HISREG

REGISTER FOR HIDRADENITIS SUPPURATIVA

Description of the register

Prepared by the steering committee for the register in cooperation with the Centre of clinical documentation and evaluation (SKDE)

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Background

Hidradenitis suppurativa (HS), also called acne inversa, is a chronic, recurrent inflammatory skin disease that normally makes its first appearance after puberty and that involves significantly reduced quality of life for people affected. The disease is characterised by pus-secreting abscesses and sores in the armpits and groin, and other areas with skin-to-skin contact. The disease can cause disfiguring and painful scarring, pus secretion and fistulas.

Epidemiological surveys indicate that between one to four per cent of the population are affected by Hidradenitis suppurativa during their lives. Women seem to be affected by Hidradenitis suppurativa to a much larger extent than men. It has proven difficult to estimate the exact prevalence, however, because patients often hide their condition and because the disease is often misdiagnosed.

There is currently no known cause of Hidradenitis suppurativa. It is regarded as a multifactorial disease, but, so far, there is only weak evidence for a limited number of risk factors.

For many of the patients who are badly affected by the disease, everyday life is characterised by great pain from sores and foul-smelling secretions of pus from affected areas. The literature describes a significantly lower quality of life (DLQI) among those severely affected, and that the reduction in life quality is greater than for other skin conditions such as psoriasis, atopic dermatitis and alopecia. For the most severely affected patients, the disease often results in a secluded social life.

There are currently no national guidelines for the treatment of Hidradenitis suppurativa. There is also great variation in the treatment offered. The disease is difficult to treat, and there is currently no established evidence-based medical treatment based on large randomised and placebo-controlled studies. The condition is treated with medication (antibiotics, steroids and TNF-α) and the most serious conditions are always treated surgically, but relapse is common.

The health service will benefit from a Nordic register in several areas. It would serve as a means of achieving more uniform practice as regards treatment and the assessment of the results of treatment, both at individual hospitals and between different countries. By collating the data in the register for Hidradenitis suppurativa with other health registers, new knowledge will also be acquired, both about the disease and its treatment.

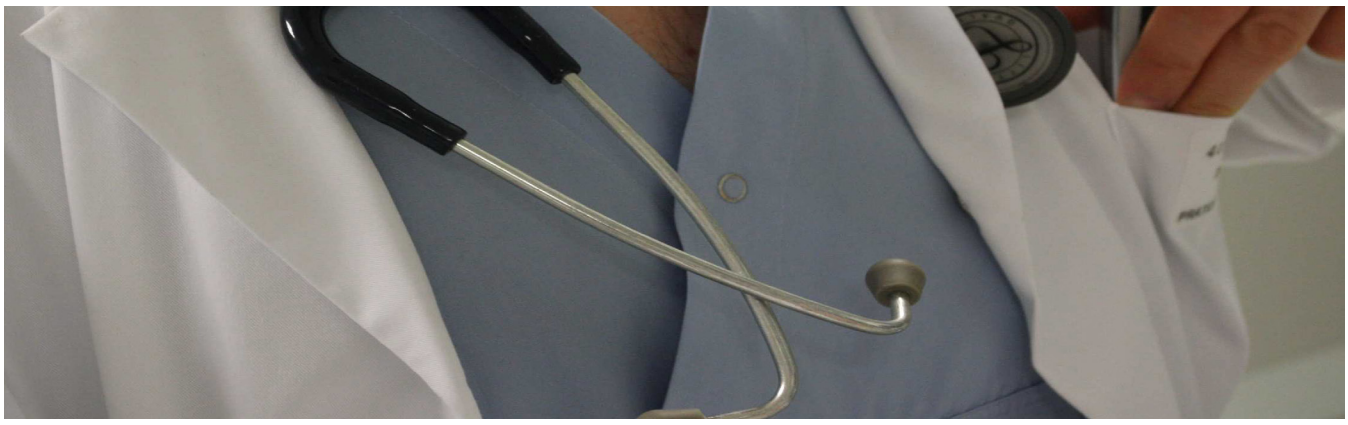
The purpose of the register

The main purpose of the Nordic register for Hidradenitis suppurativa is to contribute to better treatment and care for patients with the disease Hidradenitis suppurativa.

The register is primarily intended to serve as a tool enabling the individual hospitals to quality assure their own clinical practice. Emphasis has been placed on users having ownership of their own data and on their being able to present and process these data independently.

The goal of the register is to increase the quality of the treatment of patients with Hidradenitis suppurativa. This shall primarily be achieved by:

- Contributing to the development and improvement of diagnostics, treatment and follow up
- Documenting the effect and duration of treatment
- Enabling the treatment entities to evaluate their own activities
- Contributing to increasing research-based knowledge about Hidradenitis suppurativa and the treatment of this condition
- Spreading knowledge in both expert communities and the population at large about the condition and treatment options
- Forming a basis for research



Target group

The target group consists of all patients who are being treated for Hidradenitis suppurativa in the specialist health service.

Professional basis

The register will be established and developed on the basis of a professional cooperation model that takes both geographical representation, professional expertise and professional legitimacy into account. On the basis of available knowledge and own data, the register will undertake to deliver consensus reports, expert recommendations and annual updates from the register, both from individual hospitals and on a national basis.

The register's steering committee administers the data and decides how the information will be processed and presented. (see also: 'guidelines for the disclosure of data from HISREG')

General description of the register

• The target group consists of all patients who are being treated for Hidradenitis suppurativa in the specialist health service.

• Systematic national collection of data is a prerequisite for obtaining new knowledge about this field in which new expensive treatment methods (biological pharmaceuticals) are now being tested.

• The expert community in this field is small and a Nordic register will contribute to uniting it. The register will contribute to achieving an overview both of whether the patients receive equal treatment and of the quality of the treatment.

• There are no other corresponding registers nationally or internationally.

• The register is professionally rooted in a steering committee that represents the expert community in Norway, Denmark and Sweden.

The design of the register

Exposure variables

- Aetiology
- Intervention (medical/surgical)
- Symptom duration.

End point variables

- Change in the Hurley score (I-III)
- Change in the HS score
- Change in the Dermatology Life Quality Index (DLQI).

Adjustment variables

Depending on analysis needs, aetiology, previous treatment, age, education, gender and symptom duration are examples of relevant adjustment variables.

Procedures for maintaining the register's data quality

Data will be registered by the individual dermatology department. Systematic spot checks will be carried out to investigate whether the registered data are in compliance with the form and whether there is internal consistency. The coverage rate will be examined in relation to parts of relevant procedures from the Norwegian Patient Register (NPR).

Procedures for data capture

A web-based system has been developed for data capture. The individual clinic enters data itself. The ICT solution that has been developed will be available at helseregister.no, at Norsk Helsenett. A solution has been developed to ensure that hospitals that are not part of the Norsk Helsenett network have access to the health network.

Inclusion criteria

All patients who are being treated for Hidradenitis suppurativa in the specialist health service and who have consented to the registration.

Exclusion criteria

Patients who do not wish to consent or who, for cognitive or consciousness reasons, are not capable of giving informed consent to their own health data being included in the register. The register does not include patients under the age of 18 years.

Consent

Written consent is required in order for the registration of patient data to be lawful. This means that the declaration of consent must be signed by the patient in order for it to be valid. The declaration of consent contains general information about the quality register, its purpose, what will be registered, the duration of the registration and how protection of privacy will be ensured. It is pointed out that giving consent is voluntary and that there will be no consequences for the patient's treatment if he/she does not wish to consent.

Time perspective

HISREG will be established as a permanent quality register in all the three countries.

Analysis and reporting

Statistical processing and analysis

Descriptive and analytic epidemiology (prediction of treatment outcome)

Reporting

The individual clinics will have access to their own de-identified data that can be used for quality assurance work internally at the individual clinic. The clinics should also be able to retrieve completed reports from HISREG. Each clinic should be able to assess its own results in relation to an average based on countries or the whole register.

Access to the reporting system will be web-based.

Participating entities (hospitals/clinics)

The goal is that all treatment entities in Norway, Sweden and Denmark that treat HS patients will participate. In Norway, 18 of the country's dermatology departments have stated that they have treated HS patients in the last five years.

ICT

ICT solution for data capture

Web-based solution developed in OpenQreg

ICT solution for reporting

A separate reporting module will be developed as part of the ICT solution for registration (OpenQreg), whereby the individual department will be given access to reports concerning their own patients. This solution will also enable clinics to have access to datasets for their own patients, which it should be possible to download and process at the individual clinics.

Operation

The day-to-day operation of the register will be attended to by the Department of Dermatology at the University Hospital of North Norway.

ICT security

ICT security is the responsibility of the Northern Norway Regional Health Authority ICT pursuant to applicable procedures.

Organisation of the register

Data controller

The data controller for the register is the University Hospital of North Norway, represented by its managing director. If the register should be closed down, the data will be administered by the data controller.

Data processor

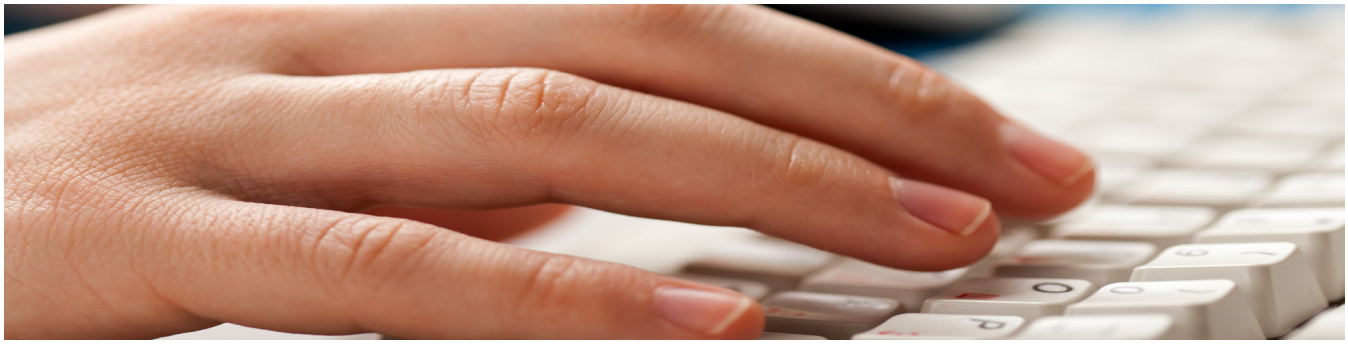
Northern Norway Regional Health Authority ICT

Steering committee

The steering committee consists of a representative group of representatives from two Regional Health Authorities and relevant expert communities in Sweden and Denmark. The group has access to statistical and epidemiological expertise in their own expert environments and at SKDE.

Day-to-day management of the register

The secretariat function and day-to-day management of the register are based at the University Hospital of North Norway, the Department of Dermatology.



Personnel, resources and funding

Discipline manager

The chair of the steering committee also functions as discipline manager. The goal is to split these functions in the long-term.

IT-related personnel

SKDE, Northern Norway Regional Health Authority ICT

IT-related operations

SKDE, Northern Norway Regional Health Authority ICT

Other operations

The secretariat has some funds for travel etc.

Privacy protection and the law

Consequences for privacy protection (based on Norwegian legislation)

Health data are defined as sensitive personal data, cf. the Personal Data Act section 2 no 8 letter c) and they are subject to a duty of secrecy, cf. the Personal Health Data Filing System Act section 2 no 1, cf. the Health Personnel Act section 21. As HISREG will contain health data, the register will have consequences for privacy protection. Data stored in the register about individual patients will largely be information about the patient, diagnosis and treatment.

Legal, organisational and technical methods of protecting privacy

The legislation sets out rules that contribute to personal information being handled in a manner that is in compliance with fundamental considerations of privacy protection. HISREG deems the following statutory requirements as being adequately met: sections 8, 9 c), f), g), h), 11, 13, 18 and 19.

Legal aspects

The requirement for a defined purpose. HISREG's purpose is clearly defined (see HISREG's statutes) and only data that are necessary to ensure the quality of the treatment of this patient group will be registered. The type of data registered in the register is not considered to be of a highly sensitive nature, although it contains information about the individual's health and, as such, is sensitive information.

• The data controller's duty to disclose information and the data subject's right of access. Pursuant to the Personal Health Data Filing System Act sections 21 and 22, the data subject has a right to be informed about the register in general and right of access to personal health data about him/herself.

• The data subject's right of rectification or erasure of personal health data. It also follows from the Health Data Filing System Act chapter 5 that the data subject has the right to request the rectification or erasure of personal health data.

Duty of secrecy.
Pursuant to the Personal Health Data Filing System Act section 15, any person who processes personal health data has a duty of secrecy pursuant to sections 13 to 13 e of the Public Administration Act and the Health Personnel Act. The duty of secrecy entails an obligation to prevent others from obtaining knowledge about confidential information in the register. The Personal Health Data Filing System Act also contains a provision that prohibits the unlawful acquisition of personal health data. The rules concerning access to information in health registers are a legal personal privacy barrier. In the case of HISREG, only a very limited number of persons in the management of the register will have access to data in the register. Physically, the data in the register will only be located in one place – a server at Northern Norway Regional Health Authority ICT.

Organisational aspects

• It follows from the Personal Health Data Filing System Act section 13 that only the data controller, the data processor and persons working under their instructions may be granted access to personal health data. Access will only be granted to data that are important to the work of the person in question and in compliance with provisions concerning the duty of secrecy. In the case of HISREG, only persons working on the register on a daily basis will have access to personal health data.

• Only anonymous data will be provided for research purposes.

Technical aspects

The stored data will be de-identified. The data will be stored on a separate password-protected server at Northern Norway Regional Health Authority ICT and will therefore be well protected. The enterprise has procedures for internal control (see the appendix). Data will be sent to HISREG via the health network, with a two-factor authentication solution.

About the statutes

The statutes address the ownership, organisation, management and operation of HISREG, a quality register for treatment of the skin disease Hidradenitis suppurativa. HISREG is an independent, clinical quality register. The register shall contain information about hospital treatment of patients suffering from the skin disease Hidradenitis suppurativa.

The object and tasks of the register

The register is intended to be a register that includes all relevant treatment institutions that treat patients with this disease. The goal of the register is to contribute to better quality in the treatment of patients with Hidradenitis suppurativa. This shall primarily be achieved by:

- contributing to developing and improving diagnostics, treatment and follow-up
- documenting the effect and duration of treatment
- giving each treatment entity an opportunity to evaluate its own practice
- contributing to increasing research-based knowledge about Hidradenitis sup purativa and the treatment of this condition
- spreading knowledge in both expert communities and the population at large about the condition and treatment options

The target group consists of all patients being treated for Hidradenitis suppurativa in the specialist health service. The aim is to give each treatment entity an overview of its own results. The register will be established and developed on the basis of a professional cooperation model that takes geographical representation, professional expertise and professional legitimacy into account. On the basis of available knowledge and own data, the register will undertake to deliver consensus reports, expert recommendations and annual updates from the register, both from individual hospitals and on a national and Nordic basis.

The register's steering committee administers the data and decides how the information will be processed and presented.

Ownership and the data controller for the register

The data controller and owner of the register is University Hospital of North Norway represented by its managing director. If the register should be closed down, the data will be administered by the data controller.

Professional and administrative responsibility

The data controller delegates the professional administration of the register's data to the steering committee. Administrative responsibility, including secretariat functions, rests with the Department of Dermatology at University Hospital of North Norway, which collaborates with the register unit in SKDE (the Centre for Clinical Documentation and Evaluation) on relevant technical, legal and register-related matters.

Funding of the register

The register is professionally independent and cannot receive financial or other support from the industry or similar interests. The register shall be entitled to apply for financial support from Regional Health Authority funds earmarked for the establishment and operation of quality registers, from relevant sources of research funding and other not-for-profit sources of funding.

Steering committee for the register

The steering committee shall consist of a representative group of clinicians from Norway, Sweden and Denmark. The individual members must have support from the national expert community in their countries.

Professional design

- The register will register patients who are being treated for Hidradenitis suppurativa. Variables will include structural data, process data and outcome data.

- Coordination with other registers. When appropriate, and contingent on a permit, the register can be linked to other registers. An exhaustive list of possible linked registers shall always be included in the declaration of consent.

Publication

The steering committee is responsible for the disclosure of data from the clinical register. Separate guidelines have been prepared for the disclosure of data from HISREG.

Consent

The register will be based on consent.

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Guidelines for access to data from HISREG for quality assurance and/or research purposes.

The purpose of the document
The purpose of these guidelines is to explain HISREG's guidelines for ensuring a high level of availability of data from HISREG for quality assurance and/or research purposes, as well as for ensuring that the work based on the register is of high scientific quality. Another purpose of the guidelines is to ensure that the disclosure of data takes place in accordance with the applicable regulations for the processing of personal data.

The subsets of data submitted to HISREG by an entity shall be freely accessible to employees of the entity in question. The disclosure of such data subsets is therefore exempt from the regulations concerning aggregate data from several entities. Data disclosed here will be de-identified.

Access to data
Access to data is granted upon application and in accordance with an agreement entered into with HISREG's steering committee. Such agreement confers rights to investigate and publish on a specific topic. If relevant, the agreement must state the period in which a time limitation will apply.

Application requirements
An application for access to data should contain a comprehensive project description and a publication plan. The application must clearly state who the project manager is and who is professionally responsible for the project.
The application must include a description of:

- The topic
- The desired sample, and the variables that will be used in the analysis
- The publication plan – articles, the internet, target groups for publications
- For all projects, it must be considered whether the project is covered by already existing approvals/licences, or whether a new recommendation from the relevant authorities is required. This may vary from country to country. The necessary approvals must be submitted before any data can be disclosed.

Processing of applications
Applications for the allocation of a topic with pertaining disclosure of data from medical quality registers shall be addressed to the steering committee for HISREG, or, if relevant, to the body appointed by the steering committee for this purpose.
If a situation were to arise in which several applicants apply for access to the same topic and it is necessary to prioritise between applicants, the following criteria should be emphasised:
Professional relevance
The project must be professionally well-founded and of such a nature that it is best researched within the framework of a register. Projects that comply with HISREG's primary objectives will be given priority.

Professional capacity
The project manager must substantiate that the project staff have the expertise and capacity required to analyse and publish data in a professionally satisfactory manner and within a reasonable period of time.

Considerations relating to ongoing projects
The application's project description and publication plan must not conflict with other approved application plans. If two projects have closely related topics, the steering committee will encourage the projects to cooperate.

Time limitation
Before any data are disclosed, an agreement should be entered into with the steering committee concerning a time limitation on access to data. For doctoral projects, it is normal to give sole right to the topic for five years. For other researchers, the practice is three years. For quality assurance purposes (continuous monitoring), it may be relevant to make data available without stipulating any requirements for an final date. In such case, the project should describe reporting procedures to the register in the event of significant changes and/or lack of progress.

Data disclosure
Data are disclosed as a text file and the applicant can then convert the text file to the relevant software. Personal health data disclosed for research purposes will normally be de-identified or anonymous. A serial number (a random series) will replace personal identification, so that individuals can be tracked in the data material.

Rules for publication
In connection with publication, here understood as all publication of research results or other presentations of data in which data from HISREG are used, it must be stated that the data are from HISREG.

Authorship
In connection with publication, co-authorship shall be based on the Vancouver protocols. This means that, to be entitled to demand to be credited as a co-author, the person in question must have contributed substantially to the conception and design, or the acquisition of data, or the analysis and interpretation of data. Before publication, co-authors must have approved the version submitted for publication.

Sanctions in the event of breach of contract
In the event of breach of contract, the steering committee for HISREG will contact the project owner to clarify the facts of the matter. If the parties fail to reach agreement, it may be relevant to send a written statement to the responsible parties at the project owner's institution to notify that the project owner has breached the agreement concerning the use of data. If this does not result in agreement between the parties, it may be necessary for the steering committee to revoke the rights to the data.

Appeals and reversals of decisions
The steering committee is responsible for the administration of the data in the register. Appeals against decisions made by the steering committee for the individual registers concerning the disclosure and use of data shall be addressed to the steering committee for HISREG.

1Data where names, personal ID numbers and other identifiable characteristics have been removed so that the data can no longer be linked to an individual, and where the identity can only be traced by comparison with the same information that was previously removed, cf. the Personal Health Data Filing System Act section 2.

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