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Content Validity, Acceptability and Usability of the Electronic Hidradenitis Suppurativa Symptom Daily Diary and the Electronic Hidradenitis Suppurativa Symptom Questionnaire

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Objectives

An observational, qualitative study was conducted to establish the content validity, including acceptability and usability, of the electronic versions of two questionnaires, the Hidradenitis Suppurativa Symptom Daily Diary (eHSSDD) and the Hidradenitis Suppurativa Symptom Questionnaire (eHSSQ), among patients with moderate-to-severe hidradenitis suppurativa (HS).

Background

- HS is a debilitating skin disease and the high burden of the disease can have a significant negative impact on the physical and mental wellbeing of patients.[1]
- The Hidradenitis Suppurativa Symptom Daily Diary (HSSDD) and the Hidradenitis Suppurativa Symptom Questionnaire (HSSQ) are patient reported outcome instruments specifically developed to assess the patient-perceived severity of core HS signs and symptoms.
- In line with FDA guidelines on instrument modification, evidence of the acceptability and usability of the electronic versions of the HSSDD and HSSQ is needed to ensure instruments are well defined and reliable to support labelling claims.[2,3]

Methods

- One-on-one semi-structured video interviews were conducted among patients with moderate-to-severe HS (at screening) recruited from the Penn State Hershey Medical Center (USA) and lasted approximately 90 minutes each.
- Interviews were conducted in US English, audio-recorded, and then subsequently transcribed.
- Interviews included gathering HS patients' symptom experiences, training on the electronic devices, completion of the eHSSDD/eHSSQ, evaluating comprehension of the eHSSDD/eHSSQ items, and collecting overall impressions and feedback on the acceptability and usability of both questionnaires.
- The eHSSDD includes five items that assess severity of core HS symptoms (worst skin pain, average skin pain, itch, smell/odour, and drainage/oozing) over the past 24 hours using a numerical rating scale (NRS) ranging from 0 (no symptom) to 10 (symptom as bad as you can imagine; **Figure 1, 2**) and was completed on a hand-held device.
- The eHSSQ includes four items that assess the severity of core HS symptoms (skin pain, itch, smell/odour, and drainage/oozing) over the past 7 days using a NRS ranging from 0 (no symptom) to 10 (symptom as bad as you can imagine; **Figure 3, 4**) and was completed on a tablet.

Results

- A total of 20 patients with HS were interviewed. The median age (range) was 41.5 (20.0–64.0) years, 80% of participants were female, and 75% reported living with an HS diagnosis for >5 years.
- The most common HS symptoms reported were drainage/oozing (100%), skin pain (95%), itching (95%), and smell/odour (90%).
- Mean symptom scores for patients completing the eHSSDD are shown in **Table 1**.
- Overall understanding of the eHSSDD items was high, however six patients (30%) had difficulty articulating average skin pain (**Table 1**).
- Half of the patients spontaneously described the eHSSDD questions as relevant for HS.
- Mean symptom scores for patients completing the eHSSQ are shown in **Table 1**.
- Overall understanding of every eHSSQ item was high (**Table 1**).
- All patients correctly interpreted the instructions in the eHSSDD and eHSSQ.
- Almost all patients (90%) accurately reflected on the 24 hour recall period for the eHSSDD and all patients considered the recall period of 7 days relevant for the eHSSQ.
- All but one patient reported spontaneously or via probing that they had no difficulty completing either questionnaire.

Conclusions

This study provides evidence that the concepts covered in the eHSSDD and eHSSQ were relevant and important to patients with moderate-to-severe HS, supporting the content validity of both instruments in this population.

The instructions, recall periods, item meanings, and response options for both instruments were relevant and easy for the majority of patients to understand, which confirms the acceptability, ease of use, and usability of the tools.

Summary

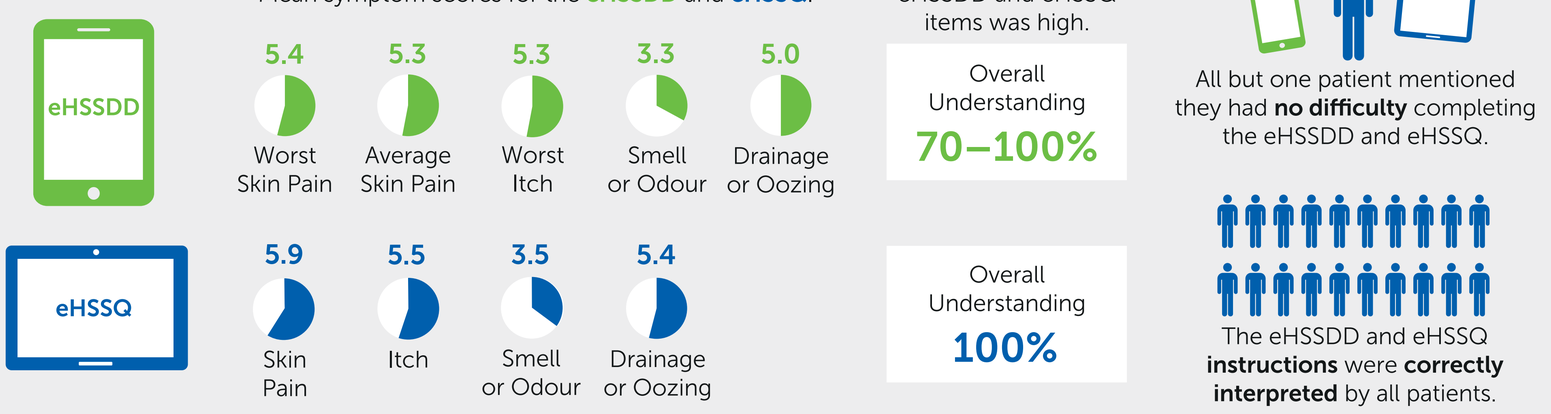


Figure 1 HSSDD questionnaire

Please select ONE number that best describes the intensity of your **hidradenitis suppurativa (HS)** symptoms **in the past 24 hours**.

Please rate your skin pain from your HS lesions at its worst in the past 24 hours
0 1 2 3 4 5 6 7 8 9 10
No skin pain — Skin pain as bad as you can imagine

Please rate your skin pain from your HS lesions on an average in the past 24 hours
0 1 2 3 4 5 6 7 8 9 10
No skin pain — Skin pain as bad as you can imagine

Please rate the itch from your HS lesions at its worst in the past 24 hours
0 1 2 3 4 5 6 7 8 9 10
No itch — Itch as bad as you can imagine

Please rate your smell or odour from your HS lesions in the past 24 hours
0 1 2 3 4 5 6 7 8 9 10
No smell or odour — Smell or odour as bad as you can imagine

Please rate the amount of drainage or oozing from your HS lesions in the past 24 hours
0 1 2 3 4 5 6 7 8 9 10
No drainage or oozing — A lot of drainage or oozing

Figure 3 HSSQ questionnaire

Please select ONE number that best describes the intensity of your **hidradenitis suppurativa (HS)** symptoms **in the past 7 days**.

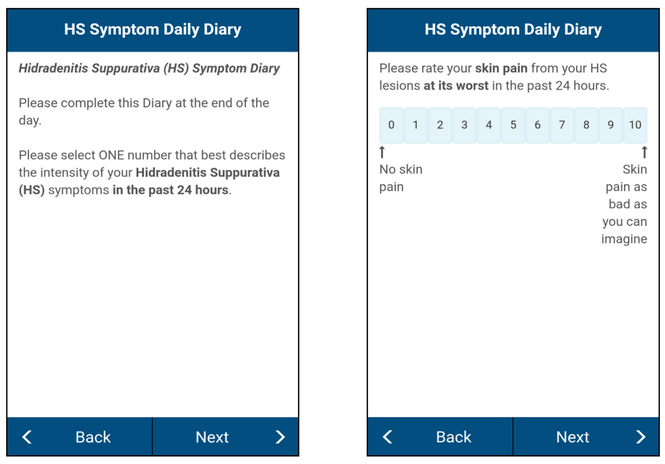
Please rate your skin pain from your HS lesions in the past 7 days
0 1 2 3 4 5 6 7 8 9 10
No skin pain — Skin pain as bad as you can imagine

Please rate your itch from your HS lesions in the past 7 days
0 1 2 3 4 5 6 7 8 9 10
No itch — Itch as bad as you can imagine

Please rate the smell or odour from your HS lesions in the past 7 days
0 1 2 3 4 5 6 7 8 9 10
No smell or odour — Smell or odour as bad as you can imagine

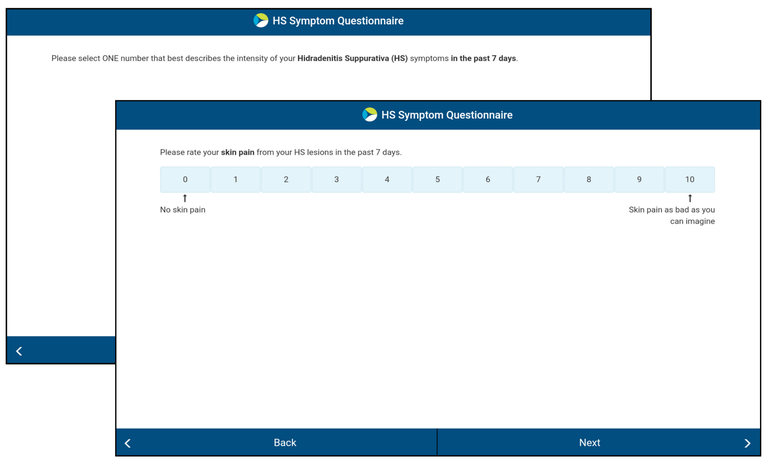
Please rate the amount of drainage or oozing from your HS lesions in the past 7 days
0 1 2 3 4 5 6 7 8 9 10
No drainage or oozing — A lot of drainage or oozing

Figure 2 Screenshots of the eHSSDD questionnaire as viewed on the hand-held device



Screenshots of only the first two pages of the electronic questionnaire are shown.

Figure 4 Screenshots of the eHSSQ questionnaire as viewed on the tablet



Screenshots of only the first two pages of the electronic questionnaire are shown.

Table 1 eHSSDD and eHSSQ symptom scores and item comprehension (N=20)

Item	Mean Scores	SD	Overall Understanding, n	Overall Understanding, %
eHSSDD				
Worst Skin Pain[a]	5.4	2.9	19	95
Average Skin Pain[a]	5.3	2.7	14	70
Worst Itch[b]	5.3	3.1	19	95
Smell or Odour[c]	3.3	3.0	20	100
Drainage or Oozing[d]	5.0	3.1	20	100
eHSSQ				
Skin Pain[a]	5.9	2.5	20	100
Itch[b]	5.5	3.0	20	100
Smell or Odour[c]	3.5	3.2	20	100
Drainage or Oozing[d]	5.4	3.2	20	100

Different 0 to 10 response scales were used for each item: [a] 0 = "No skin pain" to 10 = "Skin pain as bad as you can imagine"; [b] 0 = "No itch" to 10 = "Itch as bad as you can imagine"; [c] 0 = "No smell or odour" to 10 = "Smell or odour as bad as you can imagine"; [d] 0 = "No drainage or oozing" to 10 = "A lot of drainage or oozing".

eHSSDD: electronic Hidradenitis Suppurativa Symptom Daily Diary; **eHSSQ**: electronic Hidradenitis Suppurativa Symptom Questionnaire; **HSSDD**: Hidradenitis Suppurativa Symptom Daily Diary; **HSSQ**: Hidradenitis Suppurativa Symptom Questionnaire; **HS**: hidradenitis suppurativa; **NRS**: numerical rating scale; **SD**: standard deviation.

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References: [1]Ingram JR, et al. *J Eur Acad Dermatol Venereol*. 2022;36(9):1597–605. [2]US Food and Drug Administration. 2020. Available from: https://www.fda.gov/media/139088/download (accessed on 19/09/22). [3]Coons SJ, et al. *Value Health*. 2009;12(4):419-29. **Author Contributions:** Substantial contributions to study conception and design: **JRI**, **VC**, **RR**, **NT**, **JK**; substantial contributions to analysis and interpretation of the data: **JRI**, **VC**, **RR**, **IP**, **NT**, **JK**; drafting the article or revising it critically for important intellectual content: **JRI**, **VC**, **RR**, **IP**, **NT**, **JK**; final approval of the version of the article to be published: **JRI**, **VC**, **RR**, **IP**, **NT**, **JK**. **Author Disclosures:** **JRI**: Receives a stipend as Editor-in-Chief of the British Journal of Dermatology and an authorship honorarium from UpToDate; consultant for Boehringer Ingelheim, ChemoCentryx, Novartis and UCB Pharma and has served on advisory boards for Insmed, Kymera Therapeutics and Viela Bio, all in the field of hidradenitis suppurativa (HS); co-copyright holder of the Hidradenitis Suppurativa Quality of Life Questionnaire (HiSQOL), Investigator Global Assessment and Patient Global Assessment instruments for HS; his department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments. **VC**, **RR**, **IP**: Employees and shareholders of UCB Pharma. **NT**: Employee of Evidera. **JK**: Speaker for AbbVie, Janssen and UCB Pharma; received grants from Incyte and served as a consultant for AbbVie, ChemoCentryx, InflaRx, Incyte, MoonLake, Novartis, Janssen and UCB Pharma. **Acknowledgements:** This study was funded by UCB Pharma. The authors acknowledge Paul Gillard, Thermo Fisher Scientific, Brussels, Belgium, for contributions to this study and Susanne Wiegratz, MSc, UCB Pharma, Monheim, Germany, for publication coordination. Medical writing and editorial assistance were provided by Zoha Naveed, MBiochem, Costello Medical, London, UK, and funded by UCB Pharma.

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