

GUIDE FOR INTERNATIONAL RESEARCH ON PATIENT QUALITY REGISTRIES IN THE NORDIC COUNTRIES

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1 SUMMARY

The conclusion from this project (during 2016) is that a Nordic collaboration using quality/patient registries is possible for academic, benchmarking, observational and industry-initiated studies.

The practical implementation of legal frameworks for registries is currently not clear in all Nordic countries. Therefore it is important to plan well in advance and to discuss the following areas in detail: data, IT, legal and ethics.

A Nordic role model exist, e.g. the Nordic Arthroplasty Register Association (NARA), and the project group believes that the possibility of including Finland and Iceland in future collaboration has increased.

This document is focused especially on creating conditions for comparisons within the Nordic countries, and for promoting international and inter-professional learning to explore how to use insights on improvement and research obtained with the support of Quality Registries to further develop health care services. This guide provides a checklist of some critical aspects identified by the project groups regarding what to consider before starting to plan for a statistical report.

The overall aim is to improve the conditions for:

- international comparisons of patient treatments and care;
- international research on rare diseases;
- knowledge sharing in research;
- quality of care;
- international development of drugs and devices;
- patient involvement in Quality Registries.

The document also provides information about:

- the individual countries;
- similarities and differences between countries;
- possible actions to facilitate cooperation in the Nordic countries;
- obstacles or issues requiring further collaborative efforts.

This international project has been approved and is supported by NordForsk and the Office of the National Quality Registries in Sweden.

2 INTRODUCTION

2.1 DEFINITIONS

A register is an information system that continuously records event-based data for a particular, complete set of patients. A register contains a logically coherent collection of related data with some inherent meaning, typically reflecting events that have occurred, such as all treatment information for patients with a particular disease. Register data are micro-level data. Each event can be linked to a specific individual and all events that have occurred for a specific individual can be linked together. Most registers are either administrative or Quality Registers. To be useful for research purposes, the structure and completeness of the data sources must be well documented and stable (Sund et al., 2014).

A Quality Registry contain data (diagnosis, events, treatments, outcomes) on individual patients within the health care system.

In Sweden, there is an agreement between the Swedish state and the Swedish Association of Local Authorities and Regions that Quality Registries are aimed at supporting clinical improvement and research in order to provide patients with the best possible health care. Sweden has a legal framework for Quality Registries and a national organisation with a clear remit to support such registries. The Swedish Quality Registries include data on an individual level, collected within the health care system. The data responsibility for Quality Registries lies with the regional and local authorities (“CPUA”-central personuppgiftsansvarig) that are responsible for the data.

Norway and Denmark have systems and definitions that are similar to Sweden’s. In Norway, the main purpose of the Quality Registries is to improve quality in medical practice. At the legal level, the systems in Sweden, Norway and Denmark resemble each other but are not identical. For example, in Denmark it is mandatory for hospitals, other health care institutions and practising professionals to collect data on patients for the Quality Registries.

There is no shared, official definition of Quality Registries in Finland and Iceland. However, there are patient registries and research databases which include data on an individual level and can be utilised in Nordic collaboration.

The “Methodological guidelines and recommendations for efficient and rational governance of patient registries”, co-founded by the EU Commission, uses the term “patient registries”.

For the purposes of this document, the following terms are used in the following way:

- Quality/patient/research registries: are found within the health care/hospital record legislation. Data are collected on a patient case basis, but used on an aggregated level.
- Health/health care registries: are set up and managed by the state as a state responsibility. These registries are also on a patient case basis but used on an aggregated level.

2.2 BACKGROUND

Clinicians have a general interest in building up partnerships between countries to facilitate use of Quality Registries to compare and pool data, in order to improve health care.

The population in Europe is aging, and the number of individuals with multiple diagnoses is rising. The EU finance ministers and the Commission are facing challenges related to containing costs and improving the efficiency of health care provision. From a European perspective, given the imminent introduction of the patient mobility directives that entered into force on 25 October 2013, it is likely the mobility of patients within the EU will increase.

This will pose even greater challenges to the health care systems. In this context, comparisons of processes and data from the registers can be useful and an important tool.

The EU health strategy “Together for Health” supports the overall Europe 2020 strategy.

Europe 2020 aims to turn the EU into a smart, sustainable and inclusive economy. One prerequisite is a population in good health. The third health programme (2012-2020) seeks to promote health, prevent disease and foster supportive environments for healthy lifestyles.

The EU research and innovation framework programme, Horizon 2020, launched in 2014, has a strong clinical focus, where quality plays an important role. The programme’s first Annual Monitoring Report is a comprehensive publication encompassing the analysis of the implementation of Horizon 2020. The report helps to identify the most important issues related to health system performance. At this very early stage of implementation of Horizon 2020, the focus of this exercise has mainly been based on process indicators, while output and results of the programme will build on the outcome of completed projects.

In general, an increase in interest in patient registries can be seen on the national level (see Bengt Westerberg: “Unique knowledge through research records”, SOU 2014: 45), in the Nordic countries (Bo Könberg: “The future Nordic health cooperation,” Nordic Council of Ministers, 2014) and in the European Union (“EU Methodological guidelines and recommendations for efficient and rationale governance of patient registries”).

Furthermore, as a contribution to the SANCO Health Work Programme 2015, a concept paper for a joint action with Member States and stakeholders is being drawn up: “From early developments to patient’s use

of pharmaceutical products and medical devices”. This include pilots on collection and generation of real world clinical evidence, to measure safety and effectiveness (from registries and Electronic Health Records (EHR)).

As a contribution to EMAs Registry Task Force, the Swedish Medical Products Agency has carried out a survey from which they conclude that Swedish health care Quality Registries provide useful information on drugs in clinical practice (2016).

On 17 June 2016 the Council of the European Union published conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States. The Council sees it as constructive to increase investments at the national and EU level to expand availability of registries and to develop methods to assess the effectiveness of pharmaceuticals, including through digital means. The implementation of means to provide insight into post-marketing effectiveness of medicines should allow exchange of information between Member States, while respecting individual competencies’ applicable legislation, including on data protection.

The Council is also considering further investment at the national and EU level in the development of innovative medicines for clearly defined unmet medical needs. This would take place in particular through Horizon 2020 and the Innovative Medicines Initiative (IMI), with the involvement of the European Medicines Agency, by promoting open access to research data while fully respecting applicable legislation on data protection (where this applies to information that is considered commercially confidential, and in light of conditions such as equitable licensing) to ensure a fair return on investment for publicly funded research. Public funding has provided a major contribution to the development of successful medicinal products.

Since many international inquiries have been made about Quality/patient registries, it is important to initiate and support implementation of these potential international projects to disseminate the experiences around these processes and increase the use of data.

This document is focused especially on creating conditions for comparisons within the Nordic countries, and for promoting international and inter-professional learning to explore how to use insights on improvement and research obtained with the support of Quality Registries, to further develop health care services.

A new EU data protection law was adopted in April 2016. The directive will enter into force on 5 May 2016 and will apply from 25 May 2018. There will most likely be a difference in local and regional implementation of this law and the results of these implementation may affect the opportunities for collaboration in the future.

The Nordic countries have different approaches in relation to Quality Registries and data protection legislation. The Danish Clinical Registries has a status similar to state-owned registries in that it is exempt from patient consent to data collection. This exemption requires approval of the definition of registered population, variables and indicators according to strict criteria by the Danish Health Data Authority every 3 years. The remaining Nordic countries require patient consent to data collection in their Quality Registries.

2.3 WHY A COLLABORATION PROJECT IN THE NORDIC COUNTRIES

The Nordic countries have unique opportunities for cooperation in the field of health care quality and research. The health systems are based on equitable health care and good quality of care, public financing and ownership. There is a long Nordic tradition for use of health data in medical research and quality improvement, supported by the use of unique patient identifiers in all Nordic countries. Finally there is a well-established practice of Nordic cooperation in the field of quality improvement and patient safety through both professional networks and governmental support, via the Nordic Council of Ministers.

Patient (or Quality) registries are used by the health care service to monitor, evaluate and improve health care outcomes and processes. For health professionals, this means that patients can be monitored over time, and that the outcomes and processes can be compared between different care units, which in turn enables improvement in quality and more efficient and equitable care. Quality Registries are also an important resource for research and innovation, and many of the registers publish research findings in high impact scientific journals. In addition, there are several collaborative research projects among Quality Registries across the Nordic countries. Some registers also collaborate with industry to follow up the effect of a particular product, drug or a medical device already on the market, known as Phase IV trials.

At a time when clinical research in the Nordic region is growing weaker compared with international competition, register-based research is emerging as a growth area. With the support of the Quality Registers, the Nordic countries have the opportunity to take a leading position in the development of more efficient and equitable health care, both internationally and in the EU. For this to happen, active steps must be taken at the national level by governments and authorities in the EU, and by the WHO. Similarly, the registers themselves should initiate international collaborations in their respective fields, wherever needs or opportunities are identified.

2.4 THE OBJECTIVES OF THIS NORDIC PROJECT

The development of a guide is intended to facilitate and encourage cooperation on registries between the Nordic countries.

The overall aim is to improve the conditions for:

- international comparisons of patient treatments and care;
- international research on rare diseases;
- knowledge-sharing in research;
- quality of care;
- international development of drugs and devices;
- patient involvement in Quality Registries.

The document also provides information about:

- the individual countries;
- similarities and differences between countries;
- possible actions to facilitate cooperation in the Nordic countries;
- obstacles or issues requiring further collaborative efforts.

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3 NATIONAL OVERVIEW: SWEDEN

3.1 INTRODUCTION

The National Board of Health and Welfare works to ensure good health, social welfare and high-quality health and social care on equitable terms for the entire Swedish population. The Board's activities encompass social services, health and medical care, and communicable disease prevention.

The Swedish health care system is highly decentralised and essentially tax-funded. About 70% of the budgets of the local and regional authorities are based on income taxes, the level of which these authorities decide themselves. An additional 15% or more of the authorities' budgets comes from state funding. Municipalities are responsible for social care. County councils/regions are responsible for providing health and medical care, as well as free dental care for children and young people.

Sweden has had registries since Carl von Linné (Swedish botanist born 1707) established the system binomial (two-name) nomenclature, the modern system of naming organisms, and provided the first ecological organisation structure (the relationships between living things and their environments).

After that came the "Cause of death" registry in 1895. The first National Quality Registry started in the 1970s and developed mainly through state funding during the 1990s. Since then the registries have increased in number and have developed by size, number of variables and use.

In principle health care is run by the county councils, which means that all patients are asked to be included in the registries. Swedish patients tend to trust the Swedish health care system (Johnsson 2008 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2656925/>), which explains the success in achieving high coverage and follow-up data in the patient/quality registries.

The Swedish registries (health data registries and National Quality Registries) can be linked to compare the data from both types of registries. The Swedish National Board of Health and Welfare coordinates any linkage to be performed as part of a research project. Sweden also has biobanks containing [data on] biosamples which can be linked to the registries. At Statistics Sweden (SCB), statistics on population, education, living conditions etc. are held and data can be accessed at request. Linkage or merging of data can also be performed between Quality Registries and health data registries.

3.2 NUMBER OF REGISTRIES AND TYPES

Today (2016), there are 96 National Quality Registries and 12 candidate Quality Registries (registries initiated but not in place) in Sweden. Certification level is a rating given to each registry and represents the level of development the registry has reached in terms of:

- analyses
- inclusion of relevant indicators
- coordination with health services
- use in research
- data quality and reporting
- coverage rate
- technical solutions

There are four levels in total – 1 (highest), 2, 3 and “candidate” level (lowest).

The scope of Quality Registries tends to be defined mainly by disease area and not by drug/device product.

For list of areas covered by existing registries, see below:

- Cancer
- Circulatory system
- Dental care
- Elderly palliative care
- Emergency, anaesthesia and intensive care
- Endocrine organs
- Eyes
- Infection
- Lung diseases
- Musculoskeletal system
- Nervous system
- Other areas
- Paediatrics, obstetrics and gynaecology

- Psychiatry
- Stomach and intestines

The National Board of Health and Welfare holds national health data registries such as the medical birth, causes of death, hospital discharge and prescribed drugs register. Data from these registries can be linked or merged with data from the national Quality Registries. For more information contact the National Registry Service at the National Board of Health and Welfare:

The National Board of Health and Welfare will keep the data subjects' identifiers (numbers, coding, encryption) for a predefined period or for the duration of a study in order to maintain the required confidentiality.

Examples of other government agencies that have registries for research purposes include:

- Statistics Sweden (SCB)
- The Swedish Social Insurance Agency
- The Swedish National Council for Crime Prevention (Brå)

3.3 PURPOSE

The Quality Registries are primarily intended as a way to measure, follow-up and monitor the quality and results of the health care system at macro, meso and micro-level. Secondly, they are also used for statistics and research in health care. The principle on which registries in Sweden are founded comes from a provision in the Health and Medical Service Act which states that health care should be knowledge-based and appropriate, safe, focused on the patient, effective, equal, and given within a reasonable time.

3.4 VISION

The vision is that the National Quality Registries are used in an integrated and active way for continuous learning, improvement, research and management to create the best possible health and care together with the individual patient.

3.5 FUNDING

The National Quality Registries are currently funded by the state and public health authorities/health care providers). Additional funding is received from industry and other external funds.

3.6 LEGAL ASPECTS AND ETHICS

3.6.1 Legal

The following laws apply in Sweden for the National Quality Registries (patient registries):

The Patient Data Act, Chapter 7/**Patientdatalagen kap.7**. There are special rules on regional and national Quality Registers. These rules supersede all others concerning use of data in registries.

The Patient Data Act /**Patientdatalagen övriga regler**: If an issue that concerns National Quality Registers is not subject to special provisions in Chapter 7 of the Patient Data Act, the other provisions of the Patient Data Act apply.

The National Board of Health and Welfare Regulation SOSFS 2008:14 (**Socialstyrelsens föreskrift SOSFS 2008:14 om journalföring och informationshantering i hälso- och sjukvården**) regulates the handling of information. *Mutatis mutandis*, for Quality Registers (certain parts apply for the Quality Registries).

The Personal Data Act (**Personuppgiftslagen**) only applies when an issue is not regulated in the Patient Data Act or other special provisions.

3.6.1.1 REGULATORY QUESTIONS AND ANSWERS

In this section, answers may be found to commonly asked questions regarding regulatory aspects of Swedish National Quality Registries.

General

Use of National Quality Registries

A National Quality Registry is primarily used for improving quality of care. The sole owner – and data controller – is always a county council, see below. There is no obligation for health care providers to provide data to such a registry, nor for patients to be registered. Patients are presumed by the legislation to consent to registration by default, and have the right to opt-out if they wish.

All National Quality Registers are required to develop a more detailed version of the overall purpose – to secure and improve quality of care – specific to their area of focus. The information in a National Quality Registry may then be used under the registry-specified purposes. Additionally, the data may be used for secondary purposes statistics and research in health care.

Who is responsible?

For each National Quality Registry there is an authority, the central data controller, CPUA (central personuppgiftsansvarig). The CPUA has responsibility for the overall quality of the register, for example for

ensuring that incorrect data are corrected or destroyed on request. There is usually a county council or equivalent acting as CPUA with formal central responsibility for a registry.

Collection of data

1. Who is responsible for reporting and data input to a Quality Registry?

The health care provider who records the data in a Quality Registry is responsible for its own data management in connection with the registration or at a later stage if used for local quality assurance. This means e.g. a responsibility to keep patients correctly informed, to ensure that the correct information is entered, that the information is used correctly, that the competencies of registry access are tailored to staff needs, etc.

2. What information may be included in a national Quality Registry?

The primary purpose of a Quality Registry, to systematically and continuously develop and secure the quality of care, should be broken down in more specific purposes that are customised for each specific register (the medical specialty or equivalent to be covered by the registry). Only the data needed for these specified purposes may be collected in a Quality Register.

The Patient Data Act, Chapter 7, §8

The specific objectives of a National Quality Registry determine what information may be collected, and how the data can be used. These objectives also include providing information for patients, so that a patient can decide whether he or she wants to participate in the registry.

The Patient Data Act, Chapter 7, §4-6

3. Can a Quality Registry obtain information from any source other than the patient and their medical records?

A Quality Registry may obtain information from sources other than the patient and their medical records, but this must be made clear to the patient prior to their agreement to participate.

The Patient Data Act, Chapter 7, §3

4. Can a Quality Registry change its purpose over time?

A Quality Registry may change its stated objectives if the need arises (e.g. new research, changes in demographics, patient preferences). However, this change must only take effect after clear information concerning the change, and the new objectives, has been published. For example, publication of the details could be through the registry website, or through newspapers.

Prop 2007/08:126 s 191

Protect

5. How long can data be stored in a Quality Registry?

Personal data in a national or regional Quality Registry should be deleted when they are no longer needed. The Archive Agency for the central data controller's authority may, however, stipulate that personal information in a national or regional Quality Registry may be kept for historical, statistical or scientific purposes.

The Patient Data Act, Chapter 7, §10

6. How to protect personal data in the National Quality Registry

Details of Quality Registries are subject to the same protection as medical records. Therefore it is appropriate that personal data in Quality Registries, as far as possible, are handled in the same way as the caregiver's handling of patient records. Where data are presented openly, for example to inform the public about the quality of health care, this must be done in such a way that the individual's identity is not disclosed.

Public Access to Information and Secrecy Act, Chapter 25, §1

Secure log-in

The authority is centrally responsible for protection of the registered data from infringements and to ensure that disclosure of information is done in a safe manner. The latter means for example that the staff of a health care provider must sign in with an SITSHS card (a Public Key Infrastructure solution developed for Swedish Health Care Providers) or other similar solution to have access to reported data.

HSLF-FS 2016:40

Eligibility award

The caregiver within the central authority, should have access to personal data in accordance with the general provisions of the Patient Data Act on internal confidentiality and assignment of permissions for electronic access to personal data. Only those who need access to personal data in a national or regional Quality Registry in order to perform their work may access the data. This means that there are usually only a few people at the central authority with access to identifiable data. The caregiver has control of the award of eligibility for access and access control.

There has been strong criticism in connection with the practice in which care providers only have access to the data that they themselves have reported to a National Quality Registry. When several caregivers are part of a care chain, the individual care providers are prevented from carrying out combined reporting based on each other's data, as well as from improving and safeguarding the quality of the entire care chain. A draft proposal has been drawn up to allow care providers that report data about a patient to a national Quality Registry to have access to all reported data about the patient in question. In this way, care chains with multiple care providers will be able to be improved and quality assured.

The Patient Data Act, Chapter 1-3

Usage

7. Who can have direct access to information in a National Quality Registry?

A caregiver may, in accordance with the Patient Data Act, Chapter 7, §9, have direct access to the personal data they reported. Access to statistical data presented without the data subject's identity being disclosed is another thing. Such information can generally be provided openly and, for example, is published to inform the public about the quality and results ("Vården i Siffror"). It is important to note that it should not be possible for a third party to reconstruct the identity from the published information.

8. Is ethical review of research on data from the National Quality Registries required?

The Patient Data Act, Chapter 7, §5 states that data collected in a Quality Registry may be used for research in health care. The ability to process the data for research purposes does not imply any exemption from the act (2003: 460) concerning the ethical review of research involving humans. Research on sensitive personal data always requires approval from an ethics board, regardless of whether the data is available in a patient record, in a national Quality Registry or in any other information source in health care. Before data from a Quality Register can be disclosed it should always be subject to a privacy examination pursuant to the Public Access to Information and Secrecy Act, Chapter 25, §1. Here, an approval from the Ethics Committee entails no exception; a privacy examination should always be carried out.

See also the Ethical Review Act, webpages and links Sweden.

9. Can national Quality Registries work with private third parties such as pharmaceutical companies?

Yes, but there is an agreement between the SKL/SALAR (Swedish Association of Local Authorities and Regions) and the industry that must be respected.

Patient rights

10. Can data from a Quality Registry be transferred to another country?

There is nothing to prevent transfer of aggregated data that does not contain personal data to another country. It is also possible to transfer personal data, but there is a complex regulatory framework that must be respected. Therefore, the county or region, lawyer and/or personal data representative should always be contacted before initiating international collaborations that involves the transfer of data.

11. What rights does a patient have regarding Quality Registries?

Participation in Quality Registries is voluntary and will not affect the care that the patient is offered. If the patient does not want the data recorded, the patient can turn to the health care provider that he or she visited and request an opt-out.

The patient should have been informed and have the right to decline to participate in the registry (opt-out). The starting point in the Patient Data Act is therefore that no explicit consent is required (though presumed by the legislator), but instead the individual is given an opportunity to oppose the registration.

The patient has the right at any time to have all his or her data deleted from the register. This also means that a Quality Registry does not have the right to draw up a list of patients who do not want to be involved in the Quality Register, as this list would constitute data held concerning those patients.

The patient has the right to receive information on the use of his or her data. The patient is entitled to damages if the data is handled in violation of the Personal Data Act.

The patient can request correction of information which is incorrect.

The patient has the right, once a year and free of charge, to examine the information has been recorded about him or her. Such an application must be in writing, signed and sent to the registry or the authority responsible for the registry. These are the basic rules about the handling of personal information set out in the Patient Data Act.

12. Can the patient record information in a National Quality Registry?

The health care provider records the data in a Quality Register, and is responsible for the effective collection of data. If the health care provider believes that the patient can contribute information that is otherwise not being collected within the objectives of the registry, the caregiver can determine that the patient will record the data and train him or her in how to do this.

Protect

13. How to protect personal data in the National Quality Registry

Details of National Quality Registries are subject to the same protection as medical records. Therefore it is appropriate that personal data in Quality Registries, as far as possible, are handled in the same way as the caregiver's handling of patient records. Where data are presented openly, for example to inform the public about the quality of health care, this must be done in such a way that the individual's identity is not disclosed.

3.6.2 Ethics

3.6.2.1 VETTING THE ETHICS OF RESEARCH INVOLVING HUMANS

An act has been in force since 1 January 2004 relating to vetting the ethics of research that involves humans. It encompasses research involving living persons, and also covers such areas as research on the deceased, biological material from people and research that involves dealing with sensitive information about people or personal information concerning offences against the law.

In 2004, ethics committees became independent authorities comprising one central ethical vetting board and six local ones (Regional Ethics Review Boards/Regionala etikprövningsnämnder).

Ethics and national directives that apply

The stipulation concerning the ethical vetting of research on humans are to be found in

Act (2003:460) concerning the Ethical Review Act of Research involving Humans

The Statute (2003:615) concerning the Ethical Review of Research involving Humans

The Statute (2007:1069) with instructions for Regional Ethics Committee Review Board

The Statute (2007:1068) for the Central Ethical Review Board.

The Swedish Biobanks in Medical Care Act (SFS 2002:297)

3.6.2.2 ETHICS COMMITTEE APPLICATION

Fee

A fee is charged for each application. The fee is to be paid by the person principally responsible for the research. Currently, a researcher needs to be connected to a Swedish university/university hospital to get the application reviewed. The fee is at minimum SEK 5000.

The Swedish Biobanks in Medical Care Act, state that human biological specimens collected and/or stored within the health care system may be used for research if the patients/donors have given consent to this. Collection and/or use of human samples for research purposes require approval by an Ethics Review Board for each specific project/clinical trial.

Procedures

There are three possible outcomes for applications reviewed at the meetings: an application may be approved, approved subject to certain conditions, or rejected. An approval ceases to be valid if the research has not commenced within two years of the final decision.

Time limits

The regional boards normally make a decision within 60 days of receiving a full completed application.

Application

The application needs to be filled out in Swedish only. However there is an English version of the Swedish form available. A guide to application and guidance for the research plan/protocol is also available.

The following documents may, in appropriate cases, be appended to the application if the corresponding information is not on the form:

- The participating entity principally responsible for the research and collaborating researchers;
- Research plan intended for specialists;
- Advertising material for the recruitment of research participants;
- Written information for research participants;
- Questionnaire;

- Standard EU form (substantial amendment notification form);
- Summary of the protocol in Swedish;
- User's handbook or product insert/product summary/IB;
- Testimonial from operations manager or equivalent concerning resources and the safety of those participating in the research;
- CV of researcher;
- Description of remuneration given to research participants;
- Agreements with principals/financiers concerning, for example, terms of employment, grants or compensation awarded to the place where the research is conducted, to the principal responsible for health care, to the entity principally responsible for the research or to the researcher.

3.6.2.3 PATIENT INFORMATION AND CONSENT FORM

A verbal consent and opt-out model for patients is used by the National Quality Registries.

However, inclusion in clinical research projects requires written informed consent.

The registry steering committee must approve the use of the registry for a research project after ethics approval has been received.

3.6.2.4 APPLICATION FOR PERMISSION TO USE DATA

For researchers interested in using one or more Quality Registries, there is a simple guide describing how to apply for permission to use Swedish National Quality Registry data (Quick Guide for Researchers).

Application for permission to have data released from the Quality Registry is through a form provided by the registry or its personal data holding authority (CPUA). If no form is available, the form *Application for Registry Data from the Quality Registry for Research Purposes* may be used, and can be found on the registry centre and regional cancer centre websites. The form can be sent to the registrar or the recipient of the form designated by the CPUA for the relevant registry.

Once the application has been processed, there are two possible outcomes:

A)

A decision on disclosure is made and an agreement drafted. The agreement regulates terms such as:

- Any costs for extraction;
- What variables will be disclosed;
- How long the researcher will have access to data for the project.

See examples of templates for Application for Registry Data from National Quality Registries for Research Purposes, which also functions as an agreement.

Data are released in accordance with the agreement and the research results are reported to the registry within the agreed time and in the specified manner.

On completion of the research, the researcher archives his or her work in accordance with the principal investigator's guidelines and all working copies are destroyed.

B)

The decision is made to deny the application.

The researcher will be notified of this decision and provided with information on how to appeal the decision.

3.7 GOALS

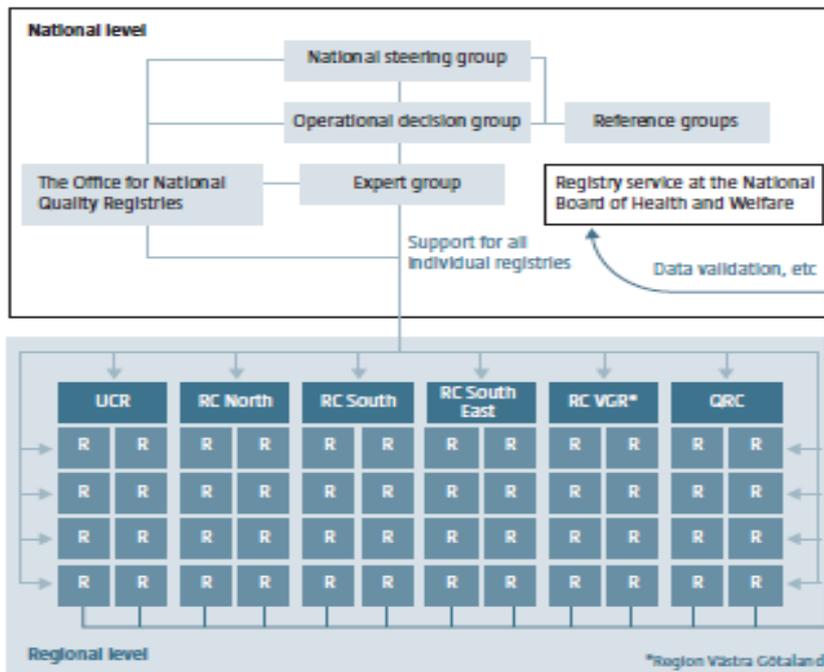
The overall goals for the National Quality Registries are to:

- monitor the quality of the Swedish health care system;
- be designed to follow-up on patient-care;
- involve patients in their health care;
- present results openly;
- be promote quality improvement activities;
- promote and be used for research for innovation;
- to participate in national activities arranged by the office of National Quality Registries;
- integrate IT support in health care documentation.

Yearly evaluations of the National Quality Registries is performed by the Office of National Quality Registries.

3.8 ORGANISATION

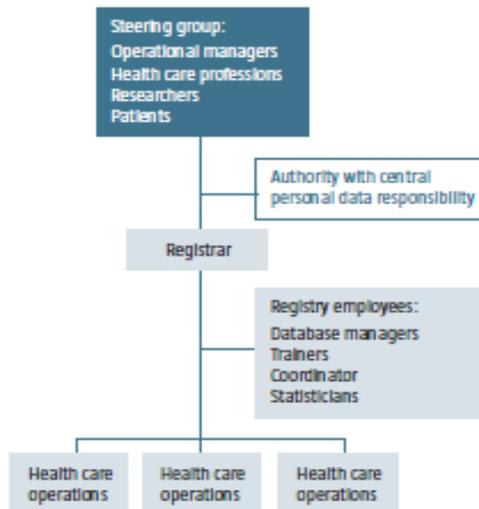
The national organisation for the Quality Registries includes a national steering board, operational decision group, the Office of National Quality Registries, an expert group, reference groups and the registry service at the National Board of Health and Welfare. See figure below.



There is an organisation around each National Quality Registry. Every Quality Registry has a registry holder, a steering committee and a CPUA (central personuppgiftsansvarig/ person responsible for personal data). See figure below.

The county council is the body that is responsible for the registry and the data.

The National Quality Registries have been developed and driven by the medical profession, which is one of the reasons behind the success of the registries.



3.9 STATUS AND ACTIVITIES IN RELATION TO GOALS

The goals are:

- 80% “coverage”;
- on-line data (openly show data and results);
- 80% of registries present data to the patients;
- 80% of management at clinics use data in change management work;
- use of registries results in statistically significant improvement for patients and a decrease in unwarranted local variation in health care outcomes for the 10 largest indications;
- Swedish health system maintains its position (regarding efficiency,) in international comparisons.

Current focus areas are:

1. strengthening the registry centre organisations (RC/RCO);
2. support the RCO;

3. useable data and support for improvement projects in the health care system;
4. better content and data quality;
5. increase patient involvement;
6. better IT support to facilitate data collection.

3.10 COLLABORATION WITH INDUSTRY

An agreement between the SKL and the industry association is in place to allow collaboration.

At the start of 2000, there were only a small number of National Quality Registries with collaboration agreements. By 2015, this number has increased to more than 20% of the registries.

3.11 NORDIC COLLABORATION PROJECTS

Nordic collaboration projects are ongoing. Examples include:

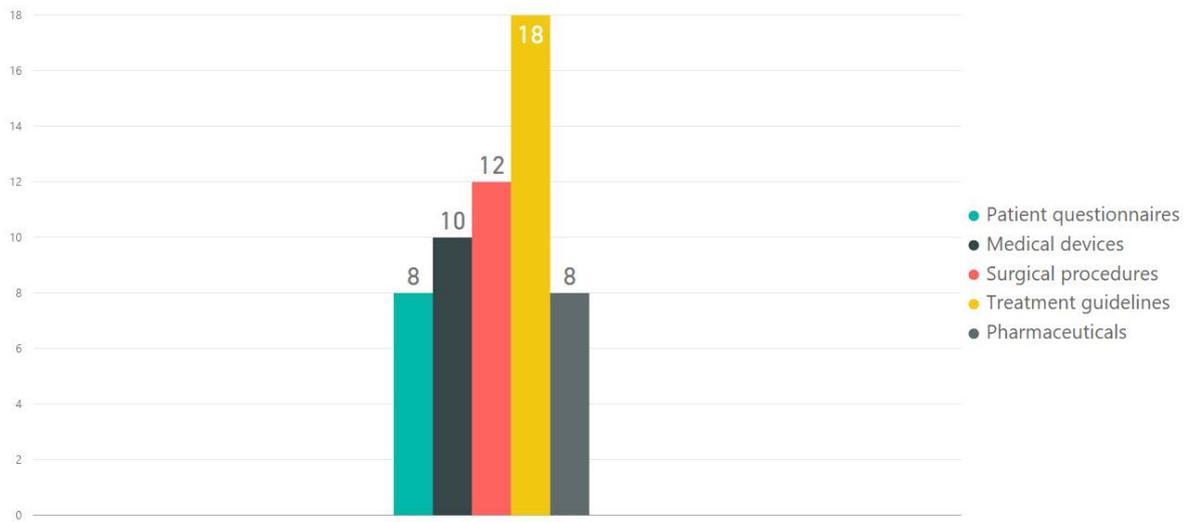
- Bladder cancer, cervix cancer, back surgery, vascular, cancer in children, CF MS/neuro, prostate cancer, tonsillectomy, “spinal cord injury” is under discussion, hyperbaric oxygen treatment, cancer in liver, haemophilia, Nordic hidradenitis suppurativa registry .
- Previously cardiology (SWEDEHEART), hiparthoplasty, cataract registry have been involved in Nordic and international collaboration.

3.12 INTERNATIONAL COLLABORATION

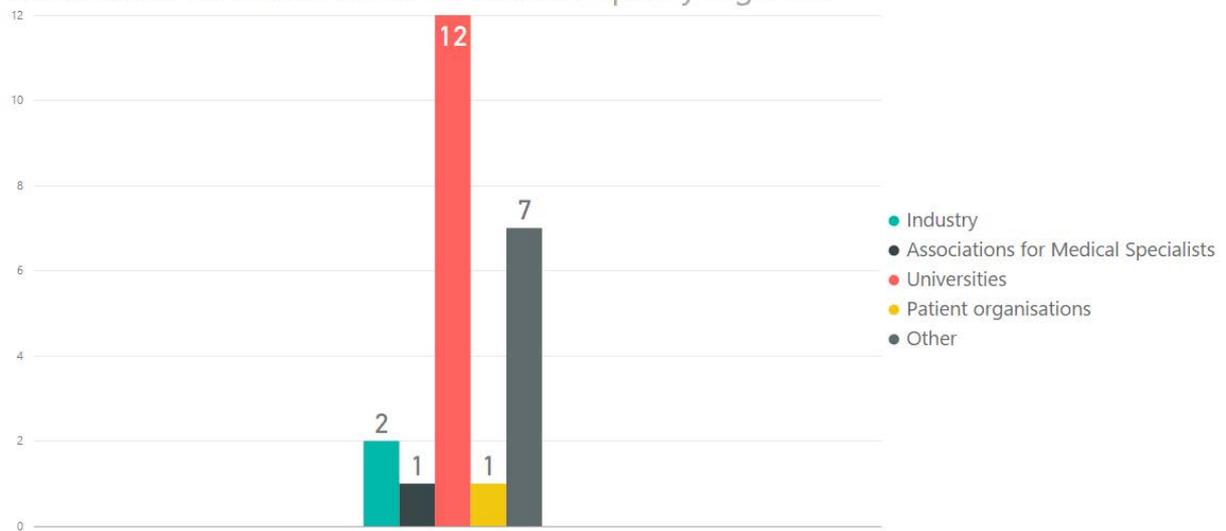
An international strategy implemented during 2014 included supporting start-up of international collaboration and staff to support international activities. Today there is increased interest in the Swedish National Quality Registries in relation to providing “real life data” to support new drugs and devices.

For distribution of research projects, other collaboration projects and international collaboration see Figures below.

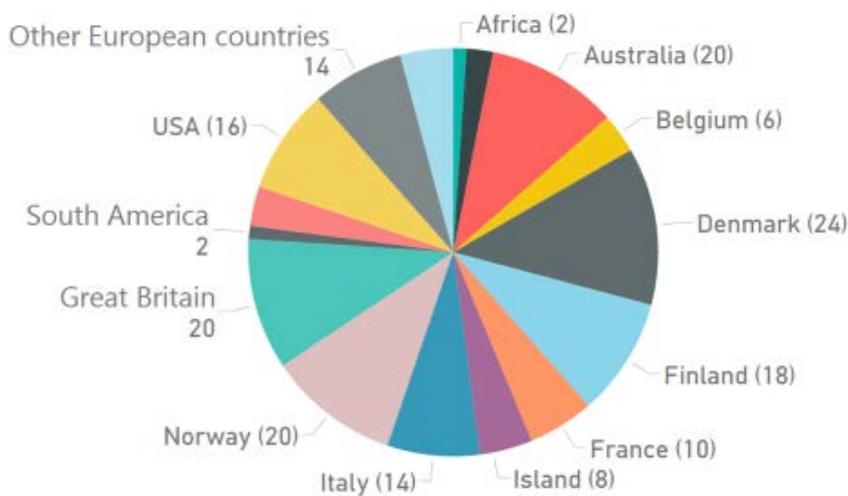
Distribution of areas for research



Distribution of collaborators for national quality registries



Global distribution of international collaboration



3.13 PATIENT INVOLVEMENT

All registries are required to have some kind of patient-related measurement included in the registry (PREM/PROM, QOL or other).

Furthermore, a patient representative should be part of the registry steering committee, unless good reasons can be given for why the patient representative should be excluded.

3.14 POSSIBILITIES INTERNATIONALLY

Another trend is the increased interest in using the patient registries in general as a source of real life data and support data for follow-up of new devices and drugs. This is the background to the PARENT Methodological Guidelines and recommendations for an efficient rationale and governance of patient registries (available as final version 2015).

Pilot projects by EMA (European Medicines Agency), health-technology-assessment (HTA) bodies involving the Swedish registries will be started 2016-2017. The Swedish Medical Product Agency has concluded in a report (Regulatory utility of disease and intervention registries, 2016) that Swedish health care and National Quality Registries provide useful information on drugs in clinical practice.

3.15 WEBPAGES AND LINKS

<https://lakemedelsverket.se/english/>

<http://www.epn.se/en/start/>

http://www.epn.se/media/1197/letter_080526__rev.pdf

<http://www.kvalitetsregister.se/englishpages/aboutqualityregistries.2422.html>

<http://www.kvalitetsregister.se/englishpages/findaregistry/allswedishqualityregistries.2028.html>

<http://attdriva.kvalitetsregister.se/>

<http://www.registerforskning.se/>

<http://www.socialstyrelsen.se/english>

http://www.scb.se/en_/

<http://www.statistikdatabasen.scb.se/pxweb/en/ssd/>

<http://www.biobanksverige.se/>

http://ec.europa.eu/health/ehealth/docs/patient_registries_guidelines_en.pdf

http://ki.se/sites/default/files/ludvigsson_journal_of_internal_medicine.pdf

3.16 SUMMARY SWEDEN

- Quality Registries are funded by the state and county councils. Other health data registries are funded by the state.
- No signed consent is required to include patients' data in a Quality Registry, but verbal consent and opt-out model is applied for the National Quality Registries.
- For every National Quality Registry there is a registry holder, a steering committee and a CUPA (central person uppgiftsansvarig/person responsible for personal data).
- "Owner"/responsible for the registry and the data is a county council.
- The registries provide a way to follow up patient care, a tool for assuring that the health care delivers high quality, and that the best possible care can be obtained.

- Types of registries are health data registries, Quality Registries and other (not funded by the state).
- Most Quality Registries focus on particular disease areas (or surgical methods) and not on products.
- The data can be used for improvement work, knowledge management, research and innovation.
- Standardisation of medical language, coding, variables, patient outcomes measurements, QOL should be performed as far as possible.
- IT systems involved are many, therefore software platforms, IT solutions and contracts have been developed to make sure that the systems are able to “talk to each other”.
- Patient-related measures should be included in all Quality Registries.

4 NATIONAL OVERVIEW: DENMARK

4.1 INTRODUCTION

Danish health care has three political and administrative levels; the state, the five regions and 93 municipalities. The health care service is organised in such a way that responsibility for the services provided is placed at the lowest possible administrative level. At the national level the Ministry of Health is responsible for drawing up overall national health policies and legislation on health care, supported by four national health boards; Danish Health Authority, Danish Health Data Authority, Danish Patient Safety Authority and The Danish Medicine's Agency.

At the regional levels, the five regions in Denmark are the main service providers in the Danish health care system with responsibility for

- All hospital and psychiatric treatment;
- Parts of the primary health care system; general practitioners and private practicing specialists, dental services for adults, physiotherapy;
- The regional health care services are financed through a block grant from the state, a state activity related subsidy and municipal contributions.

The municipal level is responsible for:

- Home nursing
- Public and school health care
- Preventive care
- Rehabilitation

4.2 HEALTH REGISTRIES IN DENMARK

The first modern, national, patient registry with full population coverage was established in 1943 when the Danish Cancer Registry was launched as a purely clinical initiative, supported and financed by the Danish Cancer Society.

The introduction of the unique personal citizen identifier in 1968 laid the foundation for both the state-owned national health register and the national clinical quality registries of Denmark. From then on there has been a continuous increase in numbers and topics of health registries in Denmark.

The Danish Health Data Authority holds the national health data registries such as the hospital discharges registry, prescribed drug registry, cancer registry, cause of death registry, histopathology registry and birth registry.

The national quality registries (like the state registries) are mandated by law so that all eligible patients are included. There is legal exemption from patient consent and therefore a very high completeness of the populations included. This means that the registries have proved to be of high value for quality improvement and research in health care.

Via the unique citizen identifier it is possible to link the national registries and the national quality registries within a highly regulated framework coordinated by Statistics Denmark and the Danish Health Data Authority. Moreover, the national quality registries are planned to be coordinated with data in the national biobanks via research projects.

4.3 NUMBER AND TYPES OF NATIONAL QUALITY REGISTRIES

In September 2016 there are 66 national quality registries, seven under implementation and two in the planning phase. The majority of the 66 registries in full function have achieved a population completeness of around 90 %.

The national quality registries cover disease entities (e.g. diabetes, lung cancer), specific interventions (e.g. hernia repair, bariatric surgery) or specific activities (e.g. intensive care, transfusion medicine).

The databases contain data related to diagnostic procedures, treatments and outcomes of patients.

Types of registries

- 29 cancer registries including quality of palliative care and national screening programmes;
- 12 major chronic diseases (excluding cardiovascular and psychiatric registries);
- 8 non-neoplastic elective surgery/orthopaedic surgery, gynaecology;
- 7 cardiovascular diseases;
- 5 emergency/acute surgical and medical care (excluding cardiovascular and psychiatric registries);
- 5 psychiatry including dementia care;
- 3 obstetrics;
- 5 miscellaneous.

A detailed list is given on the website for the Danish Clinical Registries www.RKKP.dk.

The Danish Health Data Authority (Sundhedsdatastyrelsen) holds the national health data registries such as the National Patient Registry, Medical Birth Registry, Cancer Registry and Cause of Death Registry. Data from these registries are jointly processed with data from the national quality registries so that more than 50% in the variables of these registries are derived from the state national registries.

The Health Data Authority contact: www.sundhedsdatastyrelsen.dk

4.4 PURPOSE

National clinical quality registries in Denmark have defined objectives based on the Danish health act.

A clinical quality registry is a database which presents measurable indicators, based on individual patient cases. The indicators are intended to demonstrate the quality of the regional and municipal health care organisations' efforts and outcomes in a defined patient population.

Information from clinical quality registries can only be employed according the objectives described above, and an additional objective of the clinical quality registries is to inform patients and citizens about quality of care in health care organisations.

An alternative operational definition of objectives is: The objective of clinical registries is to support groups of health care professionals in surveillance and improvement of professional practice and patient outcomes by collection, analysis, presentation and interpretation of data. This definition stresses the central role of the health care professional groups responsible for and using the registers for improvement.

4.5 VISION

The new vision for the national clinical registries has been formulated by the five regions:

“The national quality registries are the future hub of the clinical quality improvement in Danish health care. The registries will deliver significant contributions to regional quality improvement and support the development of health care as a learning organisation on all levels from individual practitioner on all individual and organisational levels. This development of registries is closely connected to the evolving national quality programme.”

4.6 FUNDING

The national quality registries are funded by the five regions. Additional funding for specific projects is received from the Ministry of Health and other external funds. Direct funding of registries from industry in the form of fees for services is presently considered to be difficult because of a clear legal formulation that

data from clinical registries can solely be employed in accessing and improving quality of health care. There is one case where a registry has unconditional direct funding from industry, but this is presently strongly discouraged by regions and health authorities.

4.7 LEGAL ASPECTS AND ETHICS

4.7.1 Legal

The following laws apply in Denmark for the national quality registries (clinical quality registries)

Sundhedsloven, kap. 60/Health Act, chapter 60: §196

<https://www.retsinformation.dk/forms/r0710.aspx?id=152710#Kap9>

Bekendtgørelsen om godkendelse af landsdækkende og regionale kliniske kvalitetsdatabaser (Administrative order on approval of national and regional clinical quality registries)

Bekendtgørelse om indberetning til godkendte kliniske kvalitetsdatabaser og videregivelse af data til Sundhedsdatastyrelsen (Administrative order about reporting to approved clinical quality registries and transfer of data to the Danish Health Authority)

<https://www.retsinformation.dk/Forms/R0710.aspx?id=183356>

The following principles apply:

Define objectives and need for specifications of patient populations.

Exemption of data collection, storage and use from patient consent.

Demand national health authority approval of fulfilment of national criteria for relevance, functionality, data safety and methodology.

Mandatory public reporting of results on clinical unit level.

90% population coverage of the specified population.

Reappraisal in the national health authority every 3 years or when changes are made in population specification, quality indicators, algorithms or variables in the registry.

Define patients' right to insight in own data in the registry.

Persondataloven/National data-protection legislation (the Act on Processing of Personal Data)

<https://www.datatilsynet.dk/english/the-act-on-processing-of-personal-data/read-the-act-on-processing-of-personal-data/compiled-version-of-the-act-on-processing-of-personal-data/>

Defines demands for data safety, general purpose (statistical, quality improvement) plus potential for research use.

Demand connection to register-responsible authority = regions (role equivalent to data-protection agency).

Defines role of register-responsible authority.

Defines rules for cross-border use of personal data (always approval from the National Data Protection Agency)

Act on Biomedical Research

Regulates specific aspects of register research (see ethics, laws and guidelines).

Exempts data collection for quality improvement from regulation.

Regulatory guidelines for receiving financial support from the Danish Regions, defined by the Board of the National Clinical Registries:

Mandatory IT, data management and epidemiological/biostatistical support from the RKKP organisation.

Format and frequency of reporting (towards real time summary reports and a yearly report with interpretations, reflections and recommendations).

Basic demands for members of clinical steering groups of registries.

Coordination with national clinical guidelines.

Register involvement in improvement projects.

Universal access to data for researchers with protocols, approved by data-protection authorities or ethical committees.

4.7.1.1 REGULATORY QUESTIONS AND ANSWERS

In this section, answers may be found to commonly asked questions regarding regulatory aspects of Danish quality registries.

General

National quality registries - used for what?

All national quality registries financed by the regions have to specify improvement goals for each individual indicator in the registry, thus emphasising documentation of improvement in the individual registries. This information is used to monitor the rate of improvement in effectiveness, patient safety and access in the Danish health care system as specified by the national quality programme.

On the micro level, more than half of the registries feed regular (presently monthly) indicator results into the regional business intelligence system where they are distributed to all levels of management and individual clinical teams in order to facilitate clinical quality management. Registry data is also used to monitor the quality of the national speciality plan with the objective of safeguarding high quality in tertiary care. As for any other health registry the data can be used for secondary purposes – statistics and research in health care.

Who is responsible?

Regions and municipalities can be the responsible authority for national quality registries. Presently, three regions function as “data-responsible authorities”. The duty of the “data-responsible authority” consists of safeguarding the conformant to national data protection legislation, while the obligations defined by the Health Act are controlled by the Health Data Authority.

Collect data

1. **Who is responsible for report and data input a Quality Registry?**

According to the Health Act it is the duty of the health care provider (regions, municipalities, private persons, institution and practising health care professionals) to report the relevant data to the national quality registries. This obligation includes more than 90% completeness of the target population.

2. **What information may be included in a National Quality Registry?**

The sole objective of the national quality registry is documentation, improvement and presentation of quality in health care institutions. Therefore only variables which serve this purpose can be entered into the registry. This definition allows for inclusion of variables of context necessary for

adjusting and interpreting the values of quality indicators.

Administrative order of approval of national and regional clinical quality registries.

3. **Can a Quality Registry obtain information from any source other than the patients and their medical records?**

Yes, when approved by the data-responsible region and the Health Data Authority.

4. **Can a Quality Registry change its purpose over time?**

Yes, if approved by the Health Data Authority and data-responsible region, e.g. if the registry is converted from a quality to a research registry:

Protect

5. **How long can data be stored in a Quality Registry?**

Indefinitely according to the archive laws of Denmark.

6. **How to protect personal data in a national Quality Registry?**

Details of quality registries are subject to the same protection as medical records. When the data are presented openly, e.g. to inform professionals or the public about the quality of health care, it must be done in such a way that the individual's identity is not disclosed.

Vejledning om informationssikkerhed i sundhedsvæsenet, version 1.0 (Guidance of information security in health care organisation, version 1.0., 19.04.16, Health Data Authority)

<http://sundhedsdatastyrelsen.dk/da/rammer-og-retningslinjer/om-informationssikkerhed>

Usage

7. **Who can have direct access to information in a National Quality Registry and what information may be accessed?**

Caregivers have direct access to the personal data in the registries for the purpose of ensuring accurate data entries. Use of the registry in the context of individual patient care is not allowed. Access to aggregated statistical data from registries presented without personal identities being

disclosed is generally available for professionals, management and the public.

8. **Is ethical review of research of data from the National Quality Registries required?**

In research use of quality registry data, notification of the ethical committee is not required if the research project only involves information in the form of signed-based symbols including figures, letters etc.

**Act on Research Ethics Review on Health Research Projects (lov om videnskabsetisk
behandling af sundhedsvidenskabelige forskningsprojekter)**

<http://www.dnvk.dk/English/actonabiomedicalresearch.aspx>,

**Vejledning om anmeldelse, indberetningspligt mv. (sundhedsvidenskabelige
forskningsprojekter) (Guidelines about notification of a biomedical research project to the
committee system on biomedical research)**

<http://www.dnvk.dk/forskere/~media/Files/cvk/vejledning%202014/PDFudgave%202014%20vejledning%20DOK1355342.ashx>

9. **Can National Quality Registries work with private actors such as pharmaceutical companies?**

No, not directly – according to very strong emphasis in the administrative orders concerning objective of data collection and use in the national quality registries. Legally approved research initiated in cooperation with private actors is however possible (and not unusual).

The act on processing of personal data

Patient rights

10. **Can data from a Quality Registry be transferred to another country?**

Yes, if approved by the National Data Protection Agency.

This is a time-consuming and often complex process

The act on processing of personal data

11. **What rights does a patient have regarding Quality Registries?**

Patients registered in national quality registries have the right of insight into own data.

Administrative order of reporting approved clinical quality registries.

12. **Can the patient record information in a national Quality Registry?**

Yes, in the form of patient-reported outcomes.

Protect

13. **How to protect personal data in the national Quality Registries**

Data in quality registries is subject to the same protection as medical records (and other confidential person related information). Therefore, it is sensible that the handling of personal data in quality registries follows the same rules as those which apply for patient records.

4.7.2 Ethics

The Danish legislation on research that involves humans is contained in Lov om videnskabetisk behandling af sundhedsvidenskabelige forskningsprojekter (Act on research ethics review of health research projects 2011, modified 2016). The law and administrative order have only a limited application in Danish research projects involving registry data. Ethical committee review is only required as indicated below.

- For research including biobank material:
It is usual for the ethical committee to demand patient consent for this type of registry research. Moreover, all citizens/patients can demand exemption from research use of their materials in biobanks by registering with the National Health Data Authority's register (vævsanvendelsesregistret).
- For research involving direct contacts with patients included in registries:
Description of the application for review, fee for application and procedures of the ethical committee in Vejledning om anmeldelse, indberetningspligt mv. (Sundhedsvidenskabelige forskningsprojekter) (Guidelines about notifications etc. of a biomedical research project to the committee system on biomedical research).

4.8 GOALS

The Danish clinical registries have three main goals:

- Improving the quality of prevention, diagnostics, treatment and rehabilitation in Danish health care;
- Documentation of quality for clinical governance and organisational priority setting;
- Information for citizens and patients.

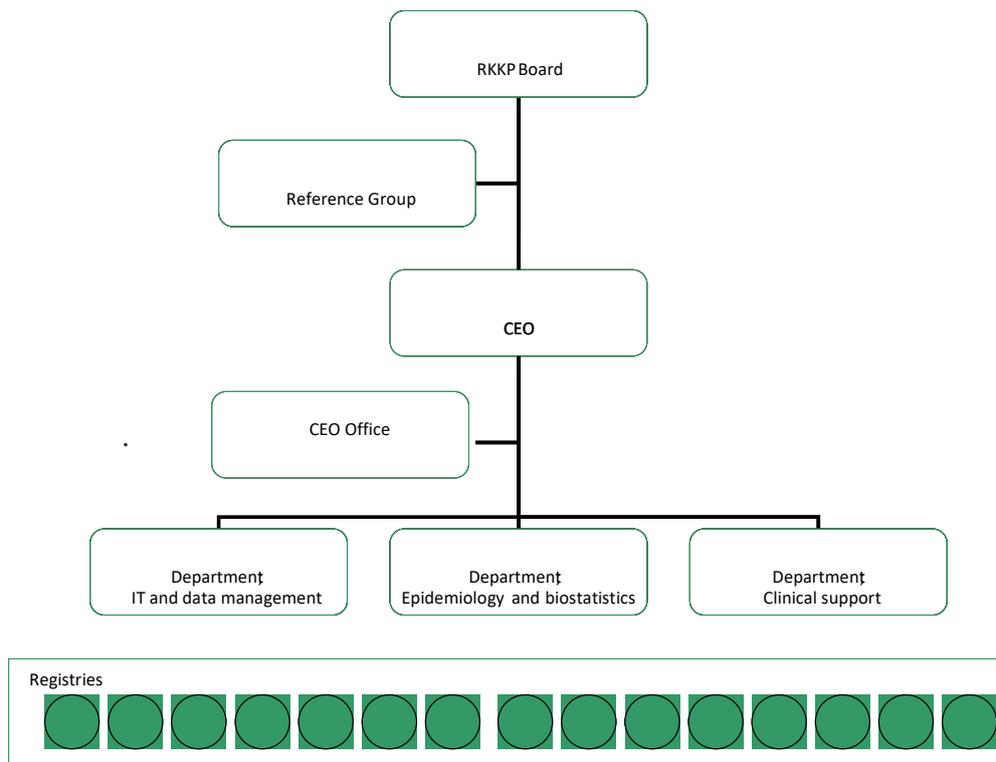
4.9 ORGANISATION

Each registry has a professional board (steering group). Board members are appointed by professional societies. The board structure depends on the type of registry – registries covering multiple units or health care sectors have representation from several specialities and professions, while registries covering a single surgical procedure have boards of limited size. The minimum size of registry boards is 5 – because of a demand for professional representation from all five regions.

Almost all registries are supported by an organisation called (RKKP) consisting of 3 sections, covering:

- IT and Data management
- Epidemiology and Biostatistics
- Clinical Support and Quality Improvement

The supporting team for each registry consists of a process coordinator with background in health care, an epidemiologist and a data manager. The CEO office contains a secretariat responsible for coordination, communication, budgets and servicing the CEO and the political board.



Requirements of outputs from the RKKP Registries.

- A yearly national report with interpretation of data, analysis and recommendations;
- Monthly/quarterly feedback to clinicians and management information systems;
- Monitoring of variation between units and regions;
- Monitoring of adoption of national clinical guidelines;
- Extensive re-use of available data in hospitals and GP-surgeries;
- QI-framework: Rapid cycle and Evaluation;
- Advice about planning of specialty functions;
- Research infrastructure.

These criteria are employed in the evaluation of continuous support to the registries from the Danish regions together with the evaluation stipulated in the Health Act performed every third year by the Danish Health Authority.

- The responsibilities and roles of the professional board (steering group) of the individual registries;
- Definition of registry content (population, indicators, analyses);
- Interpretation and evaluation of registry output;
- Responsibility for continuous evolution of registry corresponding to clinical evidence and -needs;
- Recommendation of areas for national and local improvement – and participation in data-driven quality improvement projects;
- Cooperation with RKKP experts in specification of variables, algorithms and analyses
- Cooperation with RKKP experts in specifications and necessary improvement of data quality in the registry;
- Responsibility for running dialogue with relevant professional associations about the outcomes and evolution of the registry;
- Evaluation of research potential of the registry and counselling researchers wanting data from the registry.

A special case: Organisation of the cancer registries

Although they are part of the registry organisation (RKKP), the clinical boards of the cancer registries are formed from a professional organisation: Danish Multidisciplinary Cancer Groups (DMCG) ([www. http://dmcg.dk/en/welcome/](http://dmcg.dk/en/welcome/)) representing all individual medical specialities in cancer care organised around individual cancers.

[www. http://dmcg.dk/en/welcome/](http://dmcg.dk/en/welcome/)

DMCG.dk's mission is:

- To establish multidisciplinary collaboration between the individual Danish cancer groups with the purpose of meeting DMCG.dk's main objectives, which include:

carrying-out scientific clinical protocols, the promotion of research coordination, the establishment of international contacts and scientific collaboration, the establishment of biobanks geared towards research, the monitoring of cancer care and early warning, the dissemination of knowledge and information, and creation of clinical guidelines for diagnosis and treatment.

- To advise and counsel governing organisations on the individual cancer groups' functions and activities.

- To advise and counsel governing organisations on the Danish clinical cancer databases.

The Danish Multidisciplinary Cancer Group consists of up to 3 representatives from each individual group. Each cancer group individually elects its representatives for a given term of service.

The DMCG's broad function has proven its value in terms of utility of their registries in forming coherent professional quality strategies and may be an example for the future clinical organisation of the Danish registries.

4.10 STATUS AND ACTIVITIES IN RELATION TO GOALS

Future goals

In 2015 the supporting organisation of registries was reviewed in terms of functions and outcomes. The result of the review was manifested in a new action plan with the following goals for the registries and their organisation.

- Registry scope and content should be systematic, pervasive, patient orientation.
- General use of patient reported outcomes in registries.
- Patient participation in choice of indicators.
- Patient insight into own data.
- Establishing “Patient like me” functions in selected registries.

1. General demand for registries

General demand for registries covering integrated patients pathways, both within secondary care (multidisciplinary pathways and across health care sectors, including data from general practice and municipality health care systems.

User-friendly presentation of result of value for patients, citizens and authorities.

Increased involvement of registries in improvement projects and quality management.

Standardisation of variables, indicator definitions, epidemiological analyses across registries:

1. Delivery of real time data for clinical use and increasing exploitation of mixing different registry data.
2. Extensive reuse of data from electronic patient records and central state health care registries.

2. Organisational infrastructure

1. Common IT platform for all clinical registries with focus on data capture rather than independent data registration.

2. Reorganisation of RKKP (supporting organisation with clear line management)
These changes are about to be implemented in 2017.

4.11 COLLABORATION WITH INDUSTRY

See 4.6 above.

4.12 NORDIC COLLABORATION PROJECTS/INTERNATIONAL COLLABORATION

No systematic data available about research cooperation.

Examples of international collaboration involving Danish registries:

- The Danish renal insufficiency registry reports to an EU-registry since 1970.
- The Danish vascular surgery registry is a member of the VASCUNET' audit organisation.
- The Danish Stroke registry reports thrombolysis data to a Swedish platform (SITS).
- Hip; Knee, Shoulder arthroplasty registries participates in the NARA project (Swedish platform).
- DK spinal cord injury registry reports to/part of Nordic SCI.
- DK Raredis registry part of Nordic raredis registry (congenital craniofacial anomalies).
- DK renal insufficiency registry - reports to EU-registry.
- Low volume arthroplasties reports to Swedish registries (NMC project)
- DK Childhood cancer registry contribute to Scandinavian treatment protocol coordination.
- Penile cancer – work in progress DK-S clinicians.
- Cataract DK direct reporting to Swedish registry.
- Hidrosadenitis DK direct reporting to Swedish registry.
- Danspine* (Spinal surgery) use Swedish platform.

- Planned cooperation and benchmarking – cancer quality registries DK/S.

4.13 PATIENT INVOLVEMENT

In line with the new goals outlined above, representatives from the RKKP organisation are undertaking an extensive literature review of evidence, concerning optimisation of methods of patient involvement in quality improvement activities. These representatives are also participating in a Nordic network, initiated by the Swedish clinical registries.

The Danish Clinical Registries started implementation of patient reported outcomes (PROs) in 2014, based on an extensive critical review of the literature concerning PROs as measurement tools. The main recommendation is that generally PROs should be used in clinical activities affecting individual patients before acceptance as quality measures.

4.14 POSSIBILITIES INTERNATIONALLY

It has been a positive experience to work on collaborative projects between Nordic national quality registers – generally there is a real clinical interest in Nordic cooperation.

Two types of registries seems to be especially keen on cooperation:

- The rare disease registries, where the relatively small Nordic populations give an obvious rationale for cooperation or fusion of registries.
- Cooperation has also been obvious for the fairly big registries, that have surveillance of implant function/safety as objective – here there is a direct link between sensitivity and volume.

In addition, international benchmarking based on clinical – not administrative – data sets has gained increasing clinical interest, both because of general feeling of a need for broad benchmarking, and because there is widespread clinical frustration about the political interest in international benchmarking exercises based on administrative data of dubious validity.

There are now clear demonstrations of feasibility of cooperation despite differences in the legal mandates of registries in the Nordic countries, and technical problems appear to be solved. For example, it has been demonstrated that it is possible to exchange data between Norway and Sweden.

There are downsides: international collaboration requires more bureaucracy – and is dependent on additional approval from the national data protection agencies and local administrations when reconciling the differences in Nordic legislation. There is also a significantly increased cost of going international, especially in terms of clinical time consumption. Finally there may be future problems relating to differences

in strategies between the registry organisation and management - for example regarding diversity allowed for in electronic medical records and similar IT-systems.

4.15 WEBPAGES AND LINKS

The Danish Clinical Registries <http://www.RKKP.dk>

The Health Data Authority contact: www.sundhedsdatastyrelsen.dk

The Act on Processing of Personal Data: www.datatilsynet.dk/english/the-act-on-processing-of-personal-data/read-the-act-on-processing-of-personal-data/compiled-version-of-the-act-on-processing-of-personal-data/

Danish Regions (association of the 5 regions) www.regioner.dk

4.16 SUMMARY DENMARK

The Danish Clinical Registries are similar to the other Nordic registries in terms of legal framework and formalised clinical ownership. There is strong regional ownership and collaboration with health authorities, a clear focus on quality improvement and similar choice of topics for registries.

However, there are differences in important details of both legislation and organisation.

Firstly, the Danish legislation around the registries is exempt from patient consent to data entry and allows research access to data without patient consent. In terms of organisation of the clinical function of registries, the Danish model is more institutionalised and centralised than is the case in other Nordic countries. The clinical board is responsible for defining clinical content and participation in clinical improvement activities but the responsibility for analyses, data management and reporting is centralised in one national supporting organisation.

Moreover, the responsibility for budgeting and resource use lies in the central organisation rather than in the individual registries.

In terms of data sources for registries, Denmark seems to rely more heavily on the national state-driven registries than the other Nordic countries, mainly because the clinical documentation burden in the form of registration of identical data in parallel systems has been in political focus since 2008.

5 NATIONAL OVERVIEW: FINLAND

5.1 INTRODUCTION

Currently there are neither official guidelines nor funding for establishing national quality registers in Finland. There is no national information service portal or national catalogue of the functioning health care registers. In this sense national quality registers do not exist in Finland. However, dozens of disease-specific patient registers have been established, especially on a regional level, and they can be utilised as a data source for quality and research purposes. Patient register data can be linked with other data with a unique identification code (social security number). Data can also be pooled with data from other Nordic countries. Therefore, it is meaningful to introduce the existing health care data sources in Finland. As the Finnish registers do not strictly fit into the quality register criteria presented in this guide, in most cases we have chosen to use the term *patient register* instead of *quality register*.

As a rule of thumb, there are currently three legal bases for establishing a patient register in Finland:

- 1) In most cases disease-specific patient registers are interpreted as being part of the statutory patient documents. Hospital districts are currently heavily investing in this type of patient registers for quality purposes.
- 2) In some cases the register is based on specific, written consent of the patient (e.g. the Finnish National Register for Kidney Diseases).
- 3) National registers of the National Institute for Health and Welfare (THL) are specified in the law. Some of these administrative registers are disease or procedure-specific and their data can be utilised for research purposes (especially the National Arthroplasty Register).

The data access procedure varies according to the legal base of the register. For pure register-based research, there are no legal statutes requiring ethical review. However, some register authorities, such as National Insurance Institution (Kela), may require ethical review, before giving the official permission to access data.

5.2 NUMBER OF REGISTRIES AND TYPES

According to the recent estimates there are fewer than ten functioning national patient registers that can be used both for quality and research purposes. There are more than 60 existing or planned-to-be regional quality registers in Finland. There are almost twenty national health care registers by law, but many of them have an administrative purpose, rather than being focused on quality of care. However, some of these administrative registers can be utilised to measure quality of care, as is shown by later examples.

The latest published study considering the number of Finnish patient registers is from 1997 (Ref. https://julkari.fi/bitstream/handle/10024/76718/Rap_3_1997.pdf?sequence=1). The study was able to identify 10 national registers specified by law, 28 national and 10 regional separate health care registers and several local health care unit registers. Most of the registers were maintained by large hospitals.

At the moment the situation is rapidly changing as the hospital districts are investing heavily in new registers.

Table 1. National patient registers in Finland by disease/procedure area.

Disease/Procedure	Name of the Register	Active Years (if known)	Additional Information	Contact Point/Register Holder
Intensive care	Intensive Care Database “Intensium”	1994–	The pseudonymised data is kept by Tieto Corporation. Identifiers are kept by hospital districts.	Respective hospital districts.
Kidney diseases	Finnish Register for Kidney Diseases	1964–	Based on consent.	The Finnish Kidney and Liver Association
Hip and knee arthroplasty	National Arthroplasty Register/Implant Register	1980–		National Institute for Health and Welfare (THL)

Small pre-term infants	Data file on Small Pre-term Infants in the National Medical Birth Register	2005–		National Institute for Health and Welfare (THL)
Medical births	Medical Birth Register	1987–		National Institute for Health and Welfare (THL)
Hospital infections	National Hospital Infection Register (SIRO)	1999–	Covers all university hospitals and many other hospitals.	National Institute for Health and Welfare (THL)

The biggest hospital district in Finland, the Hospital District of Helsinki and Uusimaa Region (HUS), has recently announced that it has 40 regional quality registers in use and 20 regional quality registers in development phase. (Situation in spring 2017.) Dozens of new regional registers are going to be established soon in many other hospital districts as well. However, it is too early to release the register domains in this report as many registers are in the initial phase.

The National Institute for Health and Welfare (THL) maintains several disease-specific registers by law. The Finnish Arthroplasty Register maintained by THL has been thoroughly reformed in collaboration with the clinicians. The National Medical Birth Register and its Small Pre-term Infants data file can also be used for quality measurement purposes.

The other national registers as well as regional and local registers can be linked to national registers by a unique identification number (“Social Security Code”).

Register descriptions of the national registers maintained by THL can be found from the following address:
<https://www.thl.fi/en/web/thlfi-en/statistics/information-on-statistics/register-descriptions>

Table 2. National Health care Registers.

Name of the Register	Coverage Years	Additional information	Contact Point/Register Holder
Care Register for Specialised Health care / Hospital Discharge Register (HILMO)	Inpatient care from 1972–, outpatient care from 1998–		National Institute for Health and Welfare (THL)
National Register- Register of Primary Health Care Visits (AvoHILMO)	2011–		National Institute for Health and Welfare (THL)
Care Register- Register for Social Welfare (SosiaaliHILMO)	1995–		National Institute for Health and Welfare (THL)
Cancer Register and Mass Screening Register	1952–		National Institute for Health and Welfare (THL)/Cancer Society of Finland
Register of Induced	1987–		National Institute for

Abortions and Sterilisations			Health and Welfare (THL)
Register of Congenital Malformations	1987–		National Institute for Health and Welfare (THL)
Register of Visual Impairment	1983–		National Institute for Health and Welfare (THL)
Infectious Diseases Register	1995–		National Institute for Health and Welfare (THL)
Dental Implant Register	1994–2015	The register was terminated in 2016.	National Institute for Health and Welfare (THL)
Causes of Death Register	1969–		Statistics Finland
Drug Reimbursement Databases	1964–		National Insurance Institution (Kela)
National Electronic Prescription	2010–	Digital Prescription Archive, maintained by Kela.	National Insurance Institution (Kela)/National Institute for

Centre and Archive		Permission to obtain data is given from THL.	Health and Welfare (THL)
Forensic Post-Mortem Examination Archive	2010		National Institute for Health and Welfare (THL)

The National Causes of Death Register is maintained by Statistics Finland and drug reimbursement databases by National Insurance Institution (Kela). The National ePrescription Archive of National Insurance Institution (Kela) can also be utilised for scientific research by permission from THL. THL also maintains an archive of documents on forensic post-mortem examinations and documents on forensic psychiatry. More administrative health registers are described in the article by Mika Gissler and Jari Haukka: Finnish health and social welfare registers in epidemiological research. *Norsk Epidemiologi* 2004; **14** (1): 113–120. (<https://www.ntnu.no/ojs/index.php/norepid/article/download/284/262>).

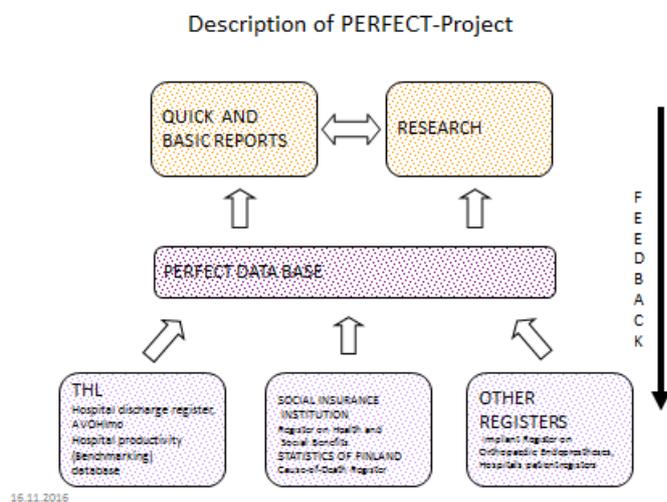
Outcomes and the use of resources in care can be measured by using national databases in combined data linkage studies. The PERFECT (PERFORMANCE, Effectiveness and Cost of Treatment episodes) project (since 2004) has adopted a so-called disease-based approach and has developed protocols for eight diseases/health problems. The disease-based model of the health care system (also called a microeconomic approach) is based on individual level health registers of the whole population. The aim is to model the natural progression of a disease, with specific interest in the role of health services as a determinant of the progress. The main idea of the approach is that it analyses time trends by using more detailed data pertaining to specific health conditions to illuminate the interconnected aspects (i.e. financing, organisational structures, medical technology choices) responsible for health system performance (i.e. health outcomes and expenditure). The main innovation is that the approach uses individual level data available from registers, which makes it possible to measure the outcome (by following what happens to patients) and the use of resources (such as number of hospital days, use of specific procedures and drugs) in selected risk-adjusted and well-defined patient groups. The general aim of the PERFECT project has been to develop methods for register-based measurement of the cost-effectiveness of treatment and to create a comparative database that allows the treatments given to be compared between hospitals, hospital districts, regions and

population groups. The previous main results of the PERFECT project were published in a special issue in *Annals of Medicine* in 2011¹.

The development of databases and indicators has been done in seven separate expert groups, whose members (totalling about 50) are leading clinical experts on the diseases included. The protocols are now under revision (2015–2017) taking into account the development of clinical practices and availability of administrative databases. At present, register-based indicators (both on the regional and hospital levels) on the content of care, costs and outcomes between 2000 and 2015 are available for five health problems (acute coronary syndrome, hip fracture, hip and knee replacements, very low birth weight infants and stroke). The indicators are available on the internet, and they will be routinely updated. The development of indicators is based on the PERFECT database, which as such is based on linking various registers such as the hospital discharge register, registers of the Social Insurance Institution and the cause of death register (Figure 1). The dataset includes all new cases for the selected health problems in the country after the late 1990s. With respect to usual quality registers, PERFECT takes a broader view into selected diseases/health problems. In addition to short period outcomes the project looks at outcomes over a longer period, and takes costs and other performance indicators into consideration. For example, in each of the selected health problems, the report includes various outcome indicators based on survival or mortality (i.e. how many days a patient has lived during the follow-up), readmission to hospital, complications, percentage of patients that have been institutionalised, the proportion of patients that have been returned home within the specified follow-up time. In the near future it will be possible to evaluate the use of home help services for those who have returned home. The reporting will be done in two phases: quick reports include some instant indicators that can be calculated after hospital discharge data is complete, whereas the basic report includes various more reliable indicators based on linking of registers. In addition, the PERFECT databases have been used in research.

¹ See <http://www.tandfonline.com/toc/iann20/43/sup1?nav=tocList>.

Figure 1. PERFECT – Combined Register Database for measuring outcomes and use of resources.



5.3 PURPOSE

Currently there are 20 hospital districts in Finland. The patient registers maintained by the hospital districts are currently planned and designed to measure and improve the quality of the specialised health care in the respective hospital districts. At the moment there is neither national follow-up nor a benchmarking scheme for quality registers.

5.4 VISION

There are ongoing discussions on whether the establishment and governance of the regionally developed quality registers should be more organised nationally. For the time being, there have not been any plans to include quality registers into the national eHealth strategy nor legislation.

5.5 FUNDING

Each hospital district decides which registers it will maintain. The registers are funded by the hospital districts and there are no national funding schemes for quality registers in Finland.

The National Arthroplasty Register (in the National Institute for Health and Welfare) and the Finnish Register for Kidney Diseases (of the Finnish Liver and Kidney Association) have received government funding as do other registers maintained by or in association with the National Institute for Health and Welfare.

5.6 LEGAL ASPECTS AND ETHICS

5.6.1 Legal

The data in the social welfare and health care registers and documents are confidential. Whenever the consent of the patient can be obtained, the consent must be sought before handling personal data for research purposes. If the subjects' consent cannot be obtained owing to the quantity or age of the data or for another comparable reason, permission to access the data can be sought from the register holder who is the permission authority for data. Register holders are usually contact points both for permissions and the actual data. Respective register holders are indicated in Tables 1 and 2 above describing registers.

In Finland the Data Protection Authority does not currently give any permission for data access. However, the National Institute for Health and Welfare is in some cases obliged by law to consult the Data Protection Authority before giving a decision granting data access.

The permission of a register holder authority is needed in order to access data contained in national registers maintained by virtue of special legislation and in other national, regional and local patient registers.

Permission is also needed in order to combine data collected through consent of research subjects with data obtained from a statutory register maintained by a public authority.

Authorities granting permissions

The National Institute for Health and Welfare (THL) or the regional or local public health care provider maintaining a register can, on a case-by-case basis, grant permission to use the registers and documents for purposes of scientific research. THL can grant permission to access data in registers maintained by THL, THL's documents on forensic post-mortem examinations since 2010 and THL's documents on forensic psychiatry.

THL requests statements on the application from register experts and the Data Protection Authority. It is statutory for THL to consult the Data Protection Authority in relation to its national health care registers. The fee for a decision on international research authorisation is EUR 700. The fee for a decision is the same whether the authorisation is granted or refused.

Permission to access data maintained by other agencies and institutes in the national administrative sector, such as Statistics Finland or the National Insurance Institution (Kela), have to be applied for separately from these institutes.

Patient registers in public services

If the research project will only use records created during the provision of public services by one municipality or region (joint municipal board), permission to access such records must be sought from a local or regional register holder (health care centre, hospital or hospital district). THL is not the permission-granting authority by law in such cases.

If the research project requires data from the patient records or social services client records of more than one municipality or region (joint municipal board) providing social and health services, THL can act as the permission-granting authority. Alternatively, permission can be applied for separately from each municipality, in which case no permission from THL is required.

When applying for permission from THL to access data held in patient or client records, the applicant must contact the service providers responsible for granting such access whilst in the process of preparing the application. The authorisation application sent to THL must specify that the data collection method, data contents, data security and reimbursement of the collection costs have been duly agreed upon with the parties disclosing the data.

Patient registers in private service provision

In this case the rule of thumb is that, for research purposes, THL grants permission to access record data collected by a private service provider.

Records produced during the provision of private services are regarded as documents belonging to the authorities in cases where the service provision in question was commissioned by the authorities.

Permission to access such records can be granted by the commissioning authority or THL, if data from the records of more than one municipality or joint municipal board having commissioned the services is required for the project. If the provision of the service was not commissioned by the authorities, permission to access the records must be sought from THL.

When applying for permission from THL to use records created during the provision of a private service, the applicant must contact the service providers managing access to the records whilst in the process of preparing the application. The authorisation application sent to THL must then specify that the data collection method, data contents, data security and reimbursement of the collection costs have been duly agreed upon with the parties disclosing the data.

The Prescription Centre and Prescription Archive (Kanta) for electronic prescriptions

THL authorises access to electronic prescription data contained in the Electronic Prescription Centre and the Electronic Prescription Archive. THL is the authority granting access to data for scientific purposes, whereas the data controller for the Prescription Centre and Prescription Archive is Kela (the Social Insurance Institution of Finland). The Electronic Prescription Centre and Prescription Archive (Kanta) should not be confused with data contained in Kela's databases on reimbursements for medical expenses, for which Kela is the body granting research authorisations. If data from Kela's reimbursement databases is required for the research project, separate authorisation must be sought from Kela. Kela's web pages on research authorisations is: http://www.kela.fi/web/en/research-projects_research-data-requests.

Preconditions for obtaining authorisation to access data

Disclosure and storage of client or patient data in the field of social and health care is possible for the purposes of a specific research project only. An appropriate research plan specifying the project and the data to be used must be attached to the application. Also a draft of the data file description must always be attached to the application. Permission can be granted to the person or organisation conducting the study, in other words, the research data controller. The data controller must be specified in the draft description of scientific research data file appended to the application. Data file description is a statutory document.

Models for data file descriptions can be found from this web page:

<http://www.tietosuoja.fi/en/index/materiaalia.html>

Data Protection Principles

The data controller is responsible for the research data and its processing. According to the Finnish Personal Data Act, data to be collected will constitute a personal data file whenever a person is directly or indirectly identifiable from the data. Even if personal identification numbers or other direct identifiers are stored separately from the data to be processed, the research data will be interpreted as being personal data under the Personal Data Act.

An important consideration in the maintenance of a personal data file is that of who has control over the study and the research data collected for it. When an individual researcher conducts a study in an employment relationship with a research institute or hospital, it is the research institute or hospital rather than the researcher that constitutes the research data controller. The decision of the organisation acting as the data controller on whether the study can be undertaken must be appended to the application. However, the researcher is usually the data controller when he or she is conducting his or her own study (such as a doctoral dissertation).

At all stages of personal data processing, the person/organisation conducting the research, i.e. the research data controller, must ensure that the privacy of the data subjects is not endangered. The implications of this for the research being conducted include the following:

- The data subjects' personal identifiers should not be collected if the study can be conducted without them;
- The procedures and implementation of the study must be designed so that as few people as possible have access to individual-level data concerning the data subjects (these persons must sign a non-disclosure agreement and authorisation to access personal data must be sought for them);
- Only authorised persons are entitled to use the research data file;
- Where possible, research forms must be designed so that the identifiers can be separated and destroyed when necessary;
- The data must be analysed without identifiers and/or personal data must be encrypted whenever possible.

Definition of the research life cycle

The research project must be limited in duration. In long-term research projects, re-evaluation of permission to access data is required at five-year intervals. If the research has not been started and the data for which the permission was granted have not been requested within the five-year permission period, such permission will be considered to have lapsed.

The Personal Data Act (523/1999) stipulates that, after the personal data are no longer required for the research or for the verification of the results achieved, the personal data file is to be

- destroyed,
- transferred into an archive, or
- the data in it are altered so that the data subjects can no longer be identified.

The research data files must be destroyed, archived, or permanently altered so that data subjects can no longer be identified at the latest upon the expiry of the research authorisation. The conditions for the research authorisation may also require that the licensing authority is notified of any destroying or archiving of data.

Since the personal data in social and health care are of sensitive nature, the research data files, as a rule, should be destroyed at the end of the research. Usually, a condition for archiving research data files

containing personal data is that the register controller is a public authority. Then, the register controller can archive the research data files in accordance with the Archives Act (831/1994).

A private register controller can archive a data file which is significant for purposes of scientific research or otherwise if the National Archives grants permission for it. The data can be transferred for archiving to an institute of higher education, a research institute operating on a statutory basis, or an authority.

The data can also be altered permanently so that the data subjects can no longer be identified. Allowing the possibility to identify data subjects must be considered on a case-by-case basis. For example, the deletion of names and personal identity numbers is often not sufficient to make the personal data file anonymous. Complete anonymity requires that the possibility for both direct and indirect identification is removed and that the code key is destroyed.

Regulatory Laws and Guidelines

National social welfare and health care registers and statistics are enacted in the Act on National Personal Records Kept under the Health Care System (556/1989), Decree on National Personal Data Registers Kept under the Health Care System (774/1989), Communicable Diseases Act (1227/2016), Act on the Statistical Service of the National Research and Development Centre for Welfare and Health (409/2001), Statistics Act (280/2004) and Act on Determining the Cause of Death (459/1973).

Social welfare and health care documents are enacted in the Act on the Status and Rights of Patients (785/1992), Decree of the Ministry of Social Affairs and Health on Patient Documents (298/2009) and Act on the Status and Rights of Social Welfare Clients (812/2000).

Regarding interventional medical research the Medical Research Act (488/1999) and the Medical Research Decree (986/1999; revised 65/2016) are applied.

When using biobank samples the relevant acts are the Biobank Act (688/2012), Act on the Medical use of Human Organs, Tissues and Cells (101/2001) and the Government Decree on Medical use of Human Organs, Tissues and Cells (594/2001).

5.6.2 Ethics

No ethical review is required by law for studies only utilising data from registers. However, some register holder authorities, such as National Insurance Institution (Kela), may require ethical review even though it is not statutory.

For interventional studies specified in the Medical Research Act (488/1999), ethical review is required from an ethical review board. It is important to note that in Finland, ethical statements from an ethical review board are not equivalent to statutory permission to access confidential data. If the study is interventional,

and thereby requires ethical approval by law, the opinion of an ethical review board must be sought before applying for authorisation to access confidential data.

5.7 ORGANISATION

Currently in Finland there are neither national guidelines nor funding for establishing quality registers. There is no national information service portal of the existing patient registers. The Finnish Information Centre for Register Research (ReTKi) has an information portal in the internet in English, in Swedish and in Finnish (<https://rekisteritutkimusen.wordpress.com>). However, ReTKi has no operative funding and it does not function anymore.

Patient registers have been established, however, on the national, regional and local level. Most of them are established and maintained by public university hospitals. In many cases they are interpreted as being part of the patient documents according to the Act on the Status and Rights of Patients (785/1992). In some cases data are collected by specific and written patient consent which determines the range of the utilisation of the register data.

The funding for the registers usually comes from the regional hospital district.

The National Institute for Health and Welfare has a service telephone line for research authorisation applications concerning health care registers. Contact details can be found at <https://www.thl.fi/en/web/thlfi-en/statistics/information-for-researchers>. Descriptions of the national register contents and the register-based statistical products are found from the webpage. Additionally, free statistical databases produced by THL in Finnish and in Swedish enable compilation of statistical tables without a separate authorisation process.

5.8 STATUS AND ACTIVITIES IN RELATION TO GOALS

Especially during the coming years many new clinical registers are going to be established by university hospital districts. There are ongoing discussions on whether the establishment and governance of the registers should be more organised nationally. For the time being, there have not been any plans to include quality registers into the national eHealth strategy nor legislation.

5.9 COLLABORATION WITH INDUSTRY

Currently register holders usually are very open for collaboration requests.

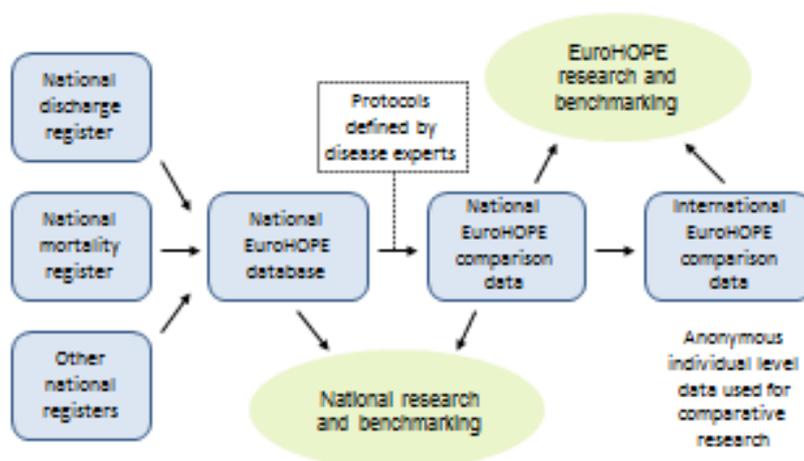
5.10 NORDIC COLLABORATION PROJECTS

Nordic collaboration is ongoing and such activities are treated positively and by the same regulatory standards as the national studies. The major register permission authorities, such as THL, have webpages available in Finnish, in Swedish and in English.

5.11 INTERNATIONAL COLLABORATION

International collaboration is treated as positively as the Nordic collaboration above. However, special restrictions apply in relation to utilising personal data outside the EU or EEA. If considering handling personal data outside of the EU or EEA, it is advisable to consult the Data Protection Authority or register permission authorities beforehand.

Figure 2 EuroHOPE databases



One very good example of international collaboration is the approach developed in PERFECT project that was adopted for evaluation of the performance of European health care systems (including Finland, Hungary, Italy, the Netherlands, Norway, Scotland and Sweden) in the EuroHOPE-project (<http://www.eurohope.info>). The EU funding (via the BRIDGE Health -project²) makes it possible to update and further develop the EuroHOPE research infrastructure towards evaluating the performance of

² BRIDGE= BRidging Information and Data Generation for Evidence-based Health Policy and Research; <http://www.bridge-health.eu/>.

health care systems in terms of outcomes, quality, use of resources and costs (Figure 2). This includes maintaining and updating the EuroHOPE protocols of selected diseases/conditions (acute myocardial infarction, stroke, hip fracture). The protocols include e.g. inclusion/exclusion criteria, definition of cycle of care (when it starts, follow-up etc.), comorbidities (used in risk adjustment) and specification of process, utilisation, and cost and outcome measures. National, regional and hospital level indicators will be calculated from Finland, Denmark, Hungary, Italy, Norway and Sweden. Furthermore, the database will be extended to include primary health care and social services in a study using data from the capital area of Finland (Helsinki, Espoo and Vantaa), Copenhagen, Madrid, Oslo and Stockholm.

5.12 PATIENT INVOLVEMENT

Currently there are no national patient involvement schemes in Finland in relation to patient registers. Patient-related measurement (such as PREM/PROM, QOL or other) is not required at the moment, but many regional registers are considering including them into the register and some are already collecting data.

5.13 POSSIBILITIES INTERNATIONALLY

International collaboration is treated as positively as the Nordic collaboration. Both academic and sponsored studies are treated affirmatively. The Ministry of Social Affairs and Health and Finnish Innovation Fund (Sitra) have together planned to establish an internationally oriented service operator for the secondary uses of Health and Welfare Data. The service operator would act as a data hub for national and international academic researchers and industry alike. The organisation is planned to begin operations at the beginning of 2018. At the moment preparatory materials of the project can be found here:

<http://www.sitra.fi/en/well-being/well-being-data>

5.14 WEBPAGES AND LINKS

The National Institute for Health and Welfare (THL)

<https://www.thl.fi/en/web/thlfi-en/statistics/information-for-researchers> (in English)

<https://www.thl.fi/sv/web/thlfi-sv/statistik/information-for-forskare> (in Swedish)

National THL Biobank

<https://www.thl.fi/sv/web/thlfi-en/topics/information-packages/thl-biobank> (in English)

<https://www.thl.fi/en/web/thlfi-sv/teman/informationspaket/thl-biobank> (in Swedish)

BBMRI.fi Finland

<http://www.bbmri.fi/> (in English)

Data Protection Authority

<http://www.tietosuoja.fi/en/> (in English)

<http://www.tietosuoja.fi/sv/index.html> (in Swedish)

Finnish Information Centre for Registry Research

<https://rekisteritutkimusen.wordpress.com/> (in English)

<https://rekisteritutkimussv.wordpress.com/> (in Swedish)

National Insurance Institution (Kela)

http://www.kela.fi/web/en/research-projects_research-data-requests

Digital Service Operator Data Hub

<http://www.sitra.fi/en/well-being/well-being-data>

5.15 SUMMARY FINLAND

Even though Finland does not have similar kind of national structure regarding quality registries as Sweden, Denmark or Norway have, health data can be utilised for quality improvement and research purposes. The majority of the national and regional data sets are in digital form and there are support functions for accessing health data especially in the university hospitals. Additional information can be found from the above mentioned web pages as well as from the national service telephone from the National Institute for Health and Welfare (THL).

NATIONAL OVERVIEW: ICELAND

5.16 INTRODUCTION

With a population of 330.000, Iceland is the smallest Nordic nation. More than half of the population lives in Reykjavik and area surrounding the capital.

Iceland maintains a universal health care system, under which all legal residents are covered by the Icelandic social insurance system. The basic structure of the Icelandic health care system is similar to the Nordic welfare model. However, the Icelandic health care differs from those of the other Nordic countries in some fundamental structural ways. The Icelandic health care system is more centralised in its governance structure, management, regulation, implementation and financing than the other Nordic countries. The Minister of Welfare oversees almost all health affairs. Decision-making, enforcement and management are all at the level of the central government.

The country is divided into seven health care regions, with limited autonomy from local management.

The funding of the health care system is mainly through taxes even though there is patient co-payment for visiting general practitioners, specialists and outpatient visits. Hospitalisation is free of charge. Children, disabled and elderly have lower co-payments. The ratio of publicly financed vs out-of-pocket costs is close to 82% / 18%.

In summary the Icelandic nation has good access to high quality services, evident by historically favourable health outcomes such as high life expectancy and low infant mortality.

The Ministry of Welfare is responsible for governing health services in the country. Most health care is delivered at primary care clinics, specialist's outpatient offices, health institutions and hospitals. There are two main hospitals, Landspítali University Hospital, Reykjavík and Akureyri Hospital, in Akureyri. Furthermore, there are twelve health institutions as well as numerous health care clinics spread out across the country.

With close to 5000 employees, Landspítali is by far the largest hospital in the country. It has a leading role in teaching, research and development in the health care sector. It serves as the only university hospital and therefore works in close collaboration with the University of Iceland and other universities around the country. All major complicated treatments and operations are performed at the hospital as well as treatment of rare diseases. Landspítali is a recognised research institution and collaborates with both domestic and international research organisations, institutions and industry.

Like the other Nordic countries, Iceland has a good reputation of collecting and using health data for quality and improvement. Data collection is carried out in a secure manner through strong information

systems. Iceland has developed a strong health data governance framework concerning health information systems with great data availability and maturity.

Around 90% or more of the key national health care datasets are being linked to other health and health care datasets to regularly monitor health care quality or system performance or to produce other approved statistics or research studies.

5.17 NUMBER OF REGISTRIES AND TYPES

There are no formal procedures for national quality registries in Iceland but health data is collected and used in a structured way that must comply with regulatory standards. There are two types of health registries in Iceland:

- Registries on health data operated by the **Directorate of Health (DOH)**. These registries are held in accordance with the Medical Director of Health and Public Health Act.
- **Landspítali** registries operated as part of medical records or as a part of quality management.

In addition to health registries, Statistics Iceland, the centre for official statistics in Iceland, collects, processes and disseminates data on the economy and society. Statistics Iceland is divided into four divisions – economic statistics, social statistics, business statistics and resources. These data can be linked to health data.

The Directorate of Health (DOH) is responsible for various types of registries concerning public health and the health care service. The DOH is a government agency operating under the authority of the Ministry of Welfare, headed by the Director of Health. Its principal role is to promote high-quality and safe health care for the people of Iceland, health promotion, and effective disease prevention measures. One of the responsibilities of the DOH, according to the Act on Medical Director of Health and Public Health, is to collect health-related information in a structured way in order to increase knowledge on health and health services as well as to ensure and increase the quality of the health services and for research purposes. The Act on Director of Health is the only legal base for operation of health registries in Iceland and is limited to the registries specified in the law. Establishment of new health registries would therefore require a modification to the pre-existing regulatory framework.

DOH operates the following health registries:

- Registry of births (maintained by Landspítali)
- Registry of cardiovascular diseases (maintained by the Icelandic Heart Association)
- Registry of cancer (established in 1954, maintained by the Icelandic Cancer Society)
- Registry of accidents
- Registry of admissions to health care facilities
- Health care centres' contact registry
- Self-employed specialist physicians' contact registry
- Diabetes registry
- Registry of causes of death
- Prescription database
- Registry of communicable diseases

All the above mentioned registries are run by the DOH, they are person-identifiable (although they are stored in encrypted form) and do not require consent from patients.

Even though the DOH is responsible for these registries it can hand over the day to day maintenance to other institutions/organisations. For example, the Icelandic Heart Association runs the cardiovascular registry and the Icelandic Cancer Society maintains the cancer registry. Any use of information from these registries must comply with the Data Protection Authority (DPA).

To access the health data from DOH's registries for scientific research purposes, an application has to be sent to the DOH. Approval from the National Bioethics Committee and the DPA is needed for all research involving the use of health care data from the registries.

Health care facilities, health care practitioners and others who provide health services are required by law to provide the DOH with the information it requires to maintain the health registries. The DOH gives health care facilities, health care practitioners, and others who provide health services, directives on the minimum required data recording for these purposes, and how data must be registered and submitted to the Directorate.

Gathering and handling of data under this provision must be in accordance with the provisions of the Act on the Protection of Privacy regarding the Processing of Personal Data, and accord with the DPA's criteria for security of personal data in health sector records.

Landspítali registries

Because of the important role of Landspítali as the largest hospital and the only university hospital, the registries kept at the hospital may in many cases be national rather than regional and are kept as a part of patient records. The purpose of the registries is to follow quality and efficacy of treatments and cost management. Secondary use of the registries includes the possibility of scientific research. For scientific research purposes, approval from an ethics committee and the DPA is needed as well as approval from the registry keeper who usually is the medical director of the department involved. The responsibility for the Landspítali registries lies in the hands of the Chief Medical Executive of Landspítali who is also responsible for the safekeeping of all medical records at Landspítali.

Landspítali has registries in the following fields:

- Paediatrics
- Gastrointestinal disease
- Communicable diseases
- Pulmonary diseases
- Renal Diseases
- Haematology
- Endocrine diseases
- Cardiovascular diseases
- Rheumatology
- Orthopaedics
- Polytrauma (as of January 2017)
- Neurology (as of 2017)
- Ophthalmology
- Gynaecology and Obstetrics

5.18 PURPOSE

The purpose of the DOH registers is to gather information on health and the health service, to monitor the service, to ensure its quality and assess its success. The registries are also used in planning for quality improvement in the health service and in scientific research.

The main purpose of the Landspítali registries is quality control, as a means of following up the outcome of treatment. Secondary uses include cost management and scientific research.

5.19 VISION

There is no current effort to establish national quality registries on behalf of Icelandic health authorities. However according to the Ministry of Welfare's policy on welfare and health to 2020, emphasis is being focused on increased use of databanks and biobanks as well as international collaboration with academia and industry. Establishment of national quality registries would harmonise with that policy. Thorough inspection is needed on the regulatory environment of registries as well as an estimation of cost versus benefit of establishing national registries.

Key players in that effort would be DOH, Ministry of Welfare, DPA and Landspítali.

The major improvement of quality registries in Iceland would be the extension of the cancer registry, operated for DOH by the Icelandic Cancer Registry. Transition is planned from health registry to quality registry in close collaboration with Landspítali and its professionals.

The structure of the Icelandic health care system, being more centralised than the other Nordic countries, could facilitate the establishment of national quality registries.

The University of Iceland is collaborating with various institutions to create a data portal which would make health-related data from disparate sources available through a single point of access. Available data would include hospital records, primary care records, data from social and health insurance, and registries maintained by the Directorate of Health. No central database is planned but a common method of cleaning and encrypting data will be established so that searching across databases, linking, and extracting data will become more efficient. Collaborators include Landspítali, Directorate of Health, Ministry of Welfare, Primary Health Care of the Capital Area, Social Insurance Administration, and Icelandic Health Insurance.

5.20 FUNDING

Funding of registries is provided from the budget of institutions involved. Public funding for research projects is provided by the Icelandic Centre for Research (Rannís), which is under supervision of the

Ministry of Education, Science and Culture. Rannís works closely with the Icelandic Science and Technology Policy Council hosted at the Prime Minister's Office.

5.21 LEGAL ASPECTS AND ETHICS

All use of registry data for scientific purpose needs approval from an ethics committee (EC) and the DPA. The EC application process automatically includes an application to the DPA, as the EC forwards the application to the DPA, which has 10 working days to review it. The EC takes up to 30 days for approval, including the 10 days the DPA has to make comments. The EC application process is free of charge.

In Iceland there are 2 types of ethics committees, the National Bioethics Committee (NBC) and institutional review boards. Currently there are 2 institutional review boards, one at Landspítali and the other one at Akureyri Hospital. For research performed using data gathered entirely within the institutions, applications to those internal review boards is sufficient. In case of clinical trials or research projects involving a sponsor or collaborator outside of the institution, NBC approval is needed. All clinical trials on medication or medical devices also need approval from the Icelandic Medicines Agency.

There was no mention of registries in laws/regulations until 2007 when new laws on DOH were enacted.

Laws and regulations regarding health registries are as follows:

Act on Medical Director of Health Act on Medical Director of Health and Public Health (no 41/2007) Article 8 covers reports and health records. The Medical Director of Health Act provides for the Medical Director's function to organise and maintain national registers on health, diseases, accidents, prescriptions, births, and the work and performance of the health services. The aim of these registers is, among other things, to provide an overall picture of the health of the Icelandic people and the utilisation of health care services, keep up monitoring and assess the quality and efficiency of the service. The act states which registries the DOH is obligated to keep and which registries are allowed to include personally identifiable information without patient consent. All personal identifiers must be encrypted. The DOH is allowed to take over already existing registers (like the cancer registry, from 1954). All data use from such registries needs approval from an EC and the DPA. All health care providers and health institutions are obligated to provide the DOH with information for the registries. The act on the DOH and public health was followed up by:

Regulation on Health Registers (no 548/2008) The regulation further explains which information should be collected for each registry and the main purpose of each registry.

Act on Scientific Research in the Health Sector (no 44/2014) The act addresses all aspects of scientific research such as retention of health information materials (health data and biological samples).

Act on Health Records (no 55/2009) Addresses access to medical records (Landspítali registries are classified as medical records).

The Biobanks and Health Database Act (no 110/2000) The main objective is to authorise the collection, keeping, handling and utilisation of human biological samples and other health data, which are acquired for scientific research in a way that ensures confidentiality. The act states that the establishment and operation of a biobank and a health data bank require a license from the Minister of Health after having received the opinion of the DOH, NBC and DPA. A board of at least 3 people is to monitor its operation. When a biological sample is collected for a scientific purpose, informed consent must be sought. A donor can at any time withdraw his or her consent. Samples and health data must be unidentifiable. An amendment from 2014 allows cohort discovery databases to evaluate the feasibility of scientific research.

Act on the protection of privacy as regards the processing of personal data and handling of personal information (Data Protection act no 77/2000) The objective is to promote the practice of personal data processing in accordance with fundamental principles and rules regarding data protection and privacy and to ensure the reliability and integrity of such data and their free flow within the internal market of the EEA. Article 29 describes transfer of personal data to countries that provide an adequate level of personal data protection and article 30 describes transfer of personal data to a country that does not provide an adequate level of personal data protection.

Rules from the Data Protection Agency on notification and approval required handling of personal data (no 712/2008) states which kind of personal data processing needs approval from the DPA and which only needs to be reported to the agency. Joining data from separate registries requires prior approval from the DPA.

Regulation on clinical trials of medicinal products in humans (no 443/2004)

Act on Public Support for Scientific Research (no 3/2003)

Medicinal Product Act (no 93/1994) states that the Directorate of Health must operate a medicinal products database covering prescriptions and dispensed products

Act on Health Security and Communicable Diseases (no 19/1997) states that the Chief Epidemiologist, located at the Directorate of Health, is responsible for maintaining a register of communicable diseases.

EU Data protection law and implications

The domestic version of the Data Protection law is being drafted by the Ministry of Welfare and the Ministry of Internal Affairs (it has to be implemented through the EEA contract) and with Data Protection Authorities. Comes in to force in 2018.

5.22 ORGANISATION

The key organisations regarding health data and registries are the Directorate of Health, Landspítali, Statistics Iceland and Primary Health Care of the Capital Area. Main domestic research collaborators include Decode Genetics, Icelandic Heart Association, The Icelandic Cancer Society, University of Iceland, University of Reykjavik and University of Akureyri.

Collaborations with industry

Landspítali has close collaboration with industry including pharmaceutical companies, companies in biotechnology and medical device industry companies.

Nordic collaboration projects

Paediatrics diabetes registries

Pan-Nordic RA Register Network

Swedheart (SCAAR (Coronary angiography and PCI)

Swedvasc

InfCare (HIV)

NordicSCIR

ANCR - Association of Nordic Cancer Registries (nordcan)

Cornea Transplant registry

CPUP

5.23 INTERNATIONAL COLLABORATION

European network of cancer registries. EUROCARE-project

International Agency for Research on Cancer, (IARC)

5.24 INTERNATIONAL POSSIBILITIES

Health care and research authorities in Iceland encourage and facilitate international collaboration.

Landspítali is active in international collaboration both with industry and academy. Around 85 % of Landspítali's publications in health science involves with foreign collaboration.

5.25 WEBPAGES AND LINKS

The Directorate of Health <http://www.landlaeknir.is/english/>

University Hospital of Iceland <http://www.landspitali.is/um-landspitala/languages/english/>

National Bioethics Committee <http://vsn.is/en>

The Icelandic Data Protection Authority <http://www.personuvernd.is/information-in-english/greinar/nr/438>

Statistics Iceland <https://www.statice.is/>

Ministry of Welfare <https://eng.velferdarraduneyti.is/acts-of-Parliament/nr/20093>

OECD Report on Health Data http://www.oecd-ilibrary.org/social-issues-migration-health/health-data-governance_9789264244566-en

5.26 SUMMARY ICELAND

-In Iceland there is no formal structure of quality registries. The establishment of new registries would demand changes in law.

-There are two types of health registries, registries operated by the Directorate of Health in accordance with law and patient registries operated as part of medical records. Health registries are used for quality improvement, statistics and research.

-Like the other Nordic countries, Iceland has a good quality health care system. Health governance is centralised which should facilitate decision making, enforcement and management.

-Generally good state of affairs on health data governance. Health data is collected and used in a structured way, it has high reliability and data availability is strong. Key national health datasets share the same unique patient ID number. Linking of health data is performed on regular basis.

6 NATIONAL OVERVIEW: NORWAY

6.1 INTRODUCTION

Norwegian health care has three political and administrative levels; the state, the four Regional Health Authorities and the 428 municipalities. The municipalities are responsible for primary health care for the population, and the four Regional Health Authorities (RHAs) provide inpatient health care for the inhabitants.

The first national quality registry was started in 1987, the Norwegian Arthroplasty register. In 2009, the Ministry of Health and Care Services (MOH) allocated earmarked funds for development of infrastructure for medical quality registries, and the number of national medical quality registries has increased from 19 in 2009 to 54 in 2017.

6.2 NUMBER OF REGISTRIES AND TYPES

Mandatory health registries

The Norwegian Institute of Public Health and the Directorate of Health holds the 18 mandatory national health registries in Norway (such as Cause of Death Registry, Medical Birth Registry of Norway, Norwegian Cardiovascular Disease Registry, Cancer Registry of Norway and Norwegian Patient Register). Data from these registries are used for health analysis, health statistics, improving the quality of health care, research, administration and emergency preparedness. Via the unique citizen identifier it is possible to link the mandatory health registries and the national quality registries.

Care providers are legally obliged to report to the 16 mandatory national health registries. For the national quality registries, the Ministry of Health has tasked the four health care regions with ensuring that the hospitals report to these, but it is not governed by law.

National quality registries

In May 2017 there are 54 national quality registries in Norway.

Certification level is a rating given to each registry and represents the level of development the registry has reached in terms of data quality and reporting, coverage rate, availability of results for clinicians and patients, use in clinical improvement work etc. There are four levels in total – 1 (lowest), 2, 3 and 4 (highest).

The national quality registries cover disease entities, specific interventions or specific activities. They contain data related to diagnostic procedures, treatment and outcomes of patients.

The type of quality registries by disease areas:

- Circulatory system (9 registries)
- Cancer (8 registries)
- Musculoskeletal system (6 registries)
- Nervous system (4 registries)
- Lung diseases (2 registries)
- Emergency medicine and intensive care (3 registries)
- Endocrine organs (3 registries)
- Rehabilitation (3 registries)
- Infection (1 registry)
- Gynaecology (2 registries)
- Psychiatry (1 registry)
- Stomach and intestines (3 registries)
- Other areas (9 registries)

A detailed list is given on this website: www.kvalitetsregistre.no

6.3 PURPOSE

The quality registries are used as a way to measure, follow-up and monitor the quality and results of the health care system.

They contain data on diagnosis, events, treatments, and results within the health care system, and are certified by the Directorate of Health.

The objective is to evaluate whether the health care meets the requirements of good quality care.

6.4 VISION

The vision is that the medical quality registries improve health care in Norway.

“Good quality registries – better health”

6.5 FUNDING

In 2009, the Ministry of Health (MOH) allocated earmarked funds for development of infrastructure for medical quality registries.

Thirty-two million Norwegian kroner (1EUR= 9 NOK) from the framework of the Regional Health Authorities were earmarked for the establishment of the Norwegian Advisory Unit for Medical Quality Registries (NOK 12 mill), further development of common technical solutions (NOK 6 mill), and for distribution between the Regional Health Authorities (RHA) for the development of common infrastructure (NOK 19 mill).

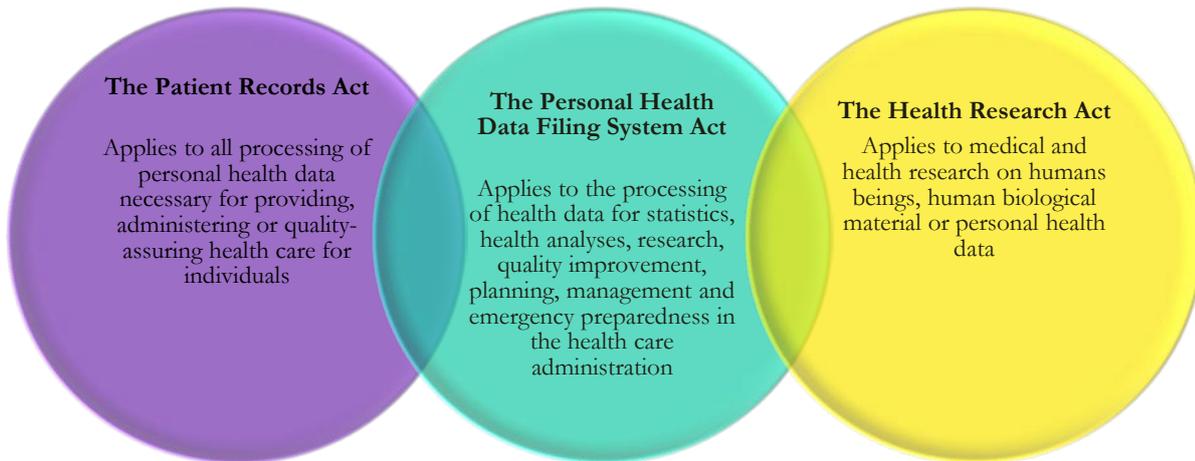
At the same time, MOH stated that the Regional Health Authorities have the financial and legal responsibility for the operation of national medical quality registers, and the responsibility to ensure that all relevant hospital units report to the established national quality registers.

The national quality registries are thus provided with developmental guidance/assistance and implementation of ICT infrastructure from national earmarked funds, while the responsible RHA ensures funding of the ongoing operations.

6.6 LEGAL ASPECTS AND ETHICS

6.6.1 Legal aspects

Scope of application for the Patient Records Act, the Personal Health Data Filing System Act, and the Health Research Act.



The Personal Health Data Filing System Act regulates the processing of personal health data where the main purpose is to form a basis for statistics, health analyses, research, quality improvement, planning, management and emergency preparedness (secondary use). The current Personal Health Data Filing System Act entered into force on 1 January 2015.

<https://lovdata.no/dokument/NL/lov/2014-06-20-43>

According to the Personal Health Data Filing System Act, Section 6, personal health data may only be processed when permitted:

- Directly pursuant to law (by the Personal Health Data Filing System Act itself or another act)
- Pursuant to regulations issued under law (such as regulations issued under the Personal Health Data Filing System Act Sections 8 to 12);
- Pursuant to a license from the Norwegian Data Protection Authority issued in accordance with the Personal Health Data Filing System Act Section 7.

If there is a legal basis in law or in regulations issued under law, there is no need to apply for a licence from the Data Protection Authority, but the data processing may nevertheless be subject to notification.

Consent as a principle

The personal health data in health registries must either be obtained from the data subject him/herself or from another source, normally patient records. Consent must normally be obtained from the data subject before his/her data can be processed in a health registry, unless otherwise provided for by or pursuant to law.

The Personal Health Data Filing System Act, Section 2, requires that the consent must be a *“freely given, specific and informed declaration by the data subject to the effect that he or she agrees to the processing of personal health data relating to him or her.”*

No requirements apply as to the form in which consent can be given (i.e. it can be given orally or in writing). As a general rule, however, it should be documentable, since the data controller must be able to substantiate that consent has been obtained.

Consent can be withdrawn at any time. In principle, withdrawal of consent only applies to future processing of the data and not to analyses that have already been carried out or to anonymous material.

Legal basis for medical research under the Act on Medical and Health Research (the Health Research Act)

Medical and health-related research is regulated by the Health Research Act. The use of data that is covered by the Health Research Act's provisions requires a processing basis in the Health Research Act, even if the registry was originally established under the provisions of the Personal Health Data Filing System Act. At the same time, research is conducted that does not fall under the Health Research Act, and where the use of the data is covered by the Personal Health Data Filing System Act. The registry's objective and nature will then be decisive in relation to which act is to apply.

<https://lovdata.no/dokument/NL/lov/2008-06-20-44>

The Health Research Act requires that an application for prior approval of a research project must be submitted with the research protocol to the regional committee for medical and health research ethics. Prior approval from the regional committee for medical and health research ethics is necessary and adequate authority to process personal health data in medical and health research.

Consent is the main rule. Consent must be obtained from participants in medical and health research, unless otherwise laid down in law. Consent must be informed, voluntary, express and documented. Consent must be based on specific information about a concrete research project, unless there is a case for granting broad consent. The regional committee for medical and health research ethics may decide that personal health data can and shall be handed over by health personnel for use in research, and that this may be done notwithstanding the duty of confidentiality. The same applies to data gathered by the health service. This may only be applied if the research in question is of significant interest to society, and the participant's welfare and integrity are ensured.

Processing of personal health data in medical and health research must have expressly indicated objectives. The personal health data must be relevant and necessary to achieve the objective of the research project. The degree of personal identification in the health data must not be greater than is necessary to serve the intended purposes.

In the event of approval pursuant, the regional committee for medical and health research ethics may deny comparison or surrender of data if this is deemed to be medically or ethically unsatisfactory.

6.6.1.1 REGULATORY QUESTIONS AND ANSWERS

In this section, answers may be found to commonly asked questions regarding regulatory aspects of Norwegian quality registries.

General

National quality registries - used for what?

All national quality registries have to adopt the overall primary purpose; securing and developing the quality of care, along with more specific purposes for the specific registry.

The precise purpose could for example be to develop and secure the quality of a specific diagnostic group. The information in a national quality registry may then be used under these specified purposes. Additionally, the data may be used for secondary purposes such as statistics and research in health care.

Who is responsible?

For each national quality registry there is a CEO at a hospital that is central data controller. This includes responsibility for the overall security of the quality of the register, that incorrect data are corrected or destroyed upon request. There is usually a health region executive or equivalent who is the central data controller and has the formal responsibility for the registry.

Collect data

1. Who is responsible for report and data input a Quality Registry?

Health care providers record data in national quality registries, and are responsible for their own data management in connection with patient registration and, at a later stage, the use of results for local quality improvement.

2. What information may be included in a national Quality Registry?

The objectives of the national quality registry are documentation, improvement and communication of quality in health care institutions. Therefore, only variables which serve this purpose can be entered into the registry. This definition allows for inclusion of variables concerning context necessary for adjusting and interpreting the values of quality indicators.

3. Can a Quality Registry obtain information from any source other than the patients and their medical records?

Yes, if the patient is informed and does consent to this.

4. Can a Quality Registry change its purpose over time?

Yes, if approved by the Data Protection Authority and central data controller. The patients included in the registry have to be informed of the change in purpose.

Protect

5. How long can data be stored in a Quality Registry?

The Norwegian Data Protection Authority decides the time limit for data storage in a quality registry. The number of years data can be stored varies between the registries. Quality registries that are regulated by law (cardiovascular diseases and cancer) do not have a time limit for data storage.

6. How to protect personal data in a national Quality Registry

Details of quality registries are subject to the same protection as medical records. Therefore it is appropriate that the handling of personal data in a quality registry, as far as possible, is similar to the caregiver's handling of patient records.

When data are to be presented openly, for example to inform the public about the quality of health care, this must be done in such a way that the individual's identity is not disclosed.

The security requirements also mean that the authority is centrally responsible for protection of the data in the registry. This includes keeping a register of infringements and ensuring that disclosure of information is done in a safe manner. The latter means e.g. the staff of a health care provider must

sign in with a solution for strong authentication to the internet to take part of the reported data at the individual level.

Usage

7. **Who can have direct access to information in a National Quality Register and what information must they access?**

Caregivers who have registered data have access to the personal data of the patients they have included in the registries, for the purpose of ensuring correct data entries, and to use the data for quality improvement. Use of the registry in the context of individual patient care is not allowed. Access to aggregated statistical data from registries presented without personal identities being disclosed are generally open for professionals, management and the public.

8. **Is ethical review of research of data from the national Quality Registries required?**

Data collected in a quality registry may be used for research in health care. Ethical review of research involving humans is required. Research on sensitive personal data always requires approval from an ethics board, regardless of whether the data is available in a patient, in a national quality registry or any other information collection in health care.

9. **Can national Quality Registries work with private actors such as pharmaceutical companies?**

Yes, but there is an agreement between the four Regional Health Authorities and the industry that must be respected.

Patient rights

10. **Can data from a Quality Registry be transferred to another country?**

With the patients' consent, it is possible to transfer personal data to another country. There are national regulations on how transferal of data should be performed.

11. **What rights does a patient have regarding Quality Registries?**

Participation in most quality registries is voluntary. Patients have to sign an informed consent statement before data are collected. If the patient does not want the data recorded, the patient can refuse to sign the informed consent. However, some quality registries are mandatory (cardiovascular diseases and cancer), and no consent is required for inclusion of patients.

The patient has the right to know what information has been recorded. The patient can request correction of information not handled in accordance with the Personal Data Act. The patient has the right at any time to have all their data deleted from the register.

12. **Can the patient record information in a national Quality Registry?**

Yes, in the form of patient-reported outcomes.

Protect

13. **How to protect personal data in the national Quality Registries**

Data in quality registries are subject to the same protection as medical records (and other confidential person related information). Therefore, the handling of personal data in quality registries follows the same rules as those which apply for patient records.

6.6.2 Ethics

Privacy, patient interests and social interests

The Personal Health Data Filing System Act safeguards three areas in particular: *privacy*, *patient interests* and *social interests*.

Privacy is not defined in more detail in the Act, but is related, among other things, to the individual's control of what information about him or her is available to others. The data subject's consent is therefore a requirement for all processing of personal health data unless otherwise provided for by law. Human rights treaties form the most important formal basis for sets of rules on privacy at both the national and the international level. The Personal Health Data Filing System Act is based on the EU's Data Protection Directive.

The key *patient interest* is the best possible health care. Relevant social interests include ensuring efficient utilisation of common resources, management and administration of the health sector. The use of personal health data and health registries for research and statistics is necessary to quality assure health care and to ensure efficient resource utilisation in the best interest of society.

In the event of conflict between considerations for the individual's integrity and other interests, weighty arguments are required to outweigh the privacy considerations.

Vetting the ethics of research involving humans

1. All processing of personal health data must have an explicitly stated purpose that is objectively justified by the activities of the data controller.
2. The controller must ensure that the personal health data that are processed are relevant to and necessary for the purpose of the processing of the data.
3. Personal health data may not be used for purposes that are incompatible with the original purpose of the collection of the data without the consent of the data subject.

Ethics committee application

The activities of the Regional Committees for Medical and Health Research Ethics (REC) are founded on the Norwegian law on research ethics and medical research.

The aim of the Health Research Act is to promote good quality, ethically acceptable medical and health research. REC carries out an assessment as to whether research is undertaken in an acceptable manner. This entails the consideration of benefit versus risk and whether data protection is assured.

REC is to provide advance approval for:

- Medical and health research projects,
- General and thematic research biobanks,
- Dispensation from professional secrecy requirements for other types of research.

The seven regional committees include people with different professional backgrounds, lay representatives and representatives for patient groups. The committees are appointed by the Ministry of Education and Research for a four-year term. The application deadlines are the same for all committees. The regional boards have 9 meetings per year. New projects are assigned to the region in which the Chief Investigator has his or her main place of work. Applications must be sent to REC in electronic format. Application to the REC is free of charge, and needs to be filled out in Norwegian.

For more information:

https://helseforskning.etikkom.no/ikbViewer/page/forside?_ikbLanguageCode=us

6.7 ORGANISATION

The Ministry of Health and Care Services (MOH) allocates the funds for development of quality registries between the four regional Health Authorities (RHAs).

The Directorate of Health approves the establishment of new registries proposed by the RHAs.

The RHAs have the legal, financial and operational responsibility for the national medical quality registries.



The Norwegian Ministry of Health and Care Services (MOH) gives the health regions specific assignments for the development of quality registries (coverage, completeness, PROMs, use in clinical quality improvement).

There is an organisation around each national quality registry. For every quality registry there is a steering committee and a person responsible for personal data. The steering committee includes professionals from all four health regions.

The quality registries are supported by the Norwegian Advisory Unit for Medical Quality Registries, which has a central office in Tromsø, and local offices in all four health regions. The Advisory Unit offers support in designing a quality registry, legal issues, development of ICT-platform, data analysis and presentation of results, validation studies and use of quality registries in clinical improvement.

For more information: www.kvalitetsregistre.no

6.8 STATUS AND ACTIVITIES IN RELATION TO GOALS

There is a national 5-year strategy for the national quality registries for 2016-2020.

The effect goals for the end of 2020 are:

- all national medical quality registries will have a coverage of at least 80%;
- all national medical quality registries will provide on-line results to clinicians who provide data to the registry
- all national medical quality registries will, in cooperation with clinicians, document the use of registry data for clinical improvement
- 85 % of the national medical quality registries will present patient-reported results.

Focus areas in the strategy are:

- Data quality and coverage in quality registries;
- The use of quality registry data in quality improvement;
- National quality indicators from national quality registries;
- Increased patient safety with the use of quality registries;
- Patient involvement in national quality registries;
- Increased use of data from quality registries in research;
- Effective ICT- solutions for quality registries;
- Legal and financial issues for quality registries.

6.9 COLLABORATION WITH INDUSTRY

There is great interest from the industry for health registry data. A general agreement between the Regional Health Authorities and the industry association has now been signed to allow collaboration.

6.10 NORDIC COLLABORATION PROJECTS

There are several Nordic research collaboration projects, in which Norwegian quality registries are involved (e.g. arthroplasty registries and cardiovascular registries). There is, however, no national overview of these projects.

There are several collaborative projects working on development of Nordic quality registries. These are two examples of Norwegian initiatives:

NordicScir

The Norwegian Spinal Cord Injury Register (NorSCIR) was established in 2009. NorSCIR includes individuals with a spinal cord injury, both traumatic and non-traumatic.

In 2013, NorSCIR was contacted by the Norwegian Directorate of Health to initiate a pilot project for establishment of Nordic cooperation on highly specialised treatments on behalf of the Nordic Council of Ministers.

Main objectives of NordicSCIR:

- to improve care for individuals with SCI;
- to facilitate comparisons regarding injuries, treatment, and outcomes between patients, centres and countries;
- to provide important data for prevention.

NordicSCIR is planned to be in operation from January 2017.

HISREG

The Nordic registry for Hidradenitis suppurativa (HISREG) was established in Norway in 2012, at first as a Norwegian registry.

Patients with Hidradenitis suppurativa (HS) have small, painful lumps under the skin. They typically develop where the skin rubs together, such as the armpits, the groin, between the buttocks and under the breasts. The lumps may break open and smell or cause tunnels under the skin.

There are no international guidelines for treatment, and differences in treatment both between and within countries.

This is a Nordic collaboration between Norway, Sweden, Denmark and Iceland.

6.11 PATIENT INVOLVEMENT

It is a requirement that all national quality registries have patient-reported measurement included in the registry (PREM/PROM).

Furthermore, patient representative(s) should be part of the registry steering committee.

6.12 POSSIBILITIES INTERNATIONALLY

There are several topics of interest in Nordic cooperation between quality registries:

- The rare disease registries with small patient populations in each Nordic country (e.g. NordicScir and HISREG)
- International benchmarking
- As a source for “real life data” for follow up and surveillance of safety

6.13 WEBPAGES AND LINKS

National Quality Registries: www.kvalitetsregistre.no

Mandatory health registries: <https://www.fhi.no/hn/helseregistre-og-registre/>

www.lovdata.no

Personal Health Data Filing System Act: <https://lovdata.no/dokument/NL/lov/2014-06-20-43?q=helseregisterloven>

The Health Research Act: <https://lovdata.no/dokument/NL/lov/2008-06-20-44>

Ethics committee application:

https://helseforskning.etikkom.no/ikbViewer/page/forside?_ikbLanguageCode=us

6.14 SUMMARY NORWAY

- The state allocates funding for development of the national medical quality registries, and the four Regional Health Authorities have the operational responsibility for these registries.

- Consent must normally be obtained from the patient before inclusion of personal health data in a national quality registry. However, some national quality registries (Cancer Registry of Norway and Norwegian Cardiovascular disease registry) are non-consent-based health registries.
- National quality registries are used as a tool to get structured information about patient care, and to assure that the health care delivered is of high quality.
- Results from national quality registries should be used for clinical improvement, but are also useful for management, statistics and research in health care.
- Patient related measures should be included in all national quality registries, and patients should be represented in the steering committees of the registries.

7 SUMMARY OF SIMILARITIES AND DIFFERENCES BETWEEN THE NORDIC COUNTRIES

7.1 COMPARISON – SIMILARITIES AND DIFFERENCES

Legal aspects-Nordic countries

The legal regulation of the Nordic countries on operation and handling of personal data and the protection of sensitive information about personal relationships have many similarities. This is because the countries share a common Nordic legal tradition, as well as national regulations on the processing of personal data harmonised through the EU Data Protection Directive.

Health care professionals in the Nordic countries are covered by penalty sanctioned confidentiality laws, which facilitate the exchange of sensitive health data, if required.

Even within registry research there are similarities. For example the Norwegian law on clinical research (Medisinsk og helsefaglig forskning), ethics committee (Regionale komiteen for Medisinsk og helsefaglig forskningsetikk) can decide by ethics approval, whether an investigator or researcher may process sensitive data in the context of a research study without the data subject's consent. The regulation is similar to the Swedish Ethical Review Act.

There are differences too. In Sweden, a decision by an ethics committee does not include the release of data from the example caregivers, while Norway handles such matters through the ethics committee/regional committee. Sweden considers a personal data processor and the controller of personal data to be different responsibilities, which means that information is usually disclosed to counsel staff. In Norway, however, a personal data processor is automatically considered to be part of the controller of personal data, and subject to the same penalty sanctioned secrecy provisions as the data controller. It helps considerably for a data controller authority to disclose information covered by strong privacy.

Existing Nordic networks

Nordic registry collaborations – examples (table) – summary of information in section 5-8

OVERALL-SIMILARITIES / DIFFERENCES

	SW	DE	NO	FI	IC
National organisational structure present	National structure with regional nodes	Different, <i>Only one supporting organisation</i>	Same	Different <i>No national organisation.</i>	Different <i>No national organisation.</i>
IT structure and data transfer	IT structure coordinated by national service contractors, many IT-platforms	Different <i>IT structure owned by supporting organisation, converging towards one system</i>	Different <i>Three approved IT-platforms supported by the national authorities</i>	Different <i>No national coordination</i>	Different <i>No national coordination</i>
Data Security	Adherence to EU legislation	<i>Acts on processing of personal data (EU directive)</i>	Same	Same	Same
Data quality monitoring and improvement, Inclusion procedures	Registries are responsible and carry out the work. National/regional support provided..	Different	Same	Different <i>No national coordination</i>	Different <i>No national coordination</i>
Inclusion procedures	Exemption from patient consent for mandatory registries Oral consent for quality registries Written consent for research	<i>Research exempted from patient consent, requires separate approval from data protection agency.</i>	Exemption from patient consent for mandatory registries Written consent for quality registries, which includes research		<i>No consent needed for mandatory registries.</i>
Research and biobanking	Registries can be used for research after application to the registry holder/responsible authority. Ethical approval is required. Biobanks are available, and are available for research after application to the responsible authority. Ethical approval is required.	Different. <i>Biobank coupling of data to registries requires ethical committee approval <u>and</u> patient consent</i>	Same	Same	Same

8 ACTION CHECKLIST

In order to support and encourage collaboration within Nordic health care, registries and their collaborators need to consider a number of important and concrete aspects of What, When, Where, Who, for Whom. This can be facilitated by the information provided in this guide, the accompanying links, and not least, contact with national experts and experts in the health care area of interest.

This checklist contains critical aspects identified by the project group for this guide, and will be continually developed and adapted within the years to come. Comments and suggestions are most welcome.

Of course, each user may also add aspects relating to their own project specific needs.

	Planned project	Present situation	Possibilities -> Revised Planned project	Necessary Actions
Definition of population	<ul style="list-style-type: none"> - One country = one population - Several countries = one population 	What established processes for data gathering, transfer and storage exist for the registries to use?	What design of process for data transfer and processing would work?	Set up secure and stable routine for data transfer and data storage
Registry data content	<ul style="list-style-type: none"> - International guidelines - National guidelines - Combination of guidelines and local adaptations 	Are there existing registries? Which data do they register? On which basis? Similarities? Differences?	Which "model" fits?	Make adaptations to make the model function in reality
Project scope	<ul style="list-style-type: none"> - One project, pre-defined - Few projects, adaptive content - Collaborative projects, > 5 years 	Are there established groups of networks for improvement work and research? Are similar projects running right now? Can we make use of previous experience, or experience from other registries?	Which "model" fits?	Form necessary collaborations and establish formal agreements Gather and re-use previous material
Required registry knowledge and/or	- Tailored project to fit on site	How much specialised knowledge on the	What level of experience and	Recruit necessary resources (hour-

registry analysis expertise	development of clinical practice - Project harmonising with multi-site international collaboration	registries do we have, and what do we need? How much expert knowledge do we have on data management and statistical analysis of registries?	expertise is needed?	by-hour, contracting etc)
Analytical scope (visualisation, quality improvement or research)	Descriptive presentation of data Analysis of aggregated data Analysis of personal data	What level of maturity of analysis do we have?	How much further do we need to reach, and what does that take?	Write up application for ethical approval? Contact authorities with application for data linking with other data sources?
Itemised project planning	For example Register historical data Revise patient information Inform registry users Extract and quality check data Analysis	Where is much work needed? What takes most time, and how long? What may need to be repeated/revised?	What would a suitable version 1.0 for an itemised time scheduled project plan look like?	Flow chart (incl. ethical approval and other applications) -> realistic time perspective and efficient project performance

9 CONCLUSION AND RECOMMENDATIONS

9.1 CONCLUSIONS

- Nordic collaboration using quality/patient registries is possible as academic, benchmarking, observational and industry initiated studies.
- The legal frameworks in all Nordic countries are currently not clear, therefore it is important to plan well in advance and to discuss the following areas in detail and in advance: data, IT, legal, ethics.
- A role model for international collaboration could be the Nordic Arthroplasty Register Association (NARA). The Nordic countries, including Denmark, Sweden, Finland and Norway have all had a long and successful tradition of arthroplasty registries. The collaboration has been successful because these countries were able to agree on a common dataset, variable definition, and merge data. Collaboration was also successful because the group was able to initiate a number of research projects and provide answers on clinical questions. A joint Nordic standpoint towards other international register associations is also part of the overall aim of NARA.
- This project has resulted in Finland and Iceland starting up discussions about possibilities, access and coordination of requests for international collaboration. This will hopefully develop further.
- A checklist has been developed for registries entering into collaboration with key questions as a tool.
- Another checklist has been developed for actors outside registries who would like to use the registries for their research. See the appendix to this document.

9.2 SUGGESTIONS FOR IMPROVEMENT

- New Data Protection Act: Implementation of this act may result in differences that make the collaboration between the Nordic countries more difficult. Therefore the legal representatives from the different Nordic countries should take actions for similar implementation of the new data protection act during the coming 6 months.
- When applying for linkage of data by the authorities, a pre-set time limit should apply in order to be able to plan the time schedule for researcher studies based on quality/patient registries.

- To develop a Nordic research infrastructure and platform that enables researchers to use quality register data and link them with other registries available in the Nordic countries
- Solutions that enable and secure financing and unbiased registry work should be supported by NordForsk and the Nordic ministries of health and welfare
- Approvals by ethical and health authorities should preferably be coordinated by a national centre.
- One ethical approval should be enough for a clinical research project using registries within the Nordic countries.
- Enabling legal, organisational and IT-solutions to follow patients through admission, transfer between different care givers, to discharge and long-time follow-up should be consider. This would result in complete follow up of patients in registries.
- A forum for exchange of experiences of collaborations between the Nordic countries, should be facilitated to improve for the future.

Checklists

- Visualisation of considerations
- Quick guide

PROCESS MAP

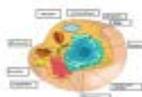


PERSPECTIVES

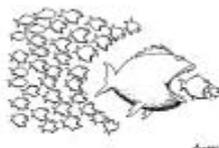
FOUNDATION



SUM AND PARTS



DIRECTION OF MOVEMENT



Quick guide

1. REVIEW THE LEGAL ASPECTS AND LAWS
2. EVALUATE POSSIBLE AND EXISTING FORMS OF COLLABORATIONS
3. EVALUATE NEEDED AND EXISTING COLLECTED VARIABLES
4. ESTABLISH CONTACT WITH AUTHORITIES AND REGISTRIES
5. EVALUATE NEEDED AND EXISTING COLLECTED VARIABLES
6. SET UP FORMAL AGREEMENTS AND PROJECT ORGANISATIONS