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STUDY PROTOCOL

Implementation Science to Improve the Diagnosis and Management of Hidradenitis Suppurativa: HELyx Study Design Overview

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ABSTRACT

Introduction: Hidradenitis suppurativa (HS) is a chronic, inflammatory skin disease associated with a high disease burden and substantial impact on patients' quality of life. Limited therapeutic options are available, with an unmet medical need for earlier diagnosis and treatment and more effective treatment options. Low awareness of HS amongst healthcare professionals (HCPs) leads to delayed diagnosis and a prolonged patient journey to HS-specific treatment. This article aims to describe the design of HELyx, an implementation science study in Germany, which aims to evaluate the effectiveness of an implementation strategy to improve screening and diagnosis of HS among HCPs (dermatologists and non-dermatologists) and timely referral to HS-treating dermatologists.

Methods: HELyx is a hybrid, effectiveness-implementation science study with a pre-post design involving HCPs and is guided by the Consolidated Framework for Implementation Research. HELyx is being conducted in Germany over four consecutive phases (context analysis, pre-implementation, implementation, and post-implementation) in a sequential manner. A similar implementation science study is also being conducted in the United Arab Emirates (UAE) and Spain. HELyx aims to identify key

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unmet medical needs in the HS patient journey, to develop and implement a tailored medical education program, and to measure the effectiveness of the implementation.

***Planned outcomes*:** The primary endpoint is the change in the proportion of HCPs who used a diagnostic screening tool to identify patients with suspected HS during the 24 weeks of the post-implementation phase (assessed at Week 24) compared to the 24 weeks before implementation (assessed at baseline). Secondary endpoints include assessment of the use of HS disease severity assessment and patient-reported outcome tools and HCP referral behaviours.

Keywords: Dermatologists; Diagnosis; General practitioners; Gynaecologists; Hidradenitis suppurativa; Implementation science; Referral; Screening; Surgeons

Key Summary Points
Why carry out this study?
Hidradenitis suppurativa (HS) often remains undiagnosed for prolonged periods because of low awareness among healthcare professionals (HCPs), leading to delayed intervention and poorer outcomes for patients
Implementing standardized assessments of HS symptoms and disease severity in clinical practice may help increase the diagnostic detection rate of HS across HCP specialties
What was learned from the study?
HELyx is an ongoing implementation science study designed to evaluate the effectiveness and feasibility of implementing an online training strategy (HS care package) on HS diagnosis and management by HCPs involved in the HS patient journey
The study findings are expected to offer insights into the effectiveness of an HS care package in enhancing disease awareness and enabling HCPs for HS screening and early diagnosis

INTRODUCTION

Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease associated with a high disease burden and substantial impact on patients' quality of life [1]. Limited therapeutic options are available, with an unmet medical need for earlier diagnosis and intervention, and more effective treatment options. On average, patients with HS often experience delays in diagnosis of 7–10 years, with an average of three misdiagnoses [2–4], leading to a prolonged patient journey. This is mainly due to the lack of awareness of HS across healthcare professional (HCP) specialties, particularly by those who first encounter cases of HS [5, 6]. Delayed diagnosis is especially complicated by the fact that HS is a progressive and destructive disease with irreversible tissue damage occurring in the disease course [1, 7]. HS must be more readily identified by HCPs to enable timely referrals to HS-treating dermatologists and the initiation of adequate treatment in the window of opportunity before permanent scarring develops [2, 4, 7].

Implementation science is defined as "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practice into routine practice and, hence, to improve the quality and effectiveness of health services" [8]. The aim of implementation science is to identify the factors that affect the uptake of a clinical innovation into routine use. Implementation of standardized assessments of HS symptoms and disease severity in clinical practice may help increase the diagnostic detection rate of HS across HCP specialties. However, the effectiveness of such implementation strategies for early HS diagnosis and optimal disease management requires evaluation [8].

HELyx is an ongoing, non-interventional implementation science study that involves the creation of an HS 'care package', i.e., the content of an HS medical education program. The HS care package is currently being locally implemented as an online training in Germany. A similar implementation science study is also being conducted in the United Arab Emirates (UAE) and Spain [9]. HELyx aims to address key unmet needs in HS by identifying

country-specific barriers (e.g., low disease awareness in HCPs and delayed diagnosis) and building upon and supporting local HCP networks. The primary objective of the study is to evaluate the effectiveness of an implementation strategy in increasing awareness and diagnostic screening in HCPs overall and by HCP specialty, i.e., dermatologists and non-dermatologists involved in the HS patient journey. This article reports on the study design of the implementation science study conducted in Germany.

METHODS

HELyx Implementation Science Study Design

HELyx is a hybrid, effectiveness-implementation science study with a pre-post design involving HCPs and guided by the Consolidated Framework for Implementation Research (CFIR) [10]. HELyx was designed by Novartis and is guided by input from a working group consisting of five dermatologists and one patient advocate with specialist HS knowledge. HELyx involves four consecutive phases (context analysis, pre-implementation, implementation, and post-implementation; Table 1) conducted in a sequential manner.

A summary of the study design is illustrated in Fig. 1, and the implementation assessment schedule is summarized in Table 2.

HS Care Package/Medical Education Program

The HS care package consists of six comprehensive online training modules covering the following topics: HS disease overview, HS etiology and pathophysiology, HS disease burden, clinical HS signs, symptoms and diagnosis, comprehensive assessment of HS, and HS treatment. The modules contain educational material in the form of educational slides, expert and patient videos, infographic figures and tables, a diagnostic screening tool, and quizzes to confirm the assimilation of knowledge by the learners. These materials were made available for download by HCPs.

Aims

HELyx aims to address the following:

- Accelerate and increase the diagnostic detection rate of patients with HS across the HCPs involved in the HS patient journey (dermatologists, gynaecologists, general practitioners [GPs], and surgeons)
- Introduce established objective assessments of HS symptoms and disease severity into routine clinical practice
- Accelerate referral of patients to HS specialists

Eligibility Criteria

HCP specialties included GPs, gynaecologists, surgeons, office-based dermatologists, and others (general practitioner internist, internal medicine physician, general practitioner in internal medicine). The eligibility criteria for all participating HCPs included signing a study contract and having access to patient medical records. GPs, gynaecologists, and surgeons also had to be personally responsible for managing patients with HS and making autonomous treatment and referral decisions. Additionally, dermatologists had to be personally responsible for diagnosing and treating patients with HS and making autonomous treatment decisions. There were no exclusion criteria.

Sample Size

Based on sample size calculations, this study initially planned to include $N=450$ participants (dermatologists, $N=200$, non-dermatologists, $N=250$ [GPs, $n=100$, gynaecologists, $n=100$ and surgeons, $n=50$]). The final number of participants enrolled was lower than initially planned. Enrolment was completed by 27 May 2024; a total of 323 HCPs were recruited, of which 246 were active in providing data (111 dermatologists and 135 non-dermatologists [53 GPs, 74 gynaecologists, 8 surgeons]). Precision of estimation is still sufficiently maintained with the

Table 1 Summary of the four consecutive phases of the HELyx implementation science study in Germany

Phase	Description
Phase 1: context analysis	This analysis aimed to understand the healthcare environment around HS management and implementation context and identify factors affecting implementation. The determinants, barriers, facilitators, and potential benefit of an implementation strategy were identified through literature review, market research and qualitative data collection from HCPs experienced with HS (dermatologists and HCPs of other specialties). This helped inform the details around the design of the HS care package
Phase 2: pre-implementation	• The pre-implementation phase involves the co-creation of HS educational material (HS care package) by the HELyx working group involving HS experts (dermatologists) and a patient advocate • HCPs were identified and enrolled • Baseline assessments evaluated the HCPs' awareness and knowledge of HS, clinical behaviours, and attitudes towards the planned implementation • The current number of patients being seen by HCPs with suspected or diagnosed HS was also assessed to analyze the effect of HS care package content on HS diagnosis and HS patient referral
Phase 3: implementation	• The co-created implementation (HS care package) is being rolled out to participating HCPs: • HS care package: Medical specialty-tailored training materials (HS pathophysiology, clinical and patient scores, HS therapies) and a diagnostic screening tool
Phase 4: post-implementation	• During the post-implementation phase, the effectiveness and sustainability of the implementation strategy will be assessed • Assessments include survey-based evaluations of change in HS management and patient population, qualitative semi-structured interviews, evaluation of clinical tool use, analysis of referral rate of suspected and confirmed patients with HS, and evaluation of HCP attitudes towards the implemented solution

GP general practitioner, *HCP* healthcare professional, *HS* hidradenitis suppurativa

actual number of enrolled HCPs to confidently detect a meaningful difference in the primary outcome.

Data Collection: Qualitative and Quantitative Survey

The primary data source is the responses of HCPs to the quantitative surveys and qualitative interviews (Table 1).

Surveys are administered to all HCPs at baseline, Week 12, and Week 24 of the implementation phase. Qualitative interviews are conducted at baseline and Week 24 of the implementation phase for a subset of HCPs. This subset is recruited from the baseline survey sample and includes at least four GPs, four gynaecologists, eight dermatologists, and one or more general surgeons; the sample size was designed to collect sufficient data around HCP perceptions, views, and experiences in line with sample size required for qualitative research in the literature [11].

The CFIR was used to facilitate the design of the quantitative survey and qualitative interview guides. Within the quantitative survey, HCP demographic information and clinic/practice information, such as years of experience, specialty, clinic size, and clinic location, are

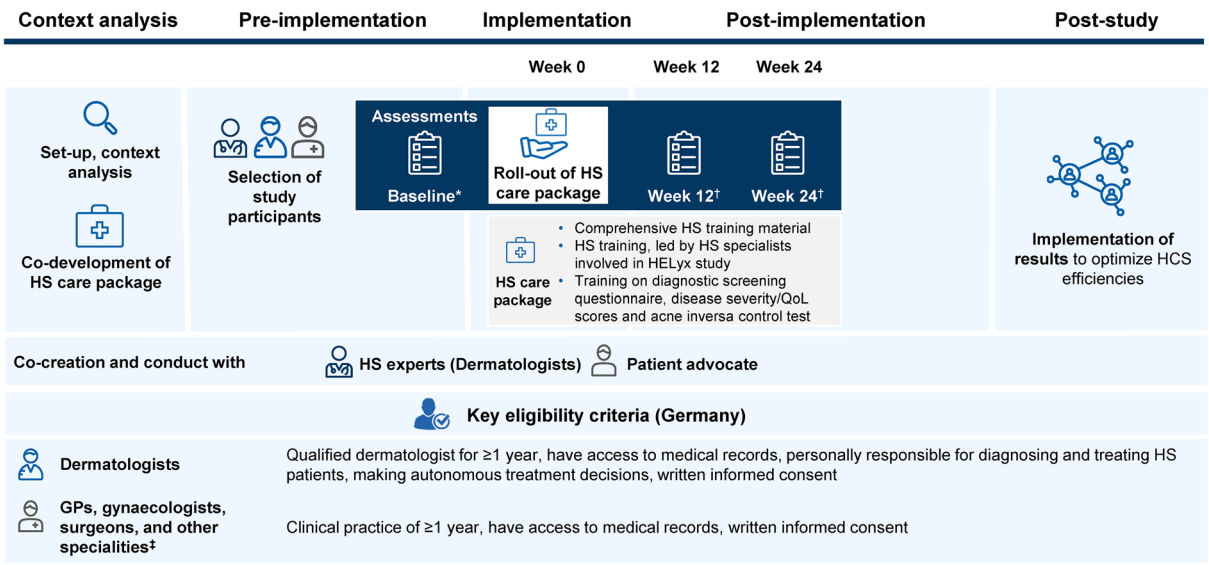

Fig. 1 HELyx study design in Germany. *Assessments include: Usage of diagnostic screening questionnaire, referral rate of suspected and confirmed HS patients, usage disease severity assessment tool, quality of life, and evaluation of therapy, attitude of HCPs towards the HS care package and perception of impact on their clinical practice. †Same questionnaire as baseline, as well as questions regarding their views on the potential success of wider implementation of the HS care package and barriers and factors that may influence wider implementation. HCPs will also be asked about their perspectives on potential improvements in HS patient management. ‡Other specialties include: general practitioner internist, internal medicine physicians, general practitioner in internal medicine. *GP* General Practitioner, *HCP* healthcare professional, *HCS* healthcare system, *HS* hidradenitis suppurativa, *QoL* quality of life

being collected. The surveys include questions pertaining to past and current use of HS diagnostic screening tools, HS severity assessment tools, and patient-reported outcome (PRO) tools.

HS severity assessment tools that are surveyed include the International Hidradenitis Suppurativa Severity Score System (IHS4) [12], Severity Assessment of Hidradenitis Suppurativa (SAHS) [13], Hidradenitis Suppurativa—Investigator's Global Assessment (HS-IGA) [14], Hidradenitis Suppurativa—Physician's Global Assessment (HS-PGA) [15], Hidradenitis Suppurativa Area and Severity Index Revised (HASI-R) [16], modified Hidradenitis Suppurativa Score (mHSS) [13], and Hurley staging [17]. PRO tools that are surveyed include the Dermatology Life Quality Index (DLQI) [18], Numerical Rating Scale-11 (NRS-11) [19], Patient Health Questionnaire-9 (PHQ-9) [20], Visual Analog Scale (VAS) for itch [21], Hidradenitis Suppurativa Quality of Life (HiSQoL) [22], Hidradenitis Suppurativa Odor and Drainage Scale (HODS) [23], and Hidradenitis Suppurativa-Patient Global Assessment (HS-PtGA) [24].

The quantitative survey assesses the past and current use of HS diagnostic screening tools, HS severity assessment tools, and PRO tools, and the proportion of HCPs who used a diagnostic screening tool to identify patients with suspected HS. In addition, it assesses referral pathways for non-dermatologists who suspect a patient has HS and their reasons for referring or not referring to a dermatologist. The survey also questions HCPs about contextual factors that may be relevant to implementation, such as attitudes towards implementing new tools or initiatives and attitudes related to PRO use. The qualitative interviews focus on the exploratory objective and cover topics such as clinic characteristics, implementation facilitators and barriers, and satisfaction with the HS care package. The interview questions are used to supplement the data obtained via the quantitative surveys.

Table 2 Summary of the HELyx implementation science study assessment schedule

Study phase	Pre-implementation	Post-implementation	
Time of assessment	**Baseline**	**Week 12**	**Week 24**
Participants eligibility criteria	X		
Information and contracting	X		
Quantitative survey			
Participant background information	X		
Usage of diagnostic screening tool	X	X	X
Identified patients with suspected and confirmed HS	X	X	X
Number of patients with suspected and confirmed HS referred to a dermatologist	X	X	X
Number of referred patients with suspected HS received (from any HCP specialty to dermatologist or from dermatologist to another dermatologist)[a]	X	X	X
Reasons for referrals to another dermatologist	X	X	X
Percentage of patients with confirmed HS among those referred with a tentative diagnosis	X	X	X
Time since onset of HS symptoms at confirmed HS diagnosis	X[b]	X[c]	X[c]
Usage of disease severity tools	X	X	X
Usage of HS-specific PROs	X	X	X
Qualitative interview questions			
Attitude towards implementation of the HS care package[a]	X	X	X
Satisfaction with HS care package[a]		X	X

HS hidradenitis suppurativa, *PRO* patient-reported outcomes

[a]Simple surveys to all HCPs, more comprehensive interviews with subgroups of HCPs

[b]Patients seen in the last 12 weeks or 13–24 weeks

[c]Patients seen in the last 12 weeks

Planned Outcomes

The primary endpoint of HELyx is the change in the proportion of HCPs who used a diagnostic screening tool to identify patients with suspected HS in the previous 24 weeks of the post-implementation phase (assessed at Week 24) versus the 24 weeks before implementation (assessed at baseline).

Secondary endpoints related to the usage of HS severity assessment and PRO tools include:

- Change in the proportion of HCPs that have used a diagnostic screening tool to identify patients with suspected HS; change in the proportion and absolute and mean number of patients with HS-like symptoms that were screened with a diagnostic tool (at first or follow-up assessments); change in the proportion of patients with suspected or diagnosed HS among all patients of the respective HCP; change in the pro-

portion of HCPs that identified any patients with HS or suspected HS.
- Change in the proportion of HCPs that used a disease severity assessment tool (e.g., IHS4) or a PRO (e.g., DLQI).
- Change in the proportion of patients with HS assessed by a disease severity tool or a PRO.

Secondary endpoints related to HCP referral behaviour include:

- Change in the proportion of HCPs that referred any patients with suspected HS to a dermatologist and change of the absolute number of patients with suspected HS referred to a dermatologist (from non-dermatologist HCPs or other dermatologists).
- Reasons for referrals if patients were referred from one dermatologist to another.
- Change in the absolute number of patients with suspected HS that were referred to a dermatologist by a non-dermatologist, with HS being confirmed by the dermatologist, and reason for not referring a patient to a dermatologist if referral had not occurred despite HS being suspected or diagnosed by a non-dermatologist.
- Average time from the first reported HS symptoms until HS diagnosis.

Exploratory endpoints include:

- Baseline attitudes toward anticipated implementation, including acceptability, feasibility, appropriateness, and satisfaction with the anticipated HS care package, and implementation conditions. HCPs participate in a standardized and mandatory study initiation session, which introduces the anticipated HS care package
- HCPs' opinion on the implementation, including acceptability, feasibility, appropriateness, and satisfaction with the HS care package, and implementation conditions; to be assessed at Week 12 and Week 24 of the post-implementation phase via quantitative survey.
- Experience with factors that support implementation, guided by CFIR constructs, including characteristics of the anticipated or actual HS care package, provider self-efficacy, clinic infrastructure, communications, needs and resources, and readiness for implementation; to be assessed at baseline and Week 24 of the post-implementation phase via qualitative interviews.
- Experience with the actual HS care package, guided by CFIR constructs, including characteristics of the HS care package, provider self-efficacy, clinic infrastructure, communications, needs and resources, and readiness for implementation; to be assessed at Week 24 of the post- implementation phase via qualitative interviews.

Data Analysis

All analyses are being conducted by a Clinical Research Organization (CRO; Evidera Inc.). Descriptive statistics for each parameter at baseline, Week 12, and Week 24 will be provided. The primary analysis population will include all survey participants who complete any item on the survey at any time point. Three additional stratifications are planned: dermatologist side by side with non-dermatologist, by individual HCP specialty, and by HS experience; analyses by these cohorts are contingent on sufficient and meaningful sample sizes, which will be assessed iteratively throughout the data collection process. The analysis of the qualitative interviews will be conducted according to the qualitative analysis plan.

Ethics and Dissemination

This study was designed, implemented, and reported in accordance with the Guidelines for good pharmacoepidemiology practice (GPP) [25], the Strengthening the Reporting of Observational Studies in Epidemiology guidelines [26], and the ethical principles laid down in the Declaration of Helsinki. Ethics committee approval was not required in Germany for this study, as only anonymized data from patients are collected. Dissemination of this study include presentations at scientific conferences and publication in peer-reviewed journals.

DISCUSSION

HS often remains undiagnosed for prolonged periods due to a low awareness among HCPs, which leads to delayed intervention and poorer outcomes for patients. The HELyx study aims to address this unmet need by implementing a structured medical education program tailored to key HCP specialties including dermatologists, gynaecologists, GPs, and surgeons. The study evaluates effectiveness of an implementation strategy to improve screening and diagnosis of HS among HCPs (reported based on dermatologists and non-dermatologists), aiming to ensure timely referral to HS-treating dermatologists.

This study design enables a comprehensive evaluation of both the effectiveness of the HS care package and the factors influencing the implementation. Additionally, the multi-phase approach, involving context analysis, pre-implementation, implementation, and post-implementation phases, ensures a systematic and sequential evaluation of the implementation strategy. The inclusion of a key HCPs specialties involved in the HS patient journey further strengthens the study by providing a broad perspective on the implementation process. The study is being conducted in Germany and may have limited generalizability to other countries. However, a similar implementation science study is being conducted in the UAE and Spain.

CONCLUSIONS

The findings of the HELyx study are expected to offer insights into the effectiveness of implementing an HS care package in enhancing disease awareness, especially among non-dermatologists, and providing HCPs with the required knowledge for screening and early diagnosis of HS.

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Data Availability. Data sharing is not applicable to this article as no datasets were generated or analyzed during development of the article.

Declarations

Conflict of interest. Antonio Martorell, Pierre-André Becherel, John R. Ingram, Barry M. McGrath, and Marco Romanelli have received honoraria for their participation in the global HS Implementation Science working group. John R. Ingram has acted as a consultant and/or advisory board member for Abbvie, Novartis, UCB Pharma, ChemoCentryx, Boehringer Ingelheim, Insmed, Viela Bio, MoonLake, Union Therapeutics, and Kymera Therapeutics; he also received an editorial stipend from the British Journal of Dermatology as Editor-in-Chief and an author honorarium from UpToDate and is co-copyright holder of HiSQoL and Investigator

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Ethical Approval. Ethics committee approval was not required in Germany for this study, as only anonymized data from patients are collected.

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