delphi survey was administered, which included the edited morphologic definitions and the two guidance statements that had not reached consensus. The study was concluded following the second round, as there was no change from the prior round in percent agreement on items not achieving consensus.

Statistical Analysis

Geographic and professional information of respondents was summarized using descriptive statistics. Frequencies and percentages of respondents endorsing each answer choice for definitions and guidance statements in the e-Delphi rounds were calculated.

Results

Characteristics of HS expert participants are summarized in **Table 1**. Expert participants had a median of approximately 20 years (IQR 10-30) of clinical experience following training. Percentages of participants from Europe and the United States ranged from 38.5% to 41.9% and 37.2% to 41.0%, respectively, across the three surveys. Response rates were 50 of 59 (84.7%), 43 of 50 (86.0%), and 40 of 44 (90.9%) in the preliminary round, e-Delphi round 1, and e-Delphi round 2 surveys, respectively.

e-Delphi Round 1

Detailed morphologic definitions for 11/11 (100%) HS lesions reached at least 70% consensus in e-Delphi round 1. Nine of 11 definitions achieved over 90% agreement, while the remaining two reached over 80% agreement. Following round 1, qualitative feedback from the virtual discussion meeting prompted minor semantic edits to 8 of 11 morphologic definitions, the revised versions of which were presented in round 2 for confirmation. **(Table 2)**

Fifteen of 17 (88.2%) guidance statements to standardize lesion assessments reached at least 70% consensus in e-Delphi round 1. Among these, 7 (41.2%) were endorsed by over 90% of respondents, 5 (29.4) were endorsed by between 80% and 90% of respondents, and 3 (17.6%) were endorsed by between 70% and 80% of respondents. The two guidance scenarios which did not achieve consensus related to assessment of plaques with multiple surface openings (i.e, fistulous plaque) and assessment of scalp lesions. **(Table 3, eTable 1)** Approximately half of participants recommended counting a fistulous plaque with multiple openings as one fistula/tunnel (n=22, 51.2%), while the remaining half recommended counting each opening on the fistulous plaque as a distinct fistulae/tunnel (n=21, 48.8%). The participant group also did not achieve consensus on whether scalp lesions should be counted, and if so, whether fistulae/tunnel openings on the scalp should be counted as a single fistulous plaque or as distinct individual fistulae/tunnels.

e-Delphi Round 2

In round 2, 8/8 (100%) morphologic descriptions having minor semantic edits were confirmed to reach the final set of HS lesion definitions. **(Table 2**)

The two guidance statements which failed to reach consensus in round 1 also did not reach consensus in round 2. Despite robust discussion on related guidance scenarios between rounds, there was minimal change in percent agreement on either one.

The complete list of detailed morphologic definitions and guidance statements standardizing lesion assessments with background and rationale are described in the **Supplement**.

Discussion

Detailed morphologic definitions for HS lesions may support accuracy of lesion classification, while guidance that standardizes assessments of HS lesions can increase intra- and inter-rater reliability among study investigators. Herein, we have achieved consensus on definitions and guidance statements that can be incorporated into study protocols and investigator training modules to improve quality of investigator ratings within clinical trials for HS. These definitions and statements were designed and developed with input from expert as well as novice investigators, so that instructions could support classification and assessment of HS lesions by an investigator pool having variable experience levels.

Unlike physical assessments in monomorphic skin diseases including plaque psoriasis, vitiligo, and alopecia areata, HS assessments are often more complex due to the myriad of lesion types and their varied presentations. Three distinct lesions characterize HS, including abscesses, nodules and tunnels. Additionally, nodules may be inflammatory or non-inflammatory, and tunnels may be draining or non-draining. These five lesion types must also be distinguished from the others presenting in the moderate to severe HS patient, including granulating growths, papules, pustules, plaques, cysts, and rope-like scars. Moreover, HS lesions may appear in close proximity or contiguously within small and crowded spaces such as the axilla or inguinal crease. Additionally, erythema, a key feature used to classify lesions as inflammatory, is more difficult to discern in darker skin toned patients. In these contexts, HS lesions may

be difficult to accurately classify, especially for novice or non-dermatologist investigators who are frequently involved in study assessments.

Morphologic definitions achieving consensus herein amplify the foundational work by Frew et al.[18] by expanding the glossary of terms to include granulating growth (to distinguish from inflammatory nodule), fistulous plaque (to distinguish from plaques without underlying tunnel network), inflammatory and non-inflammatory cysts (to distinguish from nodule and abscess), rope-like scar (to distinguish from fistula/tunnel). These definitions also add descriptive details including shape, texture, size, depth, erythema, to specific lesion types with the goal of allowing novice investigators to more easily distinguish among similar appearing HS lesions (i.e., large pustule with erythema vs abscess). **(Table 2)**

Even with accurate lesion classification supported by detailed morphologic description, there may be inconsistent assessments of lesions by the same rater. For example, there was no prior standard by which raters approached assessment of a fistula/tunnel for drainage, a high stakes evaluation on the HiSCR, with respect to method, amount and location of palpation pressure to elicit drainage. Not surprisingly, intra-rater agreement of draining fistula/tunnel count appears limited. Among over 600 patients in the PIONEER Phase 3 trials for adalimumab in moderate to severe HS, the standard error of measurement (SEM) for draining fistula/tunnel count between screening and baseline assessments was 1.4-1.6. The draining fistula/tunnel counts between the two assessments differed by 3 or more for 16% and 12% of patients in PIONEER I and PIONEER II, respectively. Measurement error was greater among patients with higher fistula/tunnel counts compared to those with lower counts.[8] This substantial disagreement between repeated fistula/tunnel counts by the same rater may influence responder rates for individual subjects when the endpoint is dichotomized based on an increase from baseline of just one draining fistula/tunnel, as is the case with HiSCR. The method, amount, and location of palpation pressure needs standardization to reduce variability for drainage-based endpoints. Differences in any of these methods of assessment can alter whether drainage is elicited, directly affecting lesion classification and HiSCR scoring.

Inconsistent assessment of lesion types between raters in the investigator pool also has the potential to influence trial results by impacting mean responder scores, and thus the separation between active and placebo curves. Even among expert investigators, inter-rater reliability of lesion assessments has been shown to be poor to moderate.[9] As an example, there was no prior consensus on whether granulating growths should be classified as inflammatory nodules or as distinct lesions, an assessment that would directly influence mean abscess-nodule (AN) count on the HiSCR.

There are numerous other ambiguous scenarios in HS lesion assessment for which standardized guidance may improve reliability of investigator ratings, and thus performance on clinician-reported endpoints that are based on physical signs. Some of these include method, amount and location of palpation pressure for abscesses and nodules in addition to single tunnels; assessment of fistulous plaques with multiple openings; assessment of non-fistulous plaques; assessment of a nodule for inflammation; assessment of nodules, abscesses and tunnels on the scalp; and assessment of nodules, abscesses, and tunnels on the trunk. **(Supplement)**

Among these, there were two guidance scenarios that did not reach consensus. The first was assessment of a fistulous plaque with multiple surface openings. A fistulous plaque may represent one branching fistula/tunnel with multiple surface openings, or it may represent multiple interconnecting fistulae/tunnels that group together to form a plaque having multiple surface openings. The group did not reach consensus on whether a fistulous plaque having 6 openings, for example, should be assessed as one fistula/tunnel or as 6 distinct fistulae/tunnels. The former simplifies tunnel counting and prioritizes precision of fistula/tunnel count for a high stakes assessment over sensitivity of change related to number of openings. Additionally, counting fistulous plaques with multiple openings as one fistula/tunnel allows for a greater number of patients with higher fistula/tunnel load to be included in the trial, since patients with a count of 20 or more fistula/tunnels are otherwise typically excluded. Counting the fistulous plaque as distinct fistula/tunnels for each opening has higher sensitivity to changes in surface openings. However, this guidance may also increase variability in measurements due to rater error or inconsistency, in the absence of a true change, for a high stakes assessment on the HiSCR.

The second scenario which did not reach consensus was assessment of nodules, abscesses and fistulae/tunnels on the scalp. Patients with HS in typical areas (i.e., axillae) may also have involvement of the scalp with HS lesions. Additionally, patients with HS in typical areas may have dissecting cellulitis of the scalp. Dissecting cellulitis of the scalp presenting with nodules, abscesses and fistulae/tunnels may also occur in the absence of typical HS. The relationship between HS and dissecting cellulitis of the scalp is not fully understood, and it is not clear whether lesions of dissecting cellulitis on the scalp respond, or respond to the same degree, to treatments intended for HS. It is also not clear whether fistulae/tunnels on the scalp are single, single and branching, and/or multiple and interconnected. Finally, the presence of scalp hair interferes with locating, evaluating and counting scalp lesions. One guidance option was for the scalp to be ignored altogether as an area for HS lesion assessment, since lesions on the scalp are at high risk for errant classification. A second option was for all fistulae/tunnels on the scalp to be counted as one fistulous plaque with the remaining scalp lesions (i.e., nodules, abscesses) recorded as per study protocol, since failure to count inflammatory lesions could lead to an underestimation of the treatment effect. This guidance also takes into consideration that fistulae/tunnels on the scalp may represent single, single and branching, and/or multiple and interconnected lesions, and assessing these lesions as one fistula/tunnel can reduce the risk of errant classification. The third option was for each surface opening on the scalp to be counted as a distinct fistula/tunnel with remaining scalp lesions (i.e., nodules, abscesses) also recorded as per study protocol. This guidance took into consideration that if an intervention reduces the number of surface openings, counting each individual opening separately could capture treatment efficacy with greater sensitivity. For the two scenarios not achieving consensus, sponsors must weigh the advantages and disadvantages of each guidance option when developing the study protocol.

A strength of this study is the diversity of the consensus panel, which included international experts across academic and clinical settings to enhance generalizability. Many participants were actively involved in conducting HS clinical trials, lending practical insight into assessment challenges and ensuring relevance to trial methodology. The use of an image-based, scenario-driven Delphi process further strengthens the clinical applicability of the guidance. However, while the inclusion of image-based

cases strengthened external validity, interpretation may have varied based on clinical context not fully conveyed by photographs. Other limitations included the non-anonymous nature of the virtual group discussion which could have influenced participant responses. Additionally, some guidance statements did not reach consensus, which highlights the persistent variability in assessment practices for complex lesion types.

In summary, the morphologic definitions and standardized guidance for lesion assessments proposed herein can be implemented into study protocols and investigator trainings with the goal of improving accuracy and reliability of investigator ratings for clinical trials in HS.

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Patents (filed, received, pending, or in preparation): NA
Royalties: NA
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Financial disclosures: NA
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Expert testimony: NA
Grants: NA
Patents (filed, received, pending, or in preparation): NA
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Expert testimony: NA
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Patents (filed, received, pending, or in preparation): NA
Royalties: NA
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John Ingram:
Dr Ingram 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, Insmed, Kymera Therapeutics, MoonLake, Novartis, UCB Pharma, UNION Therapeutics, and Viela Bio. He is co-copyright holder of HiSQOL, 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.

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Table 1. Participant characteristics [a]

Characteristic	Preliminary Survey n=50	e-Delphi Round 1 n=43	e-Delphi Round 2 (n=40)
Region			
Europe	20 (40.8)	18 (41.9)	15 (38.5)
United States	19 (38.8)	16 (37.2)	16 (41.0)
Canada	4 (8.2)	2 (4.7)	2 (5.1)
Australia	3 (6.1)	3 (7.0)	3 (7.7)
Asia	2 (4.1)	3 (7.0)	2 (5.1)
South America (Brazil)	1 (2.0)	1 (2.3)	1 (2.6)
Missing	1 (2.0)	0 (0)	1 (2.5)
Title/Position			
Dermatologist	43 (86.0)	38 (88.4)	34 (87.2)
Resident or Fellow Trainee	2 (4.0)	3[b] (7.0)	3[b] (7.7)
Registered Nurse	2 (4.0)	1 (2.3)	1 (2.6)
Licensed physician eligible to participate as an investigator in trials	3 (6.0)	1 (2.3)	1 (2.6)
Missing	0 (0)	0 (0)	1 (2.5)
Years in practice, median (Q1, Q3)	20 (10, 30)	20 (10, 30)	18 (10, 30)
Practice setting			
Academic Health System	43 (86.0)	38 (88.4)	34 (87.2)
Community-based practice	6 (12.0)	4 (9.3)	4 (10.3)
Research	1 (2.0)	1 (2.3)	1 (2.6)
Missing	0 (0)	0 (0)	1 (2.5)

Abbreviations: Q1/Q3, Quartile 1/3

a – Characteristics are summarized for expert participants. Seven novice participants (6 resident/fellow physicians and 1 nurse practitioner with no HS clinical trial experience) also provided qualitative feedback in the preliminary survey only.

b – One or more participants reporting “licensed physician eligible to participate…” in the preliminary survey may have changed their title to “resident or fellow physician”, explaining the increase in this category across rounds.

Table 2. Morphological definitions of hidradenitis suppurativa lesions achieving consensus [a,b]

Morphological Definition	Agree or Agree with Minor Modification, n (%)	Disagree, n (%)
1. **Nodule:** A rounded lesion that is elevated from the surface of the skin, has depth, is firm/rubbery to palpation, and measures ≥1cm in diameter. **Inflammatory nodule:** tender to palpation, with erythema that is red or which may have a purplish hue in darker skin tones. **Non-inflammatory nodule:** non-tender to palpation and skin colored, although there may be some residual faint erythema.	39 (97.5)	1 (2.5)
2. **Papule:** A rounded lesion that is elevated from the surface of the skin, may have depth, is firm to palpation, and measures < 1cm in diameter. **Inflammatory papule:** tender to palpation, with erythema that is red or which may have a purplish hue in darker skin tones. **Non-inflammatory papule:** non-tender to palpation and skin colored, although there may be some residual faint erythema.	39 (97.5)	1 (2.5)
3. G**ranulating growth**: A rounded, red, eroded (i.e., non-keratinized) and glistening palpable lesion of variable size which most often appear at the openings of fistulae/tunnels.	37 [b] (86.0)	6 (14.0)
4. **Pustule:** A small, rounded cavity that contains opaque white or turbid colored fluid, which may leak. The lesion has little to no depth (i.e., superficial). If erythema is present, it is limited to a narrow red rim (1-2mm) surrounding the fluid filled cavity. The lesion may also be tender, especially when erythema is present.	40 [b] (93.0)	314 (7.0)
5. **Abscess:** A spherical lesion that is that is elevated from the surface of the skin, has depth, and is of variable size. It has red erythema over its entire surface. It is fluid (pus) filled. It is fluctuant to palpation and significantly tender to palpation. It is warmer to touch than the surrounding skin. An abscess may drain a whitish to yellowish purulent fluid. An abscess may have one or more pustules on its surface.	39 (97.5)	1 (2.5)
6. **Fistula/Tunnel:** A linearized palpable tunnel under the skin surface that may have 1 or more openings to the skin surface. A fistula/tunnel may branch or connect with others to form a plaque with multiple openings to the surface (fistulous plaque). **Draining fistula/tunnel:** a fistula/tunnel with drainage of whitish or yellowish purulent fluid from a surface opening. It has red erythema and it is typically tender to palpation. **Non-draining tunnel:** a fistula/tunnel that does not drain.	33 (82.5)	7 (17.5)

7. **Rope-like scar:** A linear, firm, scar elevated above surface of the skin that resembles the shape and consistency of a rope. A rope-like scar may branch or interconnect, and it may lie over or contain a fistula/tunnel.	42 [b] (97.7)	1 (2.3)
8. **Plaque:** An elevated, firm lesion of variable shape that has greater width(typically several centimeters in diameter) than height. The plaque may contain nodules, abscesses, fistula/tunnels (fistulous plaque), rope-like scars, among other types of HS lesions. **Inflammatory plaque:** tender to palpation, with erythema that is red or which may have a purplish hue in darker skin tones. **Non-inflammatory plaque:** non-tender to palpation and skin colored, although there may be some residual faint erythema.	38 (95.0)	2 (5.0)
9. **Cyst:** A spherical, rubbery lesion that is elevated from the surface of the skin, has depth, and is of variable size. The lesion may have a punctum. **Inflammatory cyst:** a cyst with red erythema or which may have a purplish hue in darker skin tones. It is softer or fluctuant to palpation, and it is tender to palpation. It may drain a thick curd-like, whitish to yellow, malodorous material. **Non-inflammatory cyst:** a cyst that is skin colored, and rubbery and non-tender to palpation.	38 (95.0)	2 (5.0)
10. **Ulcer:** A circumscribed depressed area with complete loss of the epidermis and all or a portion of the dermis.	39 (97.5)	1 (2.5)
11. **Comedone:** Superficial dilated pore on the skin with black colored keratinous debris. Side by side or interconnected comedones are referred to as bridging comedones, which are common in HS.	37 (92.5)	3 (7.5)

a – Reported results are for final definitions assessed in e-Delphi survey 2, unless otherwise noted. There were no missing responses for any definitions assessed in e-Delphi survey 2 (N=40).
b – Definition was not modified from e-Delphi survey round 1. Numbers are based on e-Delphi survey 1 with a denominator sample size of 43.

Table 3. Lesion assessment guidance themes and summary of consensus[a]

Guidance Statement	Consensus [b]	No Consensus
1. Method of palpation pressure	●	
2. Amount of palpation pressure	●	
3. Location of palpation pressure – Nodule	●	
4. Location of palpation pressure – Abscess	●	
5. Location of palpation pressure – Single fistula/tunnel	●	
6. Assessment of a fistulous plaque with multiple surface openings		●
7. Location of palpation pressure – Fistulous plaque [c]	● [c]	
8. Assessment of a single inflamed fistula/tunnel that does not drain	●	
9. Assessment of a non-fistulous plaque	●	
10. Assessment of a nodule for inflammation	●	
11. Terminology for "granulating growth", previously "pyogenic granuloma-like lesion" or "eroded nodule"	●	
12. Distinguishing granulating growth from nodule	●	
13. Distinguishing pustule from abscess	●	
14. Distinguishing fistula/tunnel from rope-like scar	●	
15. Trial eligibility relating to nodules, abscesses and fistulae/tunnels on the scalp	●	
16. Assessment of nodules, abscesses, and fistulae/tunnels on the scalp		●
17. Assessment of nodules, abscesses, and fistulae/tunnels on the face and/or trunk	●	

a – Complete guidance statements with background and rationale are included in the **Supplement**.
b – Consensus was defined as $\geq$ 70% of respondents selecting "Agree" or "Agree with minor modification" (defined as a minor semantic or grammatical edit).
c – Guidance on location of palpation pressure for a fistulous plaque achieved consensus, but it assumes that a fistulous plaque with multiple surface openings is assessed as one fistula/tunnel. Given that there was no consensus on the assessment of a fistulous plaque with multiple surface openings, the recommended approach to palpation will depend on how the multiple openings are counted by the individual investigator. See explanations for Guidance 6 and 7 in the **Supplement** for details.