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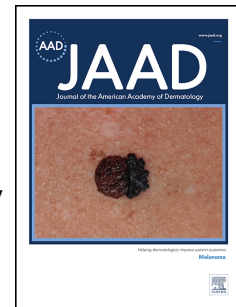
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Research Letter: Development of a Patient-Reported Outcome Questionnaire to Assess Signs and Symptoms of Hidradenitis Suppurativa: The Hidradenitis Suppurativa Symptom Diary (HSSD)

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advisory board participant from AbbVie, Janssen, Novartis, Boehringer-Ingelheim, Infla Rx, and UCB. Dr. Hamzavi has received grants or research funding from Pfizer, Bayer, and Incite; consulting fees from Pfizer, Incite, UCB, Boehringer-Ingelheim, Clarify Medical, and Jansen; a fee from Chemocentryx to serve as a Sub-Investigator; equipment from Lenicura; and has served on an Advisory Board for Abbvie in a non-compensated role and the President of the HS Foundation in a non-compensated role. Drs. Baradaran and Han are employees of Janssen Global Services. Michael Song was an employee of Janssen Global Services at the time the study was conducted. Susan D Mathias is an employee of Health Outcomes Solutions and Hilary H Colwell is a consultant of Health Outcomes Solutions which received funding from Janssen Global Services to conduct this study.

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To the Editor:

Hidradenitis Suppurativa (HS) is a chronic, recurrent inflammatory skin condition¹ that presents with painful nodules and tunnels in intertriginous areas of the skin. Pain is a cardinal symptom and has been linked to impairments in health-related quality of life.² For this reason, it is important to understand symptoms and impacts from the patient perspective. Some patient-reported HS-specific instruments exist to capture the patient perspective but fail to assess symptom severity with both a daily and weekly recall period.³⁻⁴ We developed a new patient-reported outcome (PRO) measure, the Hidradenitis Suppurativa Symptoms Diary (HSSD), in accordance with the FDA Guidance Document for PRO development,⁵ using input from individuals with HS by conducting both Concept Elicitation (CE) and Cognitive Debriefing (CD) interviews and clinical input.

All study documents were reviewed and approved by the Copernicus Group IRB (Cary, NC). Four clinical dermatology sites in the US and one in Canada identified eligible patients. To be eligible, individuals had to be adults with a confirmed diagnosis of moderate to severe HS for \geq 1 year, have HS lesions present in \geq 2 anatomic areas, and have a total abscess and inflammatory nodule (AN) count \geq 5. Exclusion criteria included the presence of any other active skin disease or condition, or an impairment that would interfere with participating in the study. Each 1-hour interview was conducted virtually via Zoom. A semi-structured interview guide was used to facilitate the interview to support the content validity of the HSSD and to evaluate its relevance and clarity.

Thirty-six individuals (75% female; mean age = 39 years) participated (6 in CE only interviews and 30 in combined CE/CD interviews) over 7 waves of interviews. The sample was mostly Caucasian but included individuals of other ethnicities (Table 1). Commonly involved HS locations were axillae and groin. Pain, drainage and itching were reported by 100% of the 36 subjects. Swelling/inflammation, odor, tenderness, warmth/heat, and pressure were also

common (Supplement). The most bothersome symptom was pain (94%, n=34 of 36). During the CD portion of the interview, participants generally found the HSSD to be clear, easy to complete and the structure and format was acceptable. All symptoms in the HSSD were endorsed by $\geq 31\%$ of subjects.

The final version of the HSSD (Table 2) contains 8 items assessing the worst severity in the past 24 hours of pain, tenderness, swelling, heat, pressure, itch, odor, and drainage, on a numeric rating scale ranging from 0 (none) to 10 (worst possible). An optional question assessing flu-like symptoms was developed and, if used, will be scored separately. An identical version of the HSSD with a recall period of the past 7 days is also available.

The HSSD was developed based on extensive patient input obtained during CE/CD interviews, clinical input, and in accordance with the FDA PRO Guidance. Based on CE/CD interviews, the HSSD demonstrated content validity and was found to be clear, comprehensive, and relevant by patients with moderate to severe HS. Its measurement properties will be evaluated in upcoming studies.

78 Table 1. Demographic and Clinical Characteristics

Characteristic	Total (n=36)
Gender, n (%) Female	27 (75)
Age, Mean \pm SD, years	39 \pm 11 (range: 21-62)
Ethnicity, n (%) Caucasian African American Asian Latino/Hispanic Other	22 (61) 4 (11) 2 (6) 5 (14) 3 (8)
Education, n (%) High School Diploma Some College College Degree Professional/ Advanced Degree	9 (25) 13 (36) 10 (28) 4 (11)
Work Status, n (%) Work full-time Work part-time Not working for pay due to HS Not working for pay, not due to HS Other (student, work different jobs with less hours)	18 (50) 7 (19) 6 (17) 1 (3) 4 (11)
Household Income, n (%) < \$25,000 \$25,000 - \$49,999 \$50,000 - \$74,999 \$75,000 - \$99,999 \geq \$100,000 Decline to answer	10 (20) 9 (25) 5 (14) 5 (14) 3 (9) 4 (11)
Disease duration (years), mean \pm SD	14 \pm 10
HS Severity (from Physician Global Assessment) (n = 34), n (%) Mild* Moderate Severe Very Severe	5 (15) 12 (35) 12 (35) 5 (15)
Hurley stage (n = 32), n (%) Stage 1 Stage 2 Stage 3	1 (3) 21 (66) 10 (31)
Lesion location and number, n (%) Axillae Groin Other Breast Stomach	29 (81) 27 (75) 21 (58) 12 (33) 8 (22)

Characteristic	Total (n=36)
Anus	6 (17)
Neck	4 (11)
Ears	0 (0)
Co-morbid conditions, n (%)	
Obesity	17 (47)
Depression	14 (39)
Anxiety	13 (36)
Other (including prediabetes, asthma, rheumatoid arthritis)	10 (28)
Cardiovascular Disease	9 (25)
Type 2 Diabetes Mellitus	8 (22)
Acne	7 (19)
Polycystic Ovarian Syndrome	6 (17)
Thyroid Disease	6 (17)
None	3 (8)
Follicular Occlusion Tetrad	1 (3)
Inflammatory Bowel Disease	1 (3)
Squamous Cell CA	0
Musculoskeletal	0
DLQI total score (range 0 to 30), mean (SD)†	14 (7)
EQ-5D-5L VAS score (range 0 to 100), mean (SD)†	67 (18)

*Although all subjects had moderate to severe HS at the time of screening (and at the time of interview), the clinician at the enrolling site rated the severity for 5 individuals as mild (0 abscesses, 0 draining fistulas, 1-4 inflammatory nodules or 1 abscess or draining fistula and 0 inflammatory nodules) when the clinical form was completed 1-2 months later.

†Completed by the subject at enrollment

Table 2. Instructions and Items from the HSSD

Hidradenitis Suppurativa Symptom Diary (HSSD)

Individuals with Hidradenitis Suppurativa (HS) may have lesions in several different parts of their body and may experience a range of symptoms. When answering the questions below, please consider your HS lesions in **all** of your affected areas.

Please indicate the severity of each symptom **at its WORST** during the **past 24 hours** using a scale of 0 to 10 (0=None and 10=Worst Possible).

Symptom
Pain from your HS lesions
Tenderness (sensitive to touch) from your HS lesions
Swelling from your HS lesions
Heat coming from your HS lesions
Pressure under your HS lesions
Itch from your HS lesions
Odor from your HS lesions
Drainage coming out from your HS lesions

Note: the finalized version of the HSSD will be available upon request from the authors after the measurement properties have been assessed

Supplement. Frequency of HS Symptoms Ever Experienced and Representative Quotes

Symptom and Frequency of HS ever Experienced from All Interviews (n=36)	Quotes
Pain; 100%	<p>It can also be painful at times depending on where things grow. It can make even like the most basic of things difficult to endure like sitting. If you get something on your rear or the underside of your legs, your thighs, that can be painful. Walking around can be painful.</p> <p>There's three steps to the pain. The first pain is when the abscess is forming. Right, a lot of pressure inside the abscess. The second step is when it's drained, it's quite uncomfortable and it's quite messy. The third step is when the tunneling forms and at that point, the inflammation has accumulated and so every day in your life, there's an discomfort and occasional very painful episodes.</p>
Tenderness; 81%	<p>When they're first starting, it begins as tenderness. It escalates to being quite painful, but when they're small, it's mostly just tender.</p> <p>They're definitely a lot more tender if you touch most of my lesions and just I've had them touched whether by mistake or if I brush up against something and I have done that and it's almost like an instant oh my gosh and it's like, oh, be really careful not to do that again.</p>

Swelling; 36%	<p>there's swelling, sometimes you can't walk correctly because if you walk it starts rubbing off the thighs and that causes pain and you don't want to do any recreational activities or you don't want to just walk even up to the kitchen.</p> <p>But sometimes I see the big one, but it's, I feel like a balloon on my body because it's soft. It's not too hard. When it's hard, I have it hard like a rock, but it's completely different. It's like in my body, I don't know, it's like a little boil in there.</p>
Heat; 64%	<p>So, on a bad day, they're all flaming and hot and raised from the skin, so that would be, you know, very painful and having a bad day. You can't really do much. A good day is a day where I'm able to take some sort of bath and not feel that pain.</p> <p>You are going to definitely feel that warmth and heat almost letting the patient know this could be infected</p>
Pressure; 64%	<p>If it's very swollen and I can feel like the pressure inside is just not going to let me exist without, you know, extreme pain</p> <p>So the first time you really feel unbearable pain is when these abscesses are first developing. Right, because it's not been drained, there's pus and blood accumulating inside and so there's quite a lot of pressure within the abscess and on top of that, the skin becomes quite hot.</p>
Itch; 100%	<p>[Itching] That's every day. That doesn't go away.</p> <p>If I'm not touching them, there's usually just like, I have like an itch, you know, like a regular type of irritation</p> <p>Like there's like something like I can't lay still enough because something is itching.</p>
Odor; 86%	<p>I don't even know how to explain it. It's like rotting meat. It's just gross. Like, I mean I have smelled pus before, but it's I don't know pus mixed with something. It, it's just, it's like, it's just rotten. It's just very rotten and stomach churning. Very smelly.</p> <p>Yeah. It almost is like a decaying kind of smell, I guess, that's worked its way out of the built-up fluid in there.</p> <p>There can be, just depending on where they're located they could smell very foul like maybe sweat, like a dirty sweat.</p>
Drainage; 100%	<p>So when it would break open, it would drain all that pus, green, yellow, red, like everything. Then it would be a foul, foul smell, but then at the same time as bad as it is, how it looks and how it smells, it was like, oh my God, such a relief.</p> <p>It's uncomfortable because you have to be careful what you wear because you always have something that's either bleeding or oozing or something.</p>

Flu-like symptoms; 31%	<p>I actually get some flu-like symptoms sometimes, which is a little bit of what I am suffering today. It kind of seems like when it's really bad, bad flare like this, I don't know if it, because of an infection. I get nauseous, very tired. Very, very tired and just drained, like there's not enough sleep in the world.</p> <p>Well, I always knew that I had a big one because I would start to feel like I had the flu. Like I get like body aches, like fever, just the pain. It's, the pain comes from the pressure of having something that big like pushing on everything else and not opening and then your instinct is to touch it and then you make it a million times worse and so, and like being embarrassed.</p>
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Saturation was reached by the 16th interview

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