Establishing the Norwegian Registry on Rare Disorders

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Introduction

Patient registries are considered as important tools for rare disorder surveillance. In Norway, a disorder is considered rare when there are less than 100 known cases per million inhabitants. Currently, there is no nationwide record of rare disorder cases in Norway. However, increased knowledge on the prevalence and incidence of rare disorders is highly requested (Loeb M, Grut L (2008), SINTEF Report A9263).

The Norwegian National Advisory Unit on Rare Disorders consists of nine centres of expertise, each responsible for specific disorders, that provide services to ensure that people with rare disorders receive holistic and individually based care. In order for a service to be established for a rare disorder, the condition must meet the criteria of being congenital/genetic as well as complex and compound. Furthermore, there must be a need for multidisciplinary and cross-institutional services throughout the course of life. In order to meet the needs for increased visibility and survey of rare disorders, the Norwegian National Advisory Unit on Rare Disorders has initiated the work of creating a national population-based patient registry, the Norwegian Registry on Rare Disorders. Establishment of the registry is part of our 2017-2021 strategy, and development of the registry is supported by the Norwegian Directorate of Health.

Purpose of the registry

The primary purpose of the registry is epidemiologic surveillance of rare disorders in Norway.

Secondary purposes:

- Ensuring equity in services to the patient population
- Facilitating recruitment of patients into clinical trials
- Enhancing research and quality of services
- Supporting policy making and health services planning

Registry design and features

- Nationwide epidemiologic patient registry consisting of personal core data on patients in Norway who are affected by a rare disorder
- Legal basis: informed consent from the participants and license from the Norwegian Data Protection Authority
- Data will be collected by health professionals
- Patients in the target population will be invited to join the registry upon diagnosis, treatment or consultation at one of our centres of expertise
- General guidelines and principles for harmonization are considered in order to facilitate future international interoperability

Photo: Shutterstock

Data set

General patient information

- Person ID (national identity number)
- Place of residence

Contact information

- Name
- Address
- Telephone number
- e-mail address

Diagnosis information

- Diagnosis (ICD-10, ORPHA-code)
- Year of diagnosis
- Diagnostic basis (including clinical, genetic and biochemical factors)
- Diagnostic institution

Appointed treatment facility

Photo: Shutterstock

Timeline

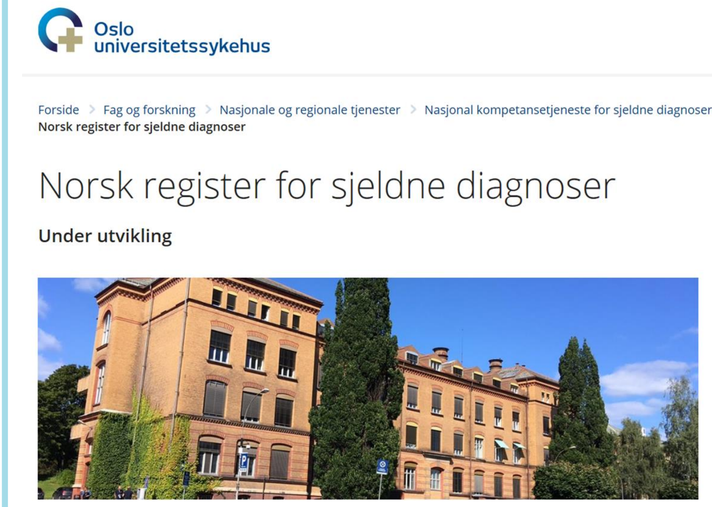
2014
- 2014: Efforts on establishing a Norwegian registry on rare disorders started
- 2016: Registry Coordinator employed

2017
- Management documents created: protocol, statutes, list of variables, patient information and declaration of consent
- Website created
- License application sent to the Norwegian Data Protection Authority

2018
- Design of electronic instrument for data collection and storage
- Start-up planned as soon as we have obtained a license from the Data Protection Authority

Further information

Updated information is available on http://sjeldenregisteret.no



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