

**FIRST EDITION**

# **HANDBOOK**

**for establishing quality registries**

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## Foreword

This handbook is primarily intended for those who wish to establish a National Quality Registry. Much of the contents are however also relevant to regional or local quality registries. The handbook has been prepared by EyeNet Sweden. Every employee has formulated different sections in the handbook: Susanne Albrecht, Mats Lundström, Irene Serring, Kristin Svensson and Eva Wendel.

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Karlskrona May 2005



Mats Lundström, EyeNet Sweden

## Background

The National Quality Registries provide Swedish healthcare a unique opportunity to follow the results and quality of healthcare services. National Quality Registries have existed for just over 25 years within certain specialties, but it was only in the 1990s that a wide build-up was begun. After having been a resource reserved for a small group within the medical profession, the registries have been developed to become one of the foremost tools for improvement efforts and quality follow-up within Swedish healthcare.

Awareness of the existence of quality registries, as well as their potential opportunities, has spread far beyond the profession. National Quality Registries can already be said to be unique tools for follow-up and results assessment in an international perspective as well.

Today (2005) there are more than 60 quality registries that are, or are being developed to become, nationwide. Another 30 to 40 registries are being planned. The National Quality Registries vary as to their objectives, as well as to how and when they arose, but have in common that they were started by representatives of the medical profession and were built up as aids to quality development at the users' own treatment facilities. The Registry Managers are found distributed among different clinics and healthcare principals.

The principal recipients of the feedback of processed and analyzed data from the National Quality Registries are the local medical profession and the units that participate in the registry. It is there that they best can analyze data as well as take measures for improvement. In pace with the increasingly open reporting of results by the registries, other interested parties have also arisen such as patients/the public and politicians as well as client organizations.



## Success factors for a National Quality Registry

### Formulate a clear objective for the registry

A registry builds on data collected from events in daily healthcare and aims to gather documentation to implement quality improvements. The registry shall illuminate issues that specialists in the field and other interested parties within healthcare consider important and cannot satisfactorily be illustrated in other ways. With support of the registry, it should be possible to indicate the extent to which healthcare services for the studied group of patients fulfill the requirements of good quality. The Health and Medical Services Act is a guide when it comes to describing what distinguishes good healthcare. Good healthcare is characterized by

being knowledge-based, suitable, safe, patient-oriented, effective, and unbiased as well as being provided within a reasonable amount of time. These characteristics can be said to be healthcare's overall quality characteristics, and the quality work's objective is to strengthen and develop them.<sup>1</sup>

### The registry's support base

The registry shall have formulated measurable targets that agree with the overall objective. The registry should have a strong support base in the specialty and should therefore have one or more specialist associations as principals or supporters. The issue should be discussed at

an association meeting. The link to a specialist association vouches for the registry's objective being considered as important within the profession and increases motivation for participation. If a new registry is of the kind that lacks a specialist association, a solid support base must be built in the profession in another manner. A broad majority should accept the registry's steering committee and the Registry Manager. It is advantageous if someone from the specialist association's board is a member of the steering committee. The specialist association should also naturally be able to influence who is to be a part of the registry's steering committee. For



the same reasons, if different categories of caregivers are involved in registries or data collection, it is advantageous if the registration has a support base in each respective caregiver category's professional association. The registry's physical placement (Registry Manager and database) is guided by practical considerations. The placement should for example not be perceived as a threat or as a competitor to established research groups.

### Rules for the registry

The registry's steering committee and users must decide what degree of transparency should apply to the data, both internally and towards the public. Both

the National Board of Health and Welfare and the Swedish Association of Local Authorities and Regions recommend considerable openness in the reporting of results, and today an increasing number of registries choose to openly report results. Reporting should only take place within the group in connection with the establishment of a registry and before reliable routines around data collection, processing and validation have been developed. A registry often needs a "maturation phase" before the results are openly reported. Openly reported results of various efforts within healthcare can be said to be a democratic civil right. Data can be reported on different levels, from individual implementers (e.g. doctors or nurses), departments, hospitals, county councils and regions to the whole country. The registry's steering committee and users must agree on how data can/may be used by individual users for research and publication purposes. The registry's steering committee and users must agree on how participation in the registry shall be allowed to be used as marketing of respective participants towards the public and patients.

From the above, it is clear that it could be a good idea to establish agreements between clinics that participate in the registration and the registry.

### Choice of variables and measures

Think through what facts the registry shall illustrate/investigate and ensure they agree with the objective. If measures of waiting times are desired, the beginning

and end of the waiting period must be defined. If the differences in the quality of results are to be established, measurable characteristics of quality must be agreed upon. If measures of patient benefit are desired, biological measures are actually surrogate variables for something that only the patient can describe. In such a case, patient questionnaires must be considered.

Only after one has established what one wants to measure based on the objective, can one start to consider what data (variables) must be collected to illustrate the facts one wants to establish/examine. The variables can consequently – directly or indirectly after processing – illustrate what is to be examined. If possible, they should reflect the entire healthcare chain. Follow-up care data, patient experiences and health-related life-quality can also be registered besides medical data. The variables form the foundation of the quality indicators used to illustrate the quality of the care of an individual patient, in a certain operation or in a care chain for an entire group of patients.

Too many variables should not be measured. Collection of data in ongoing routine healthcare is often perceived as an extra, imposed work task. Even if there is agreement that quality follow-up is to be a natural part of routine healthcare and that the resources for this are to be included in the planned operational budget, there is a psychological resistance to data collection. Therefore it is important to limit the number of variables to be



collected for the purpose of a specific registry. There is naturally a relationship between the volume of the illness or treatment and the number of variables. Operations with a very large volume demand that the number of variables gathered is relatively low while the registration of unusual treatments can allow more variables. There are several examples of registries that have gone under due to overly inflated ambitions with too many variables that were to be registered. One method primarily developed with the support of increasingly better IT is to limit the mandatory variables that everyone must register, but allow a number of optional variables for those who want to do a more detailed registration.

There should be consensus on what quality indicators are important. When one thinks of what data is to be collected in the registry, it is appropriate to draft the issue in a group of specialists. There are always a number of variables for identification, time indication and demography that can hardly be left out for the registry to be useful and fulfill its purpose. However, the more illness-specific or treatment-specific variables offer more choices and normally need a broad-based discussion to achieve agreement. For instance, the need to register these variables in particular can be discussed in the specialist association or in a future user group. The reason for this is that when the registry leaves the enthusiasts and is to be implemented among all of the involved caregivers, it is crucial that one understands why these variables in particular shall be registered and what the objective is. The degree of coverage and data validity is dependent on how well

the selection of variables has been explained to all of the users, regardless of which caregiver category or position in the organization the user is in.

The variables shall be well defined and easy to measure. Variables that are expressed in a nominal scale, i.e. in different categories, can be easy to handle if there is no doubt about which category a value belongs to (e.g. left/right, male/female). If on the other hand it deals with various kinds of stages, kinds of housing and the like, every category should be defined in a manual or on the reporting form so that no doubt arises. Dates require a definition of at which event the date shall be entered. Validation studies of registries have sometimes indicated obscurities particularly as to at what event a date has been entered (e.g. when a referral has been written or when it has been received).

Various kinds of measures, which are expressed numerically according to an interval scale or quota scale, usually do not lead to problems. One may need to define the measurement method, if it is known that different methods give different results. Measurements before and after treatment or of different units should then be done with the same kind of equipment. The measurement shall preferably be easy to make. Uncommon measurements, for which routines or equipment are lacking, naturally complicate the registration. Variables that entail a completed ranking, i.e. measures according to an ordinal scale, must be well defined.

Variables shall not be changed unnecessarily from year to year. An advantage of a National Quality Registry is that de-

velopment and trends can be seen over time. This possibility is lost if the variables are changed too often. This also makes analyses technically difficult to carry out. In the beginning of a registry's development, i.e. the first year or years, it can however be a good idea to not have too many variables. One tests the system, gets users accustomed to it and does not deter anyone with endless registration. It is always easier to add variables than to begin with too many and get a poor degree of coverage.

### Analysis and feedback of data

There are different techniques for the feedback of registry data to users. An individual user should be able to retrieve reports for a specific time period at any time. This primarily works for those registries that have Internet reporting capabilities. Moreover, annual reports and annual user meetings are common and important feedback occasions.

There are different methods for statistical processing that can be used in connection with feedback. A statistical method that is sometimes suitable to analyze registry data is statistical process control. Statistical process control is a well-known method within industry, but it is now also increasingly being used in healthcare. The method is not presented in-depth in this text, but in brief it involves data being followed over time to make it possible to understand the process' variation and thereby create conditions to make conclusions about changes in the process. The method is suitable to processes where regular measurements can be made with intervals that are not too long, e.g. weekly.

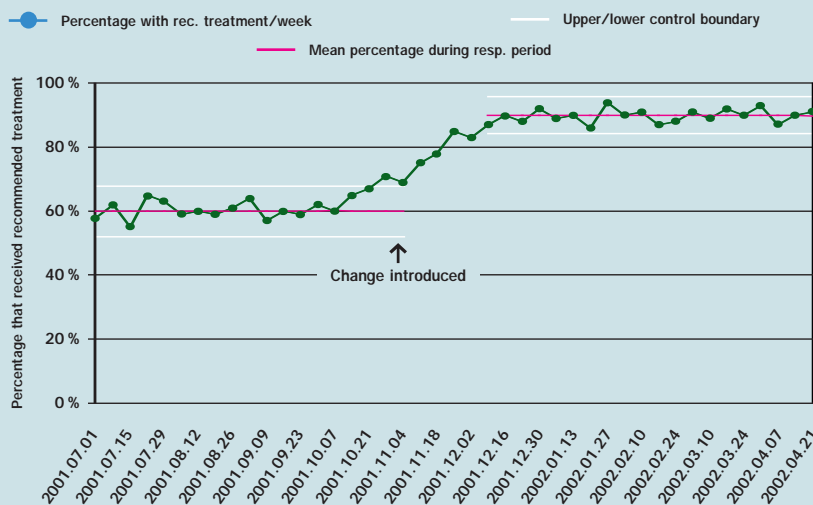
If one on the other hand only takes measurements once a year, the method is not very useful in this kind of context. With the help of statistical process control, conclusions can be drawn regarding whether one or more divergent values are due to random variation or to a statistically significant change really occurring. An example of when this method can be used is in quality improvement to determine if an implemented change has actually led to an improvement of the results, see figure 1. In general, the measure of variation and the confidence interval is provided for appropriate variables when data is analyzed and presented, see the example in figure 2.

Besides their own data, users should be able to compare themselves with the overall average of all connected users, and be able to see how other users' results are distributed. If one produces a bar chart of results from different units and wants to assert that certain units are better than others, it is important to also present confidence intervals, see figure 3. Random variation can explain the entire difference in results between different units.

User meetings should be held at least once annually and are an important institution. At user meetings, the registry's variables and potential changes can be discussed. At the user meeting, different registration participants can also present their own results, tell of ongoing improvement efforts at their own clinics with the support of registry data and explain why they have acquired the results they have. Inviting registration participants to hold their own presentations based on registry data strengthens the motivation to participate.

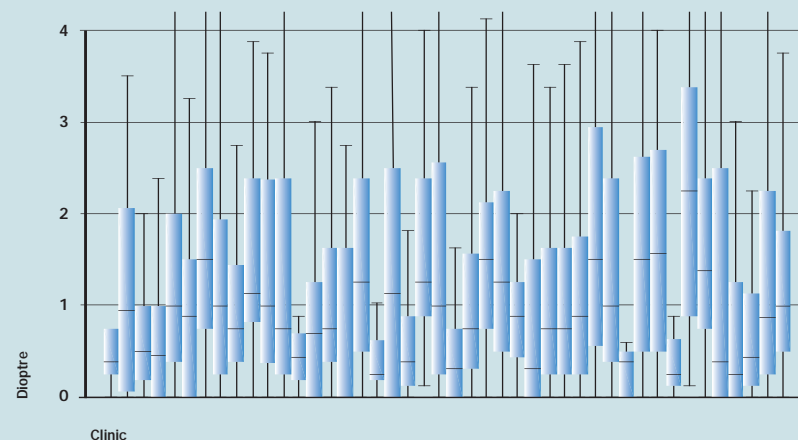
**[Figure 1] Statistical process control of process with change introduced**

Statistical process control of a fictitious process to which a change has been introduced. The process is stable prior to the change and re-stabilizes after the implementation phase, but at a new level.



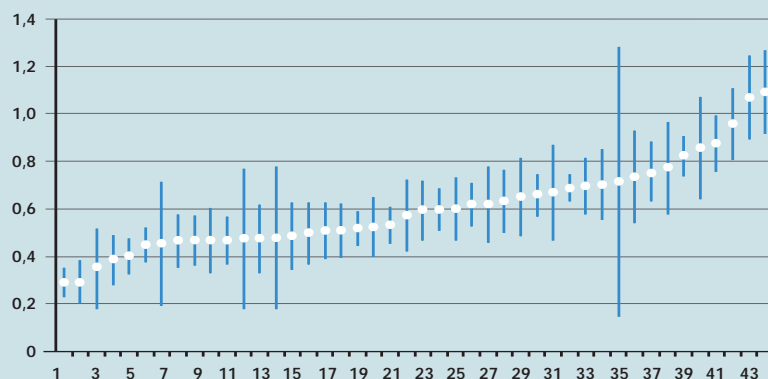
**[Figure 2] Box-plot diagram. Distribution of measurement values of different units**

The middle 50 % of the values are in the box and 95% are within the horizontal lines. The black line in the box indicates the median.



**[Figure 3] Averages of 43 units**

Shown with 95 % confidence interval. Vertical lines show the confidence interval's upper and lower value.



### Clinical improvement efforts

There are various project models to be able to utilize quality registry data in improvement efforts. A fundamental aim of a National Quality Registry is to improve the quality of healthcare to the benefit of the patient. The methods that a quality registry offers are partly concrete measures of results, and partly comparisons of results over time and between participating users. The comparison with others' results provides awareness of what can be achieved. A National Quality Registry can also be used to measure the results of specific quality improvement projects. Systematic clinical improvement efforts demand however a well-structured methodology and, like the treatment of patients, can only be done with the help of common sense. One of the most widespread working methods in both Sweden and other countries is called "Break Through Series". The methodology is

based on general principles of short learning cycles, target-controlled and measure-based change work and patient focus. In 1998 the Swedish Confederation of County Councils applied these principles in collaborative projects with a large number of clinics that used quality registries, so called Q-reg projects. The method has since been refined in collaboration with Qulturum in Jönköping and with Registry Managers and quality registry competence centers.

EyeNet Sweden has experience from two Q-reg projects. The first project was implemented in 1998 at four clinics. In the sections concerning ophthalmologic care, it described different reasons for poor patient-related benefit of a cataract operation.<sup>2</sup> The results provided information on what the operation strategy should be and what kind of operation should be minimized. The project resulted in improved care. The other project

was implemented in 2003–2004 at nine clinics, and aimed to improve the care chain and create national agreement on indications for cataract operations. The results at the clinic level were an improved care process and a more just handling of waiting times. One also agreed on a model for national indications for cataract operations. This model is currently being validated (2005) and will form the basis of the decision on a national maximum waiting time guarantee for cataract operations.

Within cardiac care, similar projects have aimed at improving the use of relevant medicines in connection with acute heart disease. During 2002–2004 the RIKS-HIA group implemented, together with Qulturum in Jönköping and with support from the then Swedish Confederation of County Councils, a quality improvement project within coronary care at 19 Swedish hospitals (the QUICC Study). Within the study, training in and support for improvement work was given to local teams consisting of doctors and nurses. The teams worked out and implemented methods to increase compliance to the national guidelines for coronary care and continuously implemented measures of the results via RIKS-HIA's online reports. The results show that participating hospitals increased their compliance with the national guidelines concerning five different therapies in case of heart attack significantly more than the 19 matching control hospitals. At the end of the project, 16 of the 19 QUICC hospitals had at least 70 percent compliance in at least four of the five therapies compared to none of the control hospitals.<sup>3</sup>



Within diabetic care, Q-reg projects have aimed to halve the gap between reality (the unit's own results) and national guidelines with regard to important risk factors for diabetic care. An initial project started in autumn 2003 and is now (February 2005) in its final phase. The participants are teams from five medical clinics and twelve healthcare centers consisting of doctors, diabetes nurses and potential dieticians or chiroprodists. With data from the National Diabetes Registry (NDR) as a basis, the teams have conducted problem analysis, developed their project targets and worked out change plans. They have had to learn new ways of working and methods that promote improvement efforts, and have been able to continuously follow their results in NDR online. Knowledge has also increased about their own unit's performance/results by analyzing their data in NDR, and patient awareness of, and participation in, the treatment of their diabetes has been increased by jointly establishing individual care agreements. The project has helped the participating units move to a more results-focused way of working and more structured operations as well as more clear work routines and better teamwork. Follow-up of the results has been standardized, i.e. to measure over time and decrease unnecessary variation in the daily routines.

As early as September 2004 a preliminary assessment showed that the results of the individual units had clearly improved. The share of patients who achieve the national targets has increased markedly and exceeds the improvements that can generally be inferred in NDR. The project management has been able to

identify that the units that had regularly analyzed their own data and actively worked out plans of measures in consultation with the entire team have achieved the absolutely best results.

### Research

The design of a National Quality Registry can be compared with a case series study; one either strives to collect data from all cases consecutively or from a selection of cases. This of course entails a limitation in that the objective can be to determine which treatment out of two that provides the best results. This kind of study should be done as a randomized clinical trial.

A pure case study often means that different kinds of selections have been made that affect the results, but a case study with sufficiently many cases still often illustrates how a certain treatment works in daily healthcare. Likewise, a registration of different kinds of healthcare service consumption cannot illustrate the prevalence of an illness in the population. A case study on a national level is however suitable to objectives such as illustrating frequencies of events in healthcare, unusual outcomes, risk analyses, gender and age differences, regional differences, differences in treatment practices between participating units, differences in outcomes between participating units and similar issues.

Even if research is not the primary objective of a National Quality Registry, sooner or later the issue of being able to utilize registry data for different kinds of research arises. A National Quality Registry is suitable for different kinds of database analyses. This can be common

frequency analyses, analyses of uncommon outcomes, survival analyses and different kinds of risk analysis. It is important to think through how validity control is done and how dropout cases are handled. There is always a risk of under-reporting when it comes to complications and poor outcomes. Different kinds of control functions should therefore be worked into the system from the start and be supplemented with sample testing or some other check of the degree of coverage and how representative the data is.

Analysis of the registry's database can incite interesting questions that cannot be answered with the help of the data gathered. One technique that sometimes can be used is to go back to record documents and retrieve the missing information with registry data as an aid. Such an in-depth study has successfully been used to e.g. find out in detail what caused poor patient benefit in operations<sup>2</sup> or poor technical outcomes in operations.<sup>4</sup> The kind of question or insufficient data can result in a proposal for randomized clinical trials. It may also be interesting to utilize data in interdisciplinary studies. Within healthcare finance and public health, there is great demand for authentic data from healthcare services. Quality registries that handle large amounts of data can contribute to filling part of this need. One must however recognize that registry data, as a rule, reflects consumption of healthcare services and therefore cannot be a basis for prevalence studies of illness or disease.



## Swedish Regulations

Although most countries have similar regulations, this chapter solely refers to Swedish conditions.

### Ethical review

Sooner or later research activities become of interest. As a rule it is a good idea to test the future registry's design with an ethical review board. As of 1 January 2004 earlier research ethics committees have been replaced by regional ethical review boards. There are six of them and they are tied to the universities in Uppsala, Lund, Göteborg, Umeå, Linköping and to the Karolinska Institutionen. The boards consist of ten members with scientific expertise, five members that represent the public and one chairperson who is or has been a judge. All members are appointed by the Government. There is also a central ethical review board with the tasks of conducting oversight, settling matters that have been submitted from regional ethical review boards, and handling appeals. All applications to the ethical review boards shall be made by the research principal.

Since 1 January 2004, research that falls under the Act on ethical review of human research (2003:460) shall be scrutinized and approved by ethical review boards. The intent of the law is to protect the individual and the respect for the value of human dignity in research. A point of departure is the Declaration of Helsinki.

The ethical review act covers research concerning:

- Sensitive personal data and information about legal transgressions, compulsory care orders and the like without prior consent.
- Physical operations on the living or dead.
- Methods that aim to physically or psychologically influence.
- Biological materials that can be traced to an individual, living or dead.

The law is very clear and comprehensive with regards to demands on information and consent. The research subject shall be informed of the objective, the methods, potential consequences or risks, that participation is voluntary and that he/she may at any time discontinue his/her participation. Consent shall be voluntary, expressed and specific to certain research and shall be documented. Special rules apply with regard to persons under the age of 18 and those who cannot themselves consent. The law's regulations on information and consent do not however apply to research that is solely based on the processing of personal data as per clause 1 above.

### Practical proceedings

The application shall be submitted by the

research principal, i.e. the employer at a university, county council, company or the like. The researcher that will implement the project shall also sign the application. All applications are subject to a fee, which in 2005 is: SEK 5 000 – one research principal, SEK 16 000 – more than one research principal, e.g. multi-center studies, or SEK 5 000 – registry studies. The application must be completely filled out for the ethical review board to consider it. The form shall be correctly completed and all appendices shall be enclosed. All agreements and interests (financial and otherwise) shall be clear and accounted for in the application. The application fee must be paid before the regional ethical review board takes up the application for consideration.

### Links:

[Ethical review act and information](http://www.forskningsetikproving.se)

[www.forskningsetikproving.se](http://www.forskningsetikproving.se)

[Declaration of Helsinki](http://www.wma.net)

[www.wma.net](http://www.wma.net)

[The Medicinal Products Council](http://www.mpa.se/klinprov)

[www.mpa.se/klinprov](http://www.mpa.se/klinprov)

[The Swedish Research Council](http://www.vr.se)

[www.vr.se](http://www.vr.se)

[National Agency for Higher Education,](http://www.doktorandhandboken.nu)

[Handbook for Post-Graduate Students](http://www.doktorandhandboken.nu)

[www.doktorandhandboken.nu](http://www.doktorandhandboken.nu)

### Short version of the Personal Data Act (1998:204)

The objective of the Personal Data Act is to protect people from personal integrity violation through the processing of personal data. This law, which went into effect in October 1998, builds on an EC directive and replaces the Data Act.

#### Fundamental requirements on the processing of personal data

The personal data manager shall ensure that personal data is only processed if it is legal, done in a proper manner and in accordance with sound practice. Personal data may only be collected for special, expressly stated and justified purposes, and it may not be processed later for a new purpose that is incompatible with the originally stated purpose. Research is however not considered an incompatible purpose according to the Personal Data Act.

Personal data may be stored over a longer period of time for historical, statistical or scientific purposes. In such cases, the personal data may not be stored longer than required for these purposes. Personal data that is processed for historical, statistical or scientific purposes may be used to undertake measures concerning the person registered only if this person has submitted his/her consent and there are extraordinary reasons with respect to the person's vital interest.

#### When processing of personal data is permitted

Personal data may be processed only if the person registered has submitted his/her consent to the processing or if the processing is necessary so that an agreement or legal obligation shall be able to

be fulfilled, vital interests shall be protected or work of public interest shall be able to be performed. Other occasions when processing of personal data is permitted are when the personal data manager or a third party to whom the personal data is handed over shall be able to carry out a work in connection with the exercise of authority or if it concerns a justified interest that weighs more heavily than the registered person's interest of protection against personal integrity violation.

#### Ban on processing of sensitive data

It is forbidden to process personal data, which reveals race or ethnic origin, political views, religious or philosophical conviction or labor union membership. It is also forbidden to process personal data that concerns health or sex life. All of these data categories are considered as sensitive personal data.

#### Consent or publication

Sensitive personal data may be processed, if the registered person has submitted his/her express consent to the processing or has clearly publicized the information.

#### Healthcare

For healthcare there are certain exceptions to the ban on the processing of sensitive personal data without the individual's consent. The Swedish Data Inspection Board has deemed that the processing of personal data – even sensitive data – that is done within the scope of the National Quality Registries is covered by the exception and is accordingly permitted, even if it is done without the consent

of those registered. In consideration of the overall objective of the registries, to improve quality within Swedish healthcare at the individual level, the Data Inspection Board has deemed that the processing of personal data that occurs in the registries is work of public interest and is also necessary for care and treatment. By virtue of Section 18 of the Personal Data Act, the sensitive personal data in the quality registries can therefore be processed without consent of those registered.

#### Research and statistics

Sensitive personal data may be processed for research purposes without the individual's consent if processing has been approved according to the Act on ethical review of human research.

Sensitive personal data may be processed for statistical purposes, if processing is necessary and if the interest of society in the statistics project of which processing is a part, clearly outweighs the risk of undue infringement of the individual's personal integrity, which processing may entail. If processing has been approved by an ethical review board, the conditions as per the second clause are considered to be fulfilled.

Personal data may be turned over for use in such research or statistical projects that have been approved by an ethical review board or the equivalent, unless otherwise indicated by rules of confidentiality and professional secrecy.

#### Security measures

The personal data manager shall undertake appropriate technical and organizational measures to protect the personal





data that is processed. The measures shall establish a level of security that is appropriate considering the technical possibilities that exist, costs and risks.

#### Information

The Personal Data Act prescribes an extensive obligation to inform individuals that personal data about them is to be processed. Information shall generally be provided voluntarily in connection with the collection of data in a registry and shall cover information about who or what body the personal data manager is and the objectives of the personal data processing, among others.

How the information shall be provid-

ed is determined by the personal data manager. There are no requirements that it be done in writing. Upon special request, the individual is entitled to receive written information about ongoing personal data processing once a year.

#### Swedish Data Inspection Board

In contrast to what applied according to the now rescinded Data Act, no permit from the Swedish Data Inspection Board is required for the establishment of a National Quality Registry.

The Data Inspection Board is however the oversight authority in matters concerning the processing of personal data in registries and has the possibility of inter-

vening against personal data processing that is counter to the Personal Data Act.

#### Links:

[Personal Data Act, full version](#)

[www.regeringen.se](http://www.regeringen.se)

[Ministry of Justice – law](#)

[www.notisum.se](http://www.notisum.se)

[Overview of new legislation, Personal Data Act](#)

[www.regeringen.se/sb/d/1966/a/13046](http://www.regeringen.se/sb/d/1966/a/13046)

[Personal Data Act Inquiry/Personal Data Act website with EC-directive 94/46/EC](#)

[www.sou.gov.se/pulutredningen](http://www.sou.gov.se/pulutredningen)

[Swedish Data Inspection Board](#)

[www.datainspektionen.se](http://www.datainspektionen.se)





### Transparency and Public record

A high degree of transparency is desirable for the registry and it is advantageous to think through the public record regulations. Hospitals and county councils are considered as an authority in the eye of the law, and documents that are submitted to authorities are considered to be public record. If the document is not covered by secrecy according to law, the general document is a public record. As per Section 1 of the Freedom of the Press Act, all Swedish citizens shall have the right to access public records. From the viewpoint of the registry, one can assert that data is solely processed statistically by the registry, which then acts as a consultant and that data thereafter is sent back to the clinic. In such a case the public record act does not apply. One can also assert that data in various forms is working material and that a document has not been established in the eyes of the law. The issue has been up for legal review in several administrative courts of appeal and the verdicts have been different, i.e. closed registries have been accepted in some cases and transparency has been demanded in others. If a registry with an administrative center at a hospital accepts data from different clinics and saves these in a database, makes compilations and annual reports, and even sends data back to the clinics, in the eye of the law it is difficult to assert that the data is not public record. One should consider this fact when a national registry is established.

#### Links:

[Freedom of the Press Act 1949:105](http://www.notisum.se/rnp/sls/lag/19490105.htm)

[www.notisum.se/rnp/sls/lag/19490105.htm](http://www.notisum.se/rnp/sls/lag/19490105.htm)

[Secrecy Act](http://www.notisum.se/rnp/sls/lag/19800100.htm)

[www.notisum.se/rnp/sls/lag/19800100.htm](http://www.notisum.se/rnp/sls/lag/19800100.htm)

[Secrecy Regulation](http://www.notisum.se/rnp/sls/lag/19800657.htm)

[www.notisum.se/rnp/sls/lag/19800657.htm](http://www.notisum.se/rnp/sls/lag/19800657.htm)

### Assessment basis in funding allocation

#### Executive Committee

##### of National Quality Registries

In a joint decision-making body, representatives from the Swedish Association of Local Authorities and Regions, the National Board of Health and Welfare, the Swedish Society of Medicine and the Swedish Society of Nursing discuss how the support of the National Quality Registries shall be modeled. The matter is jointly planned and the group makes decisions about funding allocation. Decisions are made in the month of December when notification is also sent to the applicants.

The Executive Committee has initiated annually recurring “Quality Registry Days” in October. The aim of these days is partly to make it possible for the Registry Managers to exchange experience, partly to increase awareness of the registries in healthcare among the operational managers and politicians.

#### Scientific Advisory Committee for National Quality Registries

A special committee has been engaged to assist the Executive Committee in the re-

view and prioritization of the applications. The Scientific Advisory Committee’s job is to work for the development of the quality registries and to contribute through decision data to the available funding being used as cost-effectively as possible.

General principles for funding allocation are:

**Relevance:** The registry’s relevance to quality assurance from a national perspective, the problem’s degree of severity, volume, costs and needs of quality assurance within the area concerned.

**Design:** The registry’s potential of generating relevant information that can be fed back to healthcare with quality improvement as a likely effect; design (disposition, contents, working method), professional support, process and measure of results, and degree of coverage.

**Competence:** The Registry Manager’s and other applicants’ competence regarding operating a quality registry.

**Analysis/feedback:** Analyses, reporting and feedback of knowledge to healthcare services and the registry’s significance to clinical improvement work. Applications are assessed based on their quality within these four areas. The registry shall in particular:

- Contain data, tied to individuals, on diagnosis, medical measures and results.

- Have support from within the profession, e.g. through involvement of a specialist association. Be responsible for contact conferences and feedback.
- Cover publicly financed activities regardless of operational form and if possible also include privately financed healthcare.
- Have extensive, preferably national, coverage.

The overall principles in funding allocation for continued operation of a previously established registry or a registry that obtains compensation over several years are:

- That all current documents and data are updated every year.
- That the registry submits an annual report and management report.
- That the Registry Manager can motivate the importance of continued operation of the registry e.g. through a continued good degree of coverage, development of results measures, collaboration and effects on operational development.

When a registry is recommended for a funds grant for more than a year, the Decision Body approves continued funds grants in the coming years on condition that the healthcare principal and the State make requisite funding available.

### Special statute for National Quality Registries

In the preparatory work\* on the act on health data registries\*\* and the act on healthcare service registries\*\*\* it is stated that quality registries in their current form are a special category of personal registry within healthcare. It is established that the data in these registries is used for purposes close to those of health data registries. These circumstances can indicate that the quality registries should be regulated by law in the same way as health data and healthcare service registries. In the report it is furthermore stated that the proposed health data act cannot be applied to the quality registries with the current registry management/personal data management because the law shall only be applicable when a central administrative authority is responsible. The issue of the National Quality Registries was left without any proposal for special registry legislation.

In view of the existence of comprehensive processing of very integrity-sensitive personal data in the quality registries, there is strong reason, in the view of the Swedish Data Inspection Board, for having the National Quality Registries covered by special registry legislation. A special government commission has therefore been appointed to propose special

legislation for National Quality Registries, the Patient Data Commission. In connection with an expansion of its mandate, the commission has been given more time to submit proposals until the end of 2005.

In the current situation, a great deal indicates that the coming legislation will mean that there will be requirements on the information about registration, no demand for active consent, but the potential for active withdrawal from the registry if the individual so demands.

\* SOU 1995:5 Health data registries  
Healthcare registries pp. 129–130.

\*\* SFS 1998:543.

\*\*\* SFS 1998:544.

#### Links:

[Swedish Data Inspection Board](http://www.datainspektionen.se)

[www.datainspektionen.se](http://www.datainspektionen.se)

[Patient Data Commission](http://www.sou.gov.se/patientdata)

[www.sou.gov.se/patientdata](http://www.sou.gov.se/patientdata)



## Funding

### Funding allocation

The National Board of Health and Welfare is in charge of processing funding applications, drafting decisions in the Executive Committee and payments. The application period is adjusted to the governmental fiscal year and to facilitate planning and long-term planning of the registries. The deadline for a funding application is in September, and the ambition is to be able to give the applicants notification of the decision during the month of December, to then pay out granted funds at the turn of the year. The application form and information “Applying for grants for a National Quality Registry within healthcare services” can be found at: [www.socialstyrelsen.se/Amensord/halso\\_sjuk\\_verk/Kvalitetsregister](http://www.socialstyrelsen.se/Amensord/halso_sjuk_verk/Kvalitetsregister)

#### The application consists of two parts:

- Information in an Internet-based entry form and
- An application page that is printed and signed by the principal and sent in with letters as per the deadline, see SOS’s website

#### The application form contains five sections:

- Contact information on the registry, kind of application
- Summary
- Formalities
- Contents: background/relevance/objective/design/analysis, feedback
- Budget

### Participation fee

The fee can be paid by participating clinics, hospitals or county councils. The fee can be an annual or a one-time fee. Decisions on the participation fee must be supported not only by the user group, but also by clinic management groups and, where appropriate, hospital principals.

One must decide if the fee shall be the same for everyone or if it shall be based on number of cases/registrations. It is also important to decide and agree in advance what is to be done if someone ultimately refuses to pay.

### Research funding

Research funding can as a rule only come into question as compensation for sub-projects in a registration. A National Quality Registry’s most important objective is after all to improve quality within routine healthcare services and these

activities can hardly be paid in whole by research funding.

### Sponsorship

Contributions to registries can be received from industry, foundations and patient associations. Examples of such contributions are those from the Heart & Lung Foundation, the Swedish Association of the Visually Impaired, and the Swedish Diabetes Association to name a few. Contributions can also be paid by specialist associations. Such a contribution can be tied to a certain effort, e.g. compilation and printing of an annual report with the specialist association’s logo.

When it comes to contributions from industry, one must carefully think through the effects on the registry’s credibility and neutrality. Efforts are currently underway to develop a policy concerning industry sponsorship.







## Choice of systems for data management

New National Quality Registries should strive to be web-based from the start. This technology makes data processing fast and participants can get data back when desired. This makes the registry more alive and increases the user motivation.

The ideal is of course a computerized medical records system that allows direct import of registry data, or alternatively export to the national registry's database (involving single registration at the source). This requires however registry and medical records systems that can import or export data and are otherwise constructed with a common standard for informational structure, concepts and technology.

Due to the multitude of systems, this technology has not yet been able to func-

tion on any large scale, but several pilot projects have started in 2005.

Because the quality registries partly contain central results measures based on consensus within the profession and partly have much better validity (reliability) than the medical records, one should strive to have registry data transferred to the medical records systems and not vice versa.

A web-based system for the handling of data in a National Quality Registry consists of a number of well-defined components. One must have a database, entry forms, report forms and a web address that can preferably handle encrypted material with SSL certificates (<https://>). Additionally, an administrative system is needed that among others handles usernames, passwords, form

modifications and update of the web address. There are various firms that are more or less specialized in different parts of the system and even firms that provide the whole system. It is advisable to choose an established firm, as the system must be able to function with service and support in the long term. One can also contact and make use of one of the competence centers supported by the National Board of Health and Welfare and the Swedish Association of Local Authorities and Regions (EyeNet Sweden, NKO or UCR). As competence centers develop and increase in numbers, the latter alternative will become a matter of course for increasingly more registries.

An important job when facing a procurement of web systems is writing a requirement specification.

For the handling of data, entry forms and report forms are needed.

### Links:

[EyeNet Sweden](http://www.eyenetsweden.se)

[www.eyenetsweden.se](http://www.eyenetsweden.se)

[NKO \(National Swedish Competence Centre for Musculoskeletal Disorders\)](http://www.nko.orthop.gu.se)

[www.nko.orthop.gu.se](http://www.nko.orthop.gu.se)

[UCR \(Uppsala Clinical Research Center\)](http://www.ucr.uu.se)

[www.ucr.uu.se](http://www.ucr.uu.se)

[National Quality Registries](http://www.kvalitetsregister.se)

[www.kvalitetsregister.se](http://www.kvalitetsregister.se)

### Input via the web

One should try to determine the number of forms needed for data entry. It is often natural to use one form for e.g. outcome values, background data or pre-operative data and another form for final status, follow-up data or data for individual treatment occasions. Every single data entry form costs money in preparation and in necessary updates and modifications. For financial reasons, one should therefore be restrictive with the number of forms at the same time that it is practical to have different forms for data that is collected at completely different occasions.

Personal ID numbers are practical to use as identification and are recommended. Personal ID numbers make it possible to search in other registries if so desired and one can always be sure of the individual's identity. A disadvantage of personal ID numbers is that one must use a server with encrypted data, which entails an extra cost. Likewise, differences in how identity numbers are handled in different countries are a very troubling issue when planning an international registry.

One must think through and take a position on the following in the requirement specification:

- Numerical values
- Characters
- Number of whole numbers
- Number of decimals
- Limitations

Questions with different response alternatives.

- Being able to fill in one or more responses

- Other box?
- Yes/No questions:  
If yes, open other boxes?
- Mandatory questions or having variables where one can freely fill in questions?
- Empty boxes for numbers or text for own use?

An example of data entry forms via the Web can be found in appendix 1 in this report. The example concerns registration of child cataract operations.

### Reports over the Web

One should decide if there is reason to have several kinds of reports.

#### Frequencies

A standard report can consist of frequency tables. The frequency table can consist of absolute figures and percentages.

#### Example 1

Gender: Women: 32 (60 percent). With regard to certain numerical data, the average value or median value may be desired. If so desired, the minimum and maximum values can be provided as well as percentiles.

#### Example 2

Average age 77.5, median age 75. Waiting time: Average wait 5.3 months, min 2.5, max 14.3, 90-percentile 12 months.

Sometimes the numerical values can have both negative and positive numbers. In such a case, one must decide if e.g. the average values shall be calculated on absolute numbers or with the right sign.

An example of a report via the Web can be found in appendix 2 in this handbook. The example is an excerpt from a European registry for cataract operations.

#### Selection

An important question is what selections one wants to be able to make when retrieving a standard report. Does one want to be able to request a certain time period, choose a selection based on gender, age categories, kinds of treatment, kinds of e.g. pre-operative circumstances? One must also discuss the transparency of the registry and decide if selections shall be able to be made of individual caregivers when retrieving a report.

#### Comparisons

A standard report can contain data partly for one's own unit, and partly for the entire database during a selected time period. If one is interested in comparing different units' results for benchmarking, the units' average values or frequencies are shown as bar graphs indicating one's own unit, while all other units remain anonymous. A comparison in this manner can serve as inspiration for improvement work. One's own unit sees what is possible to achieve. If the bar chart is used to celebrate the best unit or point out the worst unit, it must be supplemented with confidence intervals so that the variation that lies within the random variation is clear.

### Annual report

The annual report, which shall be analytical, commentative and evaluative, shall also present which improvement efforts

have been done during the year and are being done with guidance of registry data. Detailed accounting of work done in individual clinics or county councils naturally falls outside of the Registry Manager's scope of description. This must be done by each respective operation. It is however important that the annual report provides, beyond the degrees of coverage and connection, an illustration of the extent to which and the manner in which the registry is actually used by the clinics that enter data. This is particularly important if feedback and data availability for participating clinics has recently been improved with the help of information technology.

Quality improvements in the form of medical, functional and patient-reported data should be accounted for and analyzed over time to the greatest possible extent. Trends and changes should be related to national and/or local recommendations, guidelines etc. The annual report shall be formulated so that persons without specialist expertise can also understand and study analyses. It shall be representative of the steering committee's view.

In the annual report, data shall be presented on the aggregative level that provides the greatest possible informational value, i.e. is actionable from a development perspective on the individual operational level and on the healthcare principal level. Furthermore, data shall be reported broken down by age and gender where relevant. Time series data, graphs and tables shall be commented in text with associated discussions/analyses.

**Good luck!**



Appendices

[Appendix 1]

Register child cataract operations

<Operation list>

<Log out>

<Help>

Admin - Admin

Register new operation

Approve and save

Open

Delete

Save

Personal ID no.\*

Date of operation\*

Postal code (home)

Nationality\*

Heredity of congenital cataracts\*

Date of diagnosis (Ophthalmologist)\*

Referral initiator\*

Prior op for cataracts\*

Illness of other organ systems\*

Visible preop exists nystagmus\*

Why was the patient referred?\*

Patient to be followed up on at hospital/clinic\*

Left eye

Right eye

Operation on left eye

Description of cataract\*

Position\*

Prior therapeutic treatment\*

Other eye abnormality\*

Eye abnormality

Axis length

Horizontal corneal diameter

K1 value

in degrees

K2 value

in degrees

Operation type 1\*

Operation type 2

Operation type 3

Operation type 4

Planned refraction at time of op

Anterior capsulorhexis

Posterior capsulorhexis

Vitrectomy

Iridectomy\*

Implanted IOL\*

What kind of anti-inflammatory medicine was used?\*

Cortisone

NSAID

Tropicamide

Cyclogyl

Atropine

Version: 1,5

## References

1. Committee on Quality Health Care in America, Insitute of Medicine. Crossing the Quality Chasm: A New Health System for de 21st Century. Washington, DC: National Academy Press; 2001. (In Sweden, both the National Board of Health and Welfare and the County Council of Stockholm have chosen to describe health-care's quality areas in this way).

2. Lundström M, Brege KG, Florén I, Stenevi U, Thorburn W. Impaired visual function following cataract surgery. An analysis of poor outcomes as defined by the Catquest questionnaire. J Cataract Refractive Surg. 2000;26:101-108.

3. Lindahl, B., et al. Substantial improvement of adherence to national guidelines – preliminary results of the Swedish Quality Improvement in Cardiac Care (QUICC) project. European Society of Cardiology congress 2004, München, Germany.

4. Lundström M, Brege KG, Florén I, Lundh B, Stenevi U, Thorburn W. Postoperative aphakia in modern cataract surgery; Part 2: Detailed analysis of the cause for aphakia and the visual outcome. J Cataract Refract Surg. 2004;10:2111-2115.

### [Appendix 2] Checklist report

	Period		Accumalated		Total	
Total operated	159		159		5 341	
Male	57	35.8 %	57	35.8 %	1 893	35.4 %
Female	102	64.2 %	102	64.2 %	3 448	64.6 %
Age Average	75.0		75.0		73,5	
Number over 70 years	120	75.5 %	120	75.5 %	3 829	71.69 %
Previously operated	73	45.9 %	73	45.9 %	2 124	39.8 %
Other illness						
Glaucoma	14	8.8 %	14	8.8 %	727	13.6 %
AMD	31	19.5 %	31	19.5 %	803	15.0 %
Diabetes	5	3.1 %	5	3.1 %	238	4.5 %
Other	17	10.7 %	17	10.7 %	843	15.8 %
Type of operation						
Phaco + PCL	158	99.4 %	158	99.4 %	4 951	93.0 %
Ecce + PCL	1	0.6 %	1	0.6 %	261	5.0 %
Phaco/Ecce + ACL	0	– %	0	0.0 %	20	0.0 %
Phaco+filtr.surg+ PCL	0	– %	0	0.0 %	34	1.0 %
Other	0	– %	0	0.0 %	75	1.0 %
Ecce+ filtr.surg+ PCL	0	– %	0	0.0 %	0	0.0 %



