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WP5.2 – Orthopaedic Pilot Quality Registers in Finland

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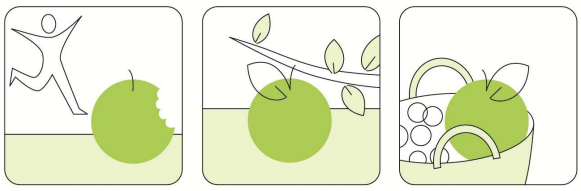

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Introduction

The purpose of this report is to describe the present development status and utilization of quality registries in Finland, including organisational and co-ordination aspects.
A similar descriptive study is being undertaken in parallel by the EUPHORIC project partners in Karolinska Institute, with the focus on Swedish quality registers.

The same data collection tool, a questionnaire developed by the WP5.2 co-ordinator, is used in both locations, in order to ensure the uniformity of background data and facilitate the juxtaposition and comparative analysis of the information available on the two countries which will be undertaken as a next step and produce its own intermediate report.

Ultimately, the purpose is to identify best practices that can be drawn from the Nordic experiences of developing and working with quality registries. Knowledge on best practices and lessons learned from several decades of experience can be subsequently utilized to inform and support similar developments in other EU countries.

Methodology

Definition of quality registries in Finland

As part of a long tradition in general record keeping, with vital statistics (including e.g. births, deaths and marriages) starting as early as 1749, Finland also has a history of several decades in establishing and maintaining health (and social welfare) registers.
In addition, national data collection has benefited greatly by the wide adoption and utilization of information technology in health and social care settings. The first nation-wide computerized disease register was the Cancer Register that started in 1952 (2).

In an extensive review of the national situation undertaken in 1997 (3) Finnish health care registers were distinguished in four separate types:
a. Statutory nation-wide registers (specified by law)
b. Research registers
c. Patient registers of healthcare units
d. Other (special) registers (usually local).

At that point in time, the authors of the study identified 10 statutory registers, 28 national and 10 regional separate health care registers and several local registers, maintained at the level of health care units. It is very likely that this distribution has changed in the meantime, not only due to the passage of time, but also due to the effects of the harmonization of national legislation to that of the EU, and more specifically to the Data Protection Directive (Ref).
An equally broad review might be in order for an up-to-date mapping of the register situation in Finland; however it is beyond the scope and resources of the EUPHORIC project.

What becomes evident from this review data is that the concept of "quality registers", which is routinely in use in other Nordic countries, does not exist as such in the Finnish context.
Therefore, for the purposes of EUPHORIC project work, the members of the Finnish team agreed on a number of criteria that a register should fulfil in order to be perceived as a 'quality' register and thus be considered for inclusion in this study.
We used the quality framework developed by the OECD Health Quality Indicators Project (1) as the reference for defining the concept of quality in the context of healthcare system performance.
According to the OECD framework, the concept of quality encompasses effectiveness, safety and responsiveness/patient centeredness. These concepts, in turn, have been defined as follows (1):

"Effectiveness is the degree of achieving desirable outcomes, given the correct provision of evidence-based health care services to all who could benefit but not to those who would not benefit.
Safety is a dimension where the system has the right structures, renders services, and attains results in ways that prevent harm to the user, provider, or environment.
Responsiveness refers to how a system facilitates people to meet their legitimate non-health expectations.
Patient-centeredness captures the degree to which a system actually functions by placing the patient/user at the centre of its delivery of health care and is increasingly being measured as patient experiences of health care with emphasis on caring. Responsiveness and patient-centeredness are often taken to be equivalent".

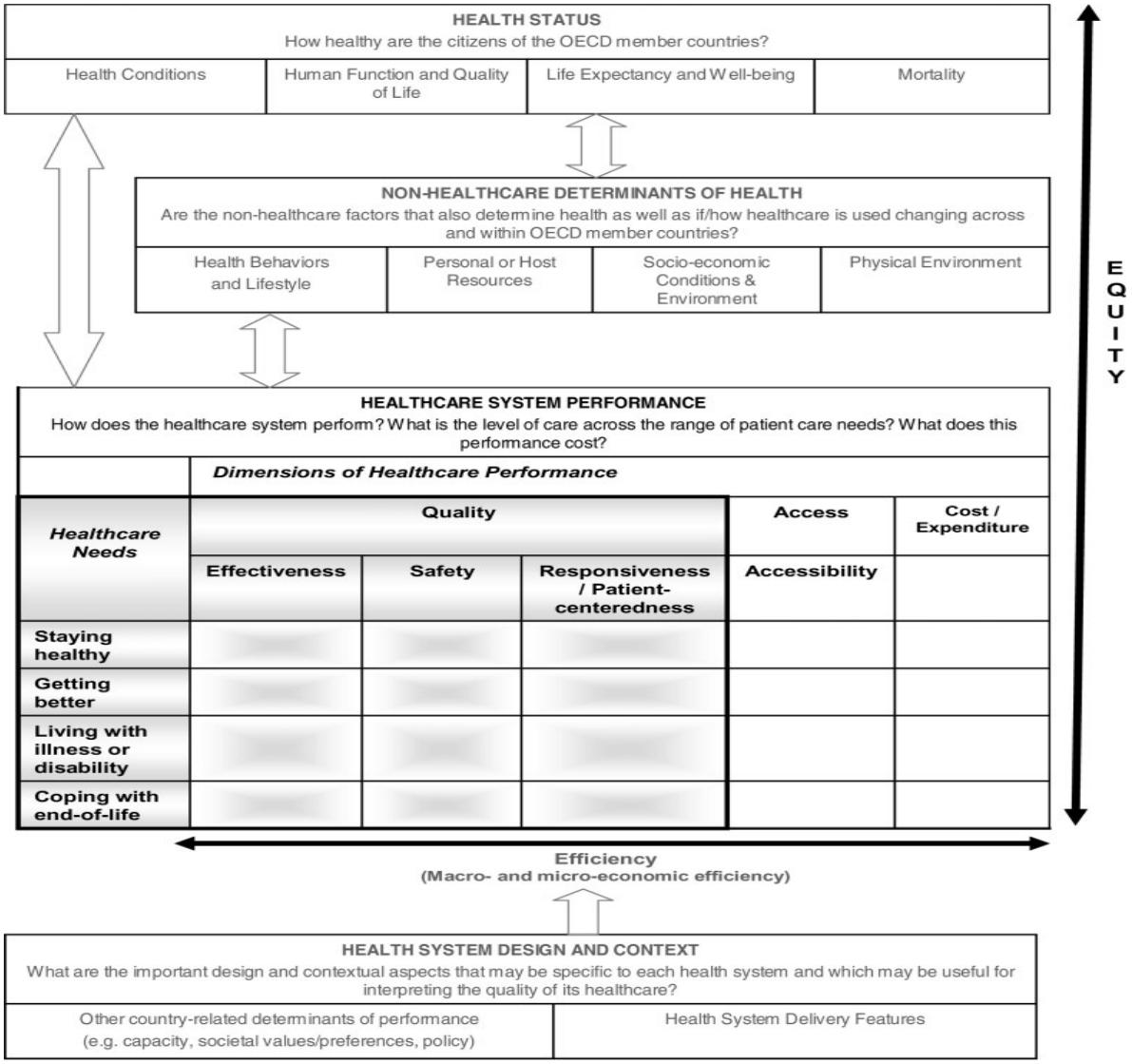

Figure 1: Quality Framework proposed by the OECD Health Quality Indicators Project (in: Arah et. al. IJQHealthcare, September 2006)

Of the above mentioned dimensions of quality, we regarded most relevant and applicable for register content and utilization primarily those of effectiveness and safety. Responsiveness and patient-centeredness are in turn more difficult to assess through register-derived data.

Materials

On the basis of this understanding of quality, the following registries were deemed to be relevant for inclusion:

Table 1. Registries considered for inclusion in analysis of Finnish 'quality' registers

	REGISTER TYPE - NAME	REVIEW STATUS	COMMENTS
	NATIONAL - STATUTORY		
1.	HILMO - Hospital discharge register	Quality report - Description file available	additional info acquired by interview - Updated questionnaire review requested
2.	Medical birth registry	Quality report - Description file available	additional info acquired by interview - Updated questionnaire reviewed
3.	Register on congenital malformations	Quality report - Description file available	additional info needed by interview - Questionnaire review requested
4.	Causes of death register	Description file available	additional info needed by interview - Questionnaire reviewed and updated
5.	Cancer register	Quality report - Description file available	additional information provided through contact persons. Questionnaire reviewed and updated
6.	Implant register (orthopaedic & dental)	General info - Report 2004, 2006	additional info needed by interview
7.	Register on visual impairments	Description file - General information available	additional info needed by interview - Questionnaire review requested
	NATIONAL - SPECIAL REGISTRIES		
8.	Finnish Registry of Renal Diseases	Description file available	Questionnaire reviewed and updated
9.	Registry of vascular procedures	General info	Nowadays focus only on HUS patients
	PROCEDURAL - not to be studied in detail		
10.	Mass screening Register (breast & cervical CA)	Quality report - Description file available	
11.	Register on adverse drug reactions	MISSING INFO	
12.	Register on induced abortions and sterilizations	Quality Report - Description file available	

All of the registers listed in Table 1 have national coverage and a considerable number of records already available (on the basis of the 1997 study). Of those, the main emphasis will be given to those of a statutory nature, as well as the two representative special registries, while the registers focusing more on healthcare service procedures rather than outcomes (numbers 10-13 in Table 1) will be briefly described, but not analysed in detail.

Data Collection

As a first step, data was collected from publically available material, primarily through the Internet. Almost all of the registers included in the study have made available the legally obligatory description file of their records and data collection and analysis procedures, and the majority of them also a quality report.

Data from these materials was then extracted to the EUPHORIC pilot questionnaire, in order to on the one hand, test its feasibility and on the other hand, shorten the time necessary for data collection through interviews (for which the questionnaire has been primarily developed).

The material available for each register appears in the second column of Table 1. The phase of data collection and extraction from publically available material has been completed for the largest part, with some further work remaining.

In a second phase, the partly completed questionnaires were made available to the contact persons of each register. They were requested to provide their feedback with regard to the accuracy of the already existing data, as well as complete (to the extent possible) the still open questions and give whenever possible references to suitable and relevant material. The progress achieved with respect to each register is again pictured in Table 1.

Results

1. STATUTORY REGISTERS

1. HILMO - Hospital Discharge Register

REGISTER NAME	**Hospital Discharge Register** (HILMO - Terveydenhuollon hoitoilmoitusrekisteri)
Address	National Research and Development Centre for Welfare and Health (STAKES) Postal address: PO Box 220 Postcode: FI-00531 Helsinki Visiting address: Lintulahdenkuja 4, 00530 Helsinki Tel.: +358-9-39 671 Fax: +358-9-3967 2324
Website	http://www.stakes.fi/FI/tilastot/tausta/Rekisteriselosteet/terveydenhuollonhoitoilmoitukset.htm (in Finnish) http://www.stakes.fi/EN/tilastot/filedescriptions/medicalbirthregister.htm
Main contact	Jouni Rasilainen, special planner
Established	Originally 1969 - In present form: 1994
Legal Status	Statutory

Registers' History

The register was established on the basis of a set of laws, by the National Board of Health (for a list, see the table under 'Legal framework').
The present register is a continuation of the earlier discharge registry, in which information was gathered during the period 1969-1993 on patients discharged from hospitals. The new register was established in 1994, on which time the data collection was expanded to include broader categories of patients (for more information see in Data Collection).

The Register is outcome-research oriented. It's main purpose is to collect data on the activities of healthcare centers, hospitals and other healthcare service provider establishments and their clients, as well as on home care clients, for the purposes of statistical analysis, research and service planning.

The so-called HILMO reports cover statistical information on somatic specialized hospital care, on in-patient care provided in the wards of healthcare centers, on specialized institutional psychiatric care, episodes of treatment including procedures, as well as on surgical and day-surgery procedures. The reports are based on the personally identifiable information received annually from hospitals through the discharge/treatment notification forms, which contain information on the patient's municipality of residence, the health service provider, the patient's admission data, treatment data and discharge data. For the area of psychiatry, in addition to the aforementioned information also information concerning medication, forced treatments and evaluations of psychological state are included in the specific extra form.

Legal Aspects

Legal framework

Laws under which the register was established and laws regulating its operation. Example:

• Law on nation-wide healthcare registers	556/89) 3 §	STAKES registers, implant register, Visual impairments
• Decree on nation-wide healthcare registers Modification 1993/1671	774/1989	STAKES registers, Visual impairments
• Law on the National Research and Development Centre for Welfare and Health	1073/92 2 and 6 §	STAKES registers
• Law on special level (hospital) care	1062/89 5§	HILMO
• Law on public health	66/72	HILMO
• Law on mental health	1116/90	HILMO

Patient consent

Because HILMO is a statutory register, there is no requirement to request patient consent for for data collection and/or use of the data for research purposes.

Ownership of data

STAKES

Budget

Part of STAKES-Budget

Staff

The registry does not have a formal supervisory board as such. However, recently a group of employees involved in registry work have formed a sort of planning team, where several matters pertaining to registry work and development are discussed.
Examples of pertinent topics include:

- Maintenance, development, utilization of the registry: how are they realized in practice, what benefits can be gained.
- Instruction booklet for contributing organisations (HILMO ohjeistus kirja): in what ways can it be changed, modified in the coming year.
- SAMPO introduction: how is data collected and in what way is it used (connection to Benchmarking(Hospital Productivity) and Perfect projects).

Normally the Register employs one physician, but presently the position is vacant.
There are 3 statisticians, one secretary, and four data entry persons. There is no exclusively appointed IT-staff, but rather the function is covered together with the statistics group.

Data Collection

Starting point of documentation

Data collection for parts of the register has started in the late '50s and 60's (since 1956 for care in tuberculosis sanatoriums, in 1957 for psychiatric hospitals and since 1960 for general hospitals). Complete identification numbers are available since 1969.

The core data collection has remained the same overtime and it concerns information on the health service provider, the patient, the arrival for treatment, discharge, the patient's diagnoses and the treatment(s) he/she received.

Follow up/Reference data collection

The hospital discharge register from 1994 and onwards includes much broader information. While the earlier registry contained information only on the patients who were discharged from hospital wards, the new register contains data on:
- clients discharged from hospital wards;
- calculation of patients present in hospital and health care center wards on 31.12 of every year
- day surgery procedures in hospitals.

Comparability of Statistics

The discharge/treatment notification system has been in use in Finnish healthcare since 1969. The Discharge notification (notification on completion of treatment) changed into notification of received treatment in the beginning of 1994. The system has covered both specialized hospital care, as well as primary level institutional care.

The comparability of data is affected by changes in the coding of diagnoses and procedures, as well as in the content of collected data. Data content has most significantly widened with the introduction of the additional data collection forms on psychiatry and on high-demand heart patients, as of 1994. The corresponding information on the aforementioned subjects is rather fragmented and incomplete for 1994.

During the period 1969-1987 diagnoses were coded on the basis of ICD-8 (International Statistical Classification of Diseases) and for the period 1987-1995 on the basis of ICD-9. Starting from 1996 ICD-10 has been the classification in use.

Procedure-related data has been collected on the discharge/treatment notification starting from 1986. In the period 1986-1995 the procedure name list prepared by the Hospital Association was used for classification. In the period 199-2003 the first procedure classification compiled by STAKES was taken into use (ohjeita ja luokituksia 1996:3). Starting from 2004, the second STAKES classification of procedures has been used (ohjeita ja luokituksia 2004:2).

Newer disease and procedure classifications are always wider than the earlier versions, which poses a challenge for comparability. Also the progress of medicine, e.g. changes in diagnostics of diseases, affect the registers and the comparability between various years, something which also needs to be taken into account when comparing time series.

Clarity and completeness/consistency

HILMO-reports contain comprehensive information on all hospital services in the country. They are based on the use of the International Classification of Diseases and on the Nordic Procedure

Classification, which has been adapted to correspond to international classifications. This enables international comparisons.

Data Management

Registers, but also their collaborating partners, need to address and agree on the processes and principles of data management to be applied.
Register data management can be distinguished to specific steps or phases, for each of which a corresponding method needs to be applied:

DATA MANAGEMENT STAGES	METHODS
Data collection at point of care	paper forms, downloaded and printed pdf., extract from ICT-system
Sending data to register	paper, disk (almost obsolete), UNIX-tape, CD-ROM (most common) - all send as registered mail
Entry of data to register data base	manual entry, IT-enabled but necessary manual work also (coding, checking of data, cleansing etc.)
Disposal of data	physical destruction of material, complete deletion or encryption of ID information
Storage and data security	limited number of named persons with access to identifiable data, storage in locked or electronic-key-accessible locations, offline server or work station protected with passwords, encryption of identification information
Processing of data	Various statistical methods (Reported in evaluation section)
Reporting and dissemination	Various formats and channels (Reported under Publications - Supporting Actions)

Data collection at point of care

Depends on hospitals and their IT-systems; some extract data directly from their own systems, some have to collect the data separately.

Data is collected at the following points in time:

- Hospitalisation (for those in hospital and health care centre wards on 31.12)
- After surgery (for heart patients)
- Discharge (for those discharged from hospital wards and from day surgery units)

Sending data to register

By registered mail.

Storage and data security

The Register databases are stationed in a protected physical location and hosted on an offline server (based on ORACLE technology), with encrypted identification numbers. Only specific members of personnel can access the data.

Processing of data

The majority of data arrives in electronic format, but still approximately 1% of the total forms are paper-based (which makes for 1,5 million forms processed by data entry personnel)

Reporting and dissemination

See under publications.

Participation supporting actions

Participation to the Register is mandatory.

Every year a guide is published regarding the data to be collected on the reporting form and how it should be sent forward.
In the guide there is information on:
- which information service providers (hospitals, health care centers, home service providers) are obliged to sent information to the register and the principles for release of the data
- the data content to be collected
- how the data should be delivered to the register
- how to attend to the confidentiality of the data.

Programmes to collect information (smaller hospitals, health centers),
Training - several times per year centrally, sometimes also on location, particularly when there are large scale changes; list of contact persons available to assist with practical questions.

Data Publication

- Annual statistical report. Procedure-related hospitalizations - first version of statistics is released online in the beginning of summer, organisations can check for missing or incorrect data. Final version is made available in the fall, when follow up requests have been replied to. Some basic statistics are available in English in the (annually published) Statistical Yearbook on Social Welfare and Health Care.
- feedback provided to each data contributing organisation separately
- separate reporting on: procedures (national level - hospital district level), psychiatric institutional care, somatic specialized hospital care, wards of healthcare centres
- HILMO "cubes" ("kuutiot" in Finnish: available for free on main group diagnosis level; for fee service: information provided on specific diagnosis and procedure level)
- Benchmarking "cubes"

Validation

Register coverage

All hospitals in Finland contribute to the data collection. There is, however, variation in terms of procedures, size of hospitals etc. with regard to the quality and completeness of data reporting (e.g. major procedures are reported better).

Validation history

Validation process started in (year)

Validation published in (year):

At least one study in 1991: Keskimäki I, Aro S. Accuracy of data on diagnoses, procedures and accidents in the Finnish Hospital Discharge Register. *Int J Health Sciences* 1991; **2**: 15-21.

Several other studies, primarily on validity of data with regard to cardiovascular diagnoses (CHD, AMI, MI, stroke).

Routine validation procedures

A special programme has been developed for use in hospitals during data input.
Quality control processes (comparisons with previous year, hospitals check themselves reported data).
Clearing of the Register's data happens once a year.

Connection to other databanks/data sources

Applying for research use of STAKES register data

There is a general application and processing procedure that applies to researchers interested to utilize data from STAKES Registers, either in themselves and/or in connection to other register data.
The procedure is described in the web pages of ReTki (the Finnish Information Centre for Register Research): http://retki.stakes.fi/kuvat/retki/prosessit/tutkimusluvat_pohja2.htm
The relevant application forms, as well as the principles and practices on the basis of which register data is released for research purposes are available at the following URL:
http://www.stakes.fi/FI/tilastot/tausta/tutkimus/index.htm

Unfortunately, most of this material is available in Finnish only (e.g. application forms, as well as the description of the application processing). Figure 2 provides an unofficial translation of the graphical representation of a research application processing by STAKES registers.

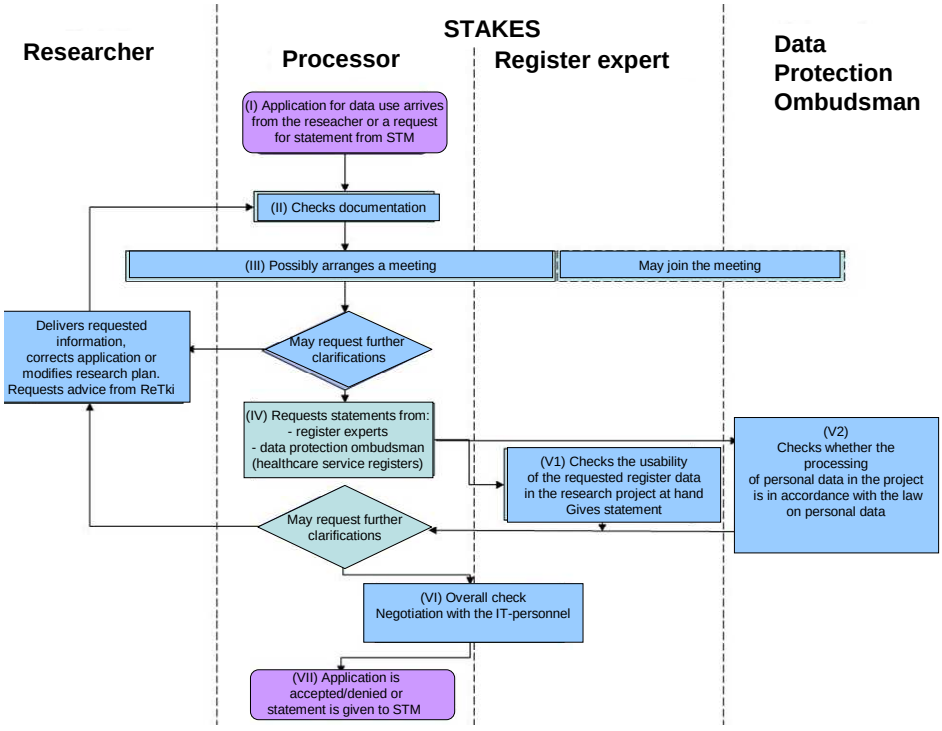

Figure 2. Processing of a research application for using STAKES register data

The Finnish Information Centre for Register Research does however provide quite extensive information in English regarding the use of register data in research (http://retki.stakes.fi/EN/registerbasedresearch/Register-based.htm) and the relevant data protection and permission regulations that apply (http://retki.stakes.fi/EN/Permitsanddataprotection/ApplicationMSH/Applying.htm). Figure 3 (available from ReTki pages on Register-based research), demonstrates the life-cycle of a research project that utilizes register data.

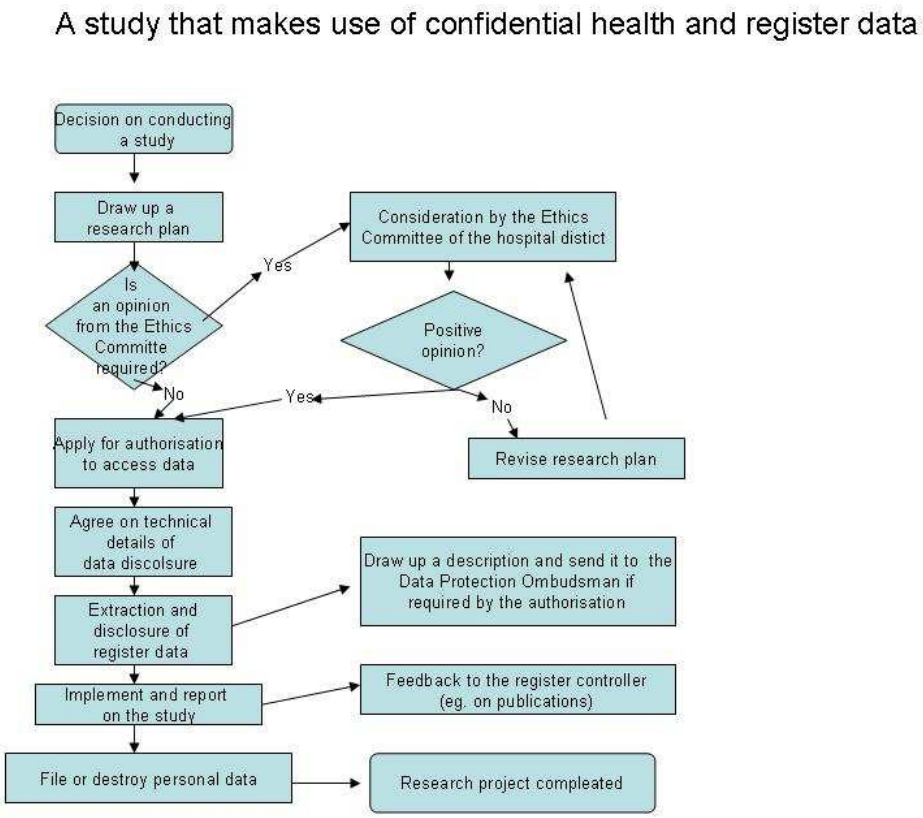

Figure 3. Steps in the life-cycle of a register-based research project

For research purposes

The generally applicable procedure for research access to STAKES Registers' data applies also to HILMO.

Linking with the data of the Population Register Center (Inhabitants/Deceased persons) is possible with specific permission.
Causes of death are not included in this register, but connection to the separate Causes of Death register maintained by Statistics Finland is possible with specific permission.
Linkage with economical data will probably be possible in the future, depending on the development of the SAMPO project. Information on economic parameters, however, is not as accurate as clinical data.(Benchmarking data includes economic data at department level)

Access of stakeholders to not published datasets

Personally identifiable information contained in the register is confidential, according to the law on national health registers (556/89) 4§. However, information can be released in accordance to principles and requirements specified in the law, for the purposes of scientific research.
Non-identifiable information and statistical data on the basis of the register's data collection can be provider to external parties.

Extraordinary Reports on Demand:

- For the press
- STM (Ministry of Social Affairs and Health- impact on planning decisions
- Physicians (diagnosis or procedure code, researchers - summary statistics)
- Hospital districts - for a fee (kuutiot), includes access to a separately prepared, password-protected database.

Evaluations

HILMO reports contain data on patients in specialized hospital care, primary ward care or day surgery care, and on the number of treatment episodes and treatment days annually. The numbers are categorized on the basis of main diagnosis, as well as main procedure. In addition, e.g. in somatic specialized hospital care, healthcare center ward care and psychiatric care the data is presented per region (municipality or hospital region), area of specialty, age group, provider of health services and as time series of the main diagnostic categories and most common diagnoses. The number of patients and treatment days are also presented according to age and gender groupings per hospital region or municipality, and per thousand inhabitants. Changes compared to the immediately previous or five previous years are calculated as percentages.

In the statistical summary regarding psychiatry also the data collected by the specific extra form are presented. The average and median length of completed periods of treatment (episodes of care including procedures) are calculated both per diagnosis and per region and hospital region.

Statistics on procedure-connected periods of care, as well as surgery and day surgery regional variations are calculated on the basis of patients on whom procedures conforming to the classification of procedures have been performed.

The statistical summaries are meant for healthcare professionals, public health authorities, planners and research, who need up-to-date information on hospital service productivity in Finland.
In the text parts of the summaries, the main terms and definitions that have been used are described.

EUPHORIC INDICATORS

Most of the EUPHORIC indicators can be calculated on the basis of HILMO data, possibly with the need to combine HILMO data to those of the Causes of Death register for mortality indicators.
An exception are neonatal and maternal indicators, since the corresponding data are contained in the Medical Births Register.

2. Medical Birth Register

REGISTER NAME	**MEDICAL BIRTH REGISTER** (Abbreviation could be added here if considered necessary; also the name of the register in the national language)
Address	National Research and Development Centre for Welfare and Health (STAKES) Postal address: PO Box 220 Postcode: FI-00531 Helsinki Visiting address: Lintulahdenkuja 4, 00530 Helsinki Tel.: +358-9-39 671 Fax: +358-9-3967 2324
Website	http://www.stakes.fi/EN/tilastot/filedescriptions/medicalbirthregister.htm
Main contact	Name: Eija Vuori Position: Planning Officer Postal address: STAKES / Stakestieto / Medical Birth Register PO Box 220, FI-00531 Helsinki Tel.: +358-9-3967 2244, +358-9-39 671 Fax: +358-9-3967 2324 E-mail: firstname.surname@stakes.fi
Established	1987
Size & Coverage	Coverage: 100%
Legal Status	Statutory

Registers' History

The **Medical Births Register (MBR)** was established in 1987, through funding provided by the Finnish Ministry for Social Affairs and Health. The focus of the register is on statistics and outcome-related research. The purpose is to collect data in order to develop and organise maternity care, obstetrical services and neonatal care.
Nation-wide collection of data started in 1987 and compliance reached 100% already on the same year. Feedback to participating hospitals also began from the first year of operation, the first annual report of the register, however, was published in 1990 through the National Board of Health.
The validation of the register's data begun in 1987 and several pertinent scientific studies were undertaken in the '90s (e.g. Teperi et al 1993, Gissler et al, 1995).
The register underwent reforms in 1990, 1996 and 2004, all aimed at improving its reliability.

Legal Aspects

Legal framework

The laws under which the register was established, and the laws regulating its operation are those that form the basic legal framework for all of the registers maintained by STAKES, the National Research and Development Center for Welfare and Health. An overview of these laws is provided in the table below.

• Law on nation-wide healthcare registers	556/89) 3 §	STAKES registers, implant register, Visual impairments
• Decree on nation-wide healthcare registers	774/1989	STAKES registers, Visual impairments

	Modification 1993/1671		
•	Law on the National Research and Development Centre for Welfare and Health	1073/92 2 and 6 §	STAKES registers

Patient consent

Patient consent is not required for collection of the register data, since the collection is mandatory and established by law.

Ownership of data

STAKES.

Staff

The MBR does not have a formal Supervisory Board, however there is an internal Reproduction Health Registers team, plus a list of external collaborating experts who convene regularly and, among others, discuss necessary steps for maintaining and improving the quality of the register.

The MBR employs at present two (part-time) physicians, two statisticians, one data entry person, and two IT-specialists.

Data Collection

Starting point of documentation

Data collection for the register starts practically around the time of birth, when the mother arrives at the delivery hospital/location. However, the register includes also information from the earlier pregnancy period (extracted by the hospital staff from the mother's maternity card, which is filled in during visits to the maternity clinic).
The delivery department's secretary usually extracts the information to be reported (some information maybe already available in the hospital's records, if the mother has already been at the hospital policlinic).

Data Collection Form

In 1990 and 1996, the data content of the Register was changed in order to improve its reliability. In 2004, the form was again updated. The purpose of the reform was to bring the form more in line with the present care practices.

Follow up/Reference data collection

The Register includes data on live births and on stillbirths of foetuses with a birth weight of at least 500 g or with a gestational age of at least 22 weeks, as well as data on the mothers.
The Register incorporates a data file on small preterm infants for which data have been collected since 1 November 2004. The data file contains additional data collected by means of a separate form concerning all live births in Finland with a birth weight of less than 1500 g or with a gestational age at birth of less than 32+0 weeks. The data are collected until the infant's age corresponds to 42 weeks' gestation.

As of 2008, also infants with birth weight of exactly 1500 gr are included (for purposes of comparability with international data collections).

Comparability of data

Beginning from 1987, the annual statistical data presented in the Statistical Summary are mutually comparable. However, the 2004 and 2005 data are not fully comparable between the hospitals, since a few hospitals failed to submit that year's data in accordance with the new form.
The preliminary data do not include the data obtained by combining the Population Register Centre's register data on live births and Statistics Finland's register data on causes of death. Therefore less than 0.1 per cent of data on births are missing in the preliminary data. No other major differences exist between the preliminary data and the final figures published in the Statistical Summary. The preliminary data on parturients, deliveries and births consist of nationwide absolute figures and percentages only.

Data Management

Registers, but also their collaborating partners, need to address and agree on the processes and principles of data management to be applied.
Register data management can be distinguished to specific steps or phases, for each of which a corresponding method needs to be applied:

DATA MANAGEMENT STAGES	**METHODS**
Data collection at point of care	paper forms (10%) - extract from ICT-system (90%)
Sending data to register	paper, CD-ROM (most common)
Entry of data to register data base	manual entry, IT-enabled but necessary manual work also (coding, checking of data, cleansing etc.)
Storage and data security	limited number of named persons with access to identifiable data, storage in locked or electronic-key-accessible locations, offline server or work station protected with passwords
Processing of data	Various statistical methods (Reported in evaluation section)
Reporting and dissemination	Various formats and channels (Reported under Publications - Supporting Actions)

Data collection at setting of care delivery

Data is collected at maternity hospitals starting at the time of admission, until discharge. Actually, in the case of premature babies, follow up (and hence data collection) is continued until the 42 weeks (of the normal gestation period) have been completed.
Out of the 34 collaborating hospitals, 5 have a separate form for data collection. In the remaining hospitals, data is extracted automatically from the hospital's IT system, where it has been entered by hospital personnel.
In the case of home births, the form is to be filled by the midwife or physician who assisted with the delivery.

Entry of data to register data base - Accuracy check

The processing of the received data collection forms is divided according to their format: 90% of the forms arrives stored on a CD and is processed by the IT-staff, while 10% of the forms is paper (about 4000) and are processed by the data entry member of staff.

Storage and data security

The data stored in the Medical Birth Register are confidential under section 4 of the Act on National Personal Data Registers Kept under the Health Care System (556/1989).
The Medical Birth Register functions in accordance with the STAKES data protection and security guidelines (updated on 1 December 2004). The material in the Register is classified in category 3, which means intensified data protection.
The materials of the Medical Birth Register, both in paper form and in electronic form, are kept in locked premises. Access to the premises is given only to certain named employees responsible for the Register. Electronic material is stored on an offline server, where an Oracle database runs with access protected by user names and passwords.

Reporting and dissemination

See under Data Publication.

Data Publication

The Statistical Summary Parturients, Deliveries and Births is produced by STAKES biannually, Preliminary data are published in June-July and the Statistical Summary itself in September-October. The statistics contained in the Statistical Summary are based on data concerning deliveries during the preceding calendar year. Hospitals submit their data at the latest by the end of March of the year following the child's year of birth.

The Statistical Summary concerning the Birth Register presents nationwide information on parturients, deliveries and births in the form of absolute figures and percentages. In addition, data on deliveries are provided by age group, by hospital district per 1000 women of the same age, and by hospital type. Data on births are given by length of gestation and birth weight, and data on perinatal mortality by number of foetuses, sex, weight, length of gestation and hospital district.

The Statistical Summary aims to provide information to health-care professionals, administrators, planning officials and researchers working in the area of reproductive health. They need statistical data on deliveries and newborn infants that are as up-to-date and detailed as possible.

In addition to being published on the STAKES website in Finnish, Swedish and English (at http://www.stakes.fi/statistics/parturients), the Statistical Summary is sent to all delivery hospitals. The Register's data are also submitted to international statistical organisations (OECD, Nomesco, WHO and Nordic perinatal statistics).

Every year, about 20 to 30 scientific articles are published based on data of the MBR and in collaboration with its staff (an indicative list is provided below, under Scientific Publications).

STATISTICAL PUBLICATIONS of MBR 1995-2006

Meriläinen, J.; Gissler, M.; Hemminki, E.;

Teperi, J., Perinataalitilastot 1993 - Finnish Perinatal Statistics 1993.
Tilastotiedote 18, Helsinki: Stakes 1995

Gissler, M.; Rasimus, A.; Ritvanen, A.; Toukomaa, H.,
Lisääntyminen ja sen trendit
-tilastoja raskauksista, syntymistä, steriloinneista ja lasten epämuodostumista;
Förökningen och dess trender
-statistik över graviditeter, förlossningar, steriliseringar och missbildningar hos barnen i Finland
Reproduktion and its trends
-statistics on pregnancies, childbirths, sterilisations and congenital malformations in Finland
SVT Terveys/Hälsa/Health 1996:2, Helsinki: Stakes 1996

Gissler, M.; Toukomaa, H.; Virtanen, M., Perinataalitilastot 1995 -
Perinatalstatistik 1995 - Finnish Perinatal Statistics 1995
Tilastotiedote 16, Helsinki: Stakes 1996

Koskinen, R.; Meriläinen, J.; Gissler, M.; Virtanen, M,
Perinataalitilastot 1996 - Perinatalstatistik 1996 - Finnish Perinatal Statistics 1996
Tilastotiedote 31, Helsinki: Stakes 1998

Koskinen, R.; Meriläinen, J.; Gissler, M.; Virtanen M., Perinataalitilastot 1997-1998,
Perinatalstatistik 1997-1998, Finnish Perinatal Statistics 1997-1998
Tilastoraportti - Statistikrapport - Statistical Report, 41, Helsinki: Stakes 1999

Gissler, M.; Rasimus, A.; Ritvanen, A.,
Syntymät, abortit, steriloinnit ja epämuodostumat 1999
Födelser, aborter, steriliseringar och missbildningar 1999
Births, abortions, sterilisations and congenital anomalies 1999
Tiedonantajapalaute 14, Helsinki: Stakes 2000

Vuori, E.; Gissler, M., Synnyttäjät, synnytykset ja vastasyntyneet 2000
Föderskor, förlossningar och nyfödda 2000 - Parturients, births and newborn infants 2000
Tiedonantajapalaute 16, Helsinki: Stakes 2001

Vuori, E.; Gissler, M., Synnyttäjät, synnytykset ja vastasyntyneet 2001 -
Föderskor, förlossningar och nyfödda 2001 - Parturients, births and newborn infants 2001
Tiedonantajapalaute 15, Helsinki: Stakes 2002

Vuori, E.; Gissler, M., Kivunlievitys ja muita synnytystoimenpiteitä sairaaloittain 2000-2001
Smärtlindring och andra ingrepp vid förlossning efter sjukhus 2000-2001
Tiedonantajapalaute 19, Helsinki: Stakes 2002

Gissler, M.; Vuori, E.; Rasimus, A.; Ritvanen, A.
Lisääntymistilastot 2000 - Reproduktionsstatistik 2000 - Reproduction statistics 2000
Tilastoraportti - Statistikrapport - Statistical Report, 3, Helsinki: Stakes 2002

Vuori, E.; Gissler, M., Synnyttäjät, synnytykset ja vastasyntyneet - ennakkotiedot 2002,
Föderskor, förlossningar och nyfödda - preliminära data för år 2002,
Parturients, births and newborn infants - preliminary data for 2002

Tilastotiedote 13, Helsinki: Stakes 2003

Vuori, E.; Gissler, M., Synnyttäjät, synnytykset ja vastasyntyneet 2002
Föderskor, förlossningar och nyfödda 2002
Parturients, births and newborn infants 2002
Tilastotiedote 24, Helsinki: Stakes 2003

Vuori, E.; Gissler, M., Synnyttäjät, synnytykset ja vastasyntyneet - ennakkotiedot 2003,
Föderskor, förlossningar och nyfödda - preliminära data för år 2003,
Parturients, births and newborn infants - preliminary data for 2003
Tilastotiedote 15, Helsinki: Stakes 2004

Vuori, E. ; Gissler, M., Synnyttäjät, synnytykset ja vastasyntyneet 2003 -
Föderskor, förlossningar och nyfödda 2003 - Parturients, births and newborns 2003
Tilastotiedote 26, Helsinki: Stakes 2004

Vuori, E.; Gissler, M., Kivunlievitys ja muita synnytystoimenpiteitä sairaaloittain 2002-2003,
Smärtlindring och andra ingrepp vid förlossning efter sjukhus 2002-2003
Tilastotiedote 34, Helsinki: Stakes 2004

Vuori, E. ; Gissler, M., Synnyttäjät, synnytykset ja vastasyntyneet - ennakkotiedot 2004,
Föderskor, förlossningar och nyfödda - preliminära data för år 2004,
Parturients, deliveries and births - preliminary data for 2004
Tilastotiedote 13, Helsinki: Stakes 2005

Vuori, E.; Gissler, M., Synnyttäjät, synnytykset ja vastasyntyneet 2004 -
Föderskor, förlossningar och nyfödda 2004 - Parturients, births and newborns 2004
Tilastotiedote 21, Helsinki: Stakes 2005

Gissler, M.; Vuori, E., Pohjoismaiset perinataalitilastot - Nordisk perinatalstatistik
Perinatal statistics in the Nordic countries
Tilastotiedote 28, Helsinki: Stakes 2005

Vuori, E.; Gissler, M., Synnyttäjät, synnytykset ja vastasyntyneet - ennakkotiedot 2005 ,
Föderskor, förlossningar och nyfödda - preliminära data för år 2005,
Parturients, Deliveries and Births - preliminary data for 2005
Tilastotiedote 13, Helsinki: Stakes 2006

Vuori, E.; Gissler, M., Synnyttäjät, synnytykset ja vastasyntyneet 2005 -
Föderskor, förlossningar och nyfödda 2005 - Parturients, births and newborns 2005
Tilastotiedote 18, Helsinki: Stakes 2006

Vuori, E.; Gissler, M., Kivunlievitys ja muita synnytystoimenpiteitä sairaaloittain 2004-2005 ,
Smärtlindring och andra ingrepp vid förlossning per sjukhus 2004-2005
Tilastotiedote 27, Helsinki : Stakes 2006

SCIENTIFIC PUBLICATIONS 1995-2007:

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Participation supporting actions

The definitions and concepts related to pregnancy and neonatality are based on the STAKES publication Ohjeita ja luokituksia 1999:2, Tautiluokitus ICD-10. The Statistical Summary also uses established international concepts and classifications.

When something changes in the data collection (e.g. update of data collection forms), there is also an update of the instructions available online. These are also sent to the hospitals in paper form. There is no monetary support provided by the register to collaborating units, neither any extra educational activities.

Contact persons provide advice when necessary, and assist with possible data corrections required.

Validation

Routine validation procedures

The data are correct in so far as they have been reported correctly. The data submitted to STAKES by hospitals are checked. The process is partly automated, whereby a programme goes through data and identifies most common/probable errors (often IT-related, or then human error in data entry). Any missing or supposedly incorrect data are confirmed by contacting the treating hospitals, and then corrected in the database.

In addition to the annual data entry and checking, data is cleared continuously throughout the year, e.g. when there are specific requests for data or information, additional errors may be identified and corrected.

Some birth data are missing in the Birth Register. The Register is therefore completed by data compiled by the Population Register Centre on live births and by data compiled by Statistics Finland on stillbirths and deaths during the first week of life. After these additions, the statistics practically speaking have a coverage of 100%.

Connection to other databanks/data sources

Routine

As mentioned earlier, as part of standard validation procedures and in order to achieve complete coverage, the data of the MBR are regularly linked to the data of the Population Register Center on live births, as well as to the Causes of Death statistics (for stillbirths, and deaths during the first week of life).

For research purposes

STAKES is authorized to disclose data of the MBR to researchers for scientific research purposes, after consulting the Data Protection Ombudsman.
In principle, linking to any register is possible, provided that there is special research permission and approval by the Data Protection authorities. Linking to economical data has only been undertaken to a limited extend in the PERFECT project.

The general application and processing process of STAKES registers, described on pages 12-13 of this report also applies to the Medical Birth Register.

Access of stakeholders to not published datasets

The National Authority for Medico-legal Affairs (TEO in Finnish), can access non-identifiable data without special permission.
Regional public health institutions, on the other hand, require a permission in order to access MBR data.
Physicians can access data concerning admissions to their own department, but without personal identification numbers. They also have access to the annual feedback which is provided to each hospital contact person, and in addition they can also make specific requests (most commonly, the reason for the latter is related research work, rather than regular activities).
The data subjects themselves have no right of to and no right to rectify the data entered into the register, because the Medical Birth Register is a statutory statistical and research register and the personal data stored in it are not used in decision-making or care concerning the data subjects.

Reports on demand

Requests for extraordinary reports (i.e. in addition to the annual statistical summary), are received with a frequency of 2-3 per week. The primary sources are:

- students (mostly midwives),
- hospital districts (specific questions on own district) / doctors
- nurses - higher positions
- reporters, journalists

Mostly the service of providing the requested information is provided for free .

Evaluations

EUPHORIC INDICATORS

All of the indicators included in the EUPHORIC list for neonatal/maternal care (neonatal/infant mortality rate, perinatal mortality rate, percentage of births carried out by caesarean section) can be calculated on the basis of the MBR data, with the exception of perinatal intensive care mortality rate.

Impact and external Auditing

The Register's personnel perceive that the Register's work is of high impact from the viewpoint of public health and physicians' work, as well as of quality control activities. With regard to patients themselves, the impact is most likely average.

The register has not undergone external auditing, there are only ad-hoc meetings of the register's internal team and group of collaborating experts.

3. Register on Congenital Malformations

REGISTER NAME	**Register of Congenital Malformations** (Epämuodostuma rekisteri)
Address	National Research and Development Centre for Welfare and Health (STAKES) Postal address: PO Box 220 Postcode: FI-00531 Helsinki Visiting address: Lintulahdenkuja 4, 00530 Helsinki Tel.: +358-9-39 671 Fax: +358-9-3967 2324
Website	http://www.stakes.fi/EN/tilastot/statisticsbytopic/reproduction/congenitalmalformations.htm
Main contact	Name: Annukka Ritvanen Position: Senior Researcher Postal address: STAKES / STAKES Information / Register of Congenital Malformations PO Box 220, 00531 Helsinki, Finland Tel.: +358 9 3967 2376 Fax: +358 9 3967 2324 E-mail: annukka.ritvanen[at]stakes.fi
Established	29 December 1962
Size Coverage	Annual case input: The Register of Congenital Malformations contains national-level data on congenital chromosomal and structural anomalies detected in stillborn and live born infants and foetuses. Data on some 4000 congenital anomalies are annually reported to the Register, of which some 2000 are major congenital anomalies.
Legal Status	Statutory

Registers' History

Registration of anomaly data began on 1 January 1963.

The activities of the register were revised in 1993 and due to better quality of notification by hospitals and an increased activity on the side of the register the prevalence of births with major congenital anomalies increased steeply in the early 1990s, although the real prevalence remained unchanged. Furthermore, data on major congenital anomalies detected in selective terminations of pregnancy performed for foetal indications have been collected into the register since 1986.

The Register of Congenital Malformations has an outcome-research orientation. The main purpose of the register is to prevent catastrophes - such as the one caused by thalidomide - by means of quick and continuous monitoring of congenital anomalies.
The Register continuously monitors the prevalence and kind of congenital anomalies for an early identification of any new environmental factors that potentially cause foetal defects, and for the prevention of congenital anomalies by influencing these factors.
Since 1993, the production of statistics for national and international purposes has become an increasingly important element of the Register's activities. Such statistical data are used for monitoring congenital anomalies nationally and regionally, for planning prenatal screening and diagnostics, as well as treatment of congenital anomalies, and for conducting research on congenital anomalies.

Received > 90% compliance:
Data coverage can be regarded as very good as of 1993, although there have been no coverage analysis since the 1993 revision. The prevalence of cases with congenital anomalies corresponds to the normal prevalence described in the literature and reported internationally. Prevalence rates of different types of congenital anomalies have also been consistent with the findings of other national and international studies on congenital anomalies.

Legal Aspects

Legal framework

Laws under which the register was established and laws regulating its operation.

• Law on nation-wide healthcare registers	556/89) 3 §	STAKES registers, implant register, Visual impairments
• Decree on nation-wide healthcare registers Modification 1993/1671	774/1989	STAKES registers, Visual impairments
• Law on the National Research and Development Centre for Welfare and Health	1073/92 2 and 6 §	STAKES registers

Patient consent
The Register is statutory, hence no patient consent is needed for collection and research use of the data.

Ownership of data
STAKES.

Data Collection

Starting point of documentation
Notification of congenital anomaly should be made as soon as possible after the detection of a congenital anomaly after birth or termination of pregnancy.
Data is collected upon admission to the hospital, at the time of discharge and, in addition, during follow up examinations, in the case of additional congenital malformations being detected.

Follow up/Reference data collection
Although the Register mainly collects data from the first year of the infant, it also collects data on subsequently detected congenital anomalies.

Comparability of data
The statistical data collected after the 1993 revision of the Register of Congenital Malformations are not directly comparable with the Register's earlier data, as the revision considerably improved the coverage and quality of the data compared with the data for 1963-1992. In addition to changes in the data collection and registration practices of the Register, and in the degree to which hospitals

fulfil their notification obligations, there have been changes in the definitions, classifications, coding systems, diagnostics and treatment of congenital anomalies and related mortality rates over the decades. With the development of prenatal screening and diagnostics, terminations of pregnancy performed for foetal indications have increased. The impact of these developments has been seen particularly as regards certain severe congenital anomalies. In the late 1980s, the coverage of the Register was considerably reduced as a result of the 1985 revision of the Register. Moreover, the reform of the Act on Induced Abortion in 1985, and the redefinition of stillbirth in 1986 affect the comparability of data entered in the Register in different years and decades. The 1986-1992 data of the Register are being complemented by congenital anomaly data drawn from other registers.
The activities of the register were revised in 1993 and due to better notifying by hospitals and an increased activity on the side of the register the prevalence of births with major congenital anomalies increased steeply in the early 1990s, although the real prevalence remained unchanged. Correspondingly, the prevalence increased in the Malformation Register when a new data source (Outpatient Specialised Health Care) was introduced in 2005. Furthermore, data on major congenital anomalies detected in selective terminations of pregnancy performed for foetal indications have been collected into the register since 1986.

Beginning from 1993, the annual statistical data presented in the Statistical Summary are mutually comparable. Internationally, the statistics are of high quality and comparable. The prevalence rates of preliminary statistics are comparable with the final annual statistics. In some hospital districts, the degree of meeting the notification requirement is lower than usual, as a result of which the total coverage of cases with congenital anomalies may be somewhat lower within these districts than elsewhere in the country.
The concept of cases with congenital anomalies (births, terminations of pregnancy or spontaneous abortions involving congenital anomalies), and that of major congenital anomalies, as well as the definitions and classifications of major congenital anomalies, and the data collection practices and content of the Register have remained unchanged since 1993. The basic definitions used (ICD-10) have remained the same.

Data Management

Registers, but also their collaborating partners, need to address and agree on the processes and principles of data management to be applied.
Register data management can be distinguished to specific steps or phases, for each of which a corresponding method needs to be applied:

DATA MANAGEMENT STAGES	**METHODS**
Data collection at point of care	paper forms, downloaded and printed pdf.
Storage and data security	limited number of named persons with access to identifiable data, storage in locked or electronic-key-accessible locations, offline server or work station protected with passwords
Processing of data	Various statistical methods (Reported in evaluation section)
Reporting and dissemination	Various formats and channels (Reported under Publications - Supporting Actions)

Data collection at setting of care

Regular Data sources of Register:
a) Health-care authorities, institutions and professionals (physicians, hospitals, prenatal and child-welfare clinics)
b) Cytogenetic laboratories
c) Medical Birth Register, Care Register for Health Care, Register of Induced Abortions, Register of Visual Impairment
d) Statistics Finland: Cause-of-Death Statistics

Entry of data to register data base - Accuracy check

From the notification forms and other sources, the data are stored in the Register electronically.

Storage and data security

The data stored in the Register of Congenital Malformations are confidential under section 4 of the Act on National Personal Data Registers Kept under the Health Care System (556/1989).
The Register of Congenital Malformations functions in accordance with the STAKES data security guidelines, which were adopted on 1 December 2004.
The materials of the Register of Congenital Malformations, both in paper and electronic form, are kept in locked premises. Access to the premises is given only to certain named employees responsible for the Register. Electronic material is protected by user names and passwords. The Register uses access control software (auditing log).

Processing of data

The controller is not liable to inform the data subjects of data processing, because the Register of Congenital Malformations is a statutory register.

Data Publication

The Statistical Summary of the Register of Congenital Malformations is compiled annually by STAKES. It is published in Finnish, Swedish and English in March or April and it is made available for download on the STAKES web site. From 1993 onwards, the statistics are complete, excluding the two previous calendar years only. The preliminary data are from end of the first calendar year after the birth, termination of pregnancy or spontaneous abortion. As it is possible that congenital anomalies are not diagnosed or their principal cause, such as a chromosomal defect, is not identified until at a later stage in the infant's life, the numbers in the final annual statistics may change slightly over the years - this, however, only concerns a few individual cases.

The key information is released in the Statistical Summary on the STAKES website. In addition the Statistical Summary is sent to hospitals and other units submitting data to the Register. The text material of the Summary describes major findings and specifies concepts, definitions, symbols and methods. Further information on the numbers and prevalence rates of congenital anomalies is available from the Register.

The Statistical Summary shows statistics on cases with congenital anomalies included into the Register of Congenital Malformations, i.e. live births, stillbirths or induced abortions in Finland

with at least one detected major congenital anomaly and with a mother who has been resident in Finland at the time of the delivery and also during most of the pregnancy.

Clarity and consistency
The Statistical Summary uses established international concepts and classifications. They are mostly consistent with other national registers and databases that contain data on congenital anomalies.

Validation

Routine validation procedures
The data are correct if they have been reported correctly. Several notifications to the Register may be concerned with the same infant or foetus, specifying previously received data and ascertaining diagnoses of congenital anomalies. In case of uncertainty, the treating hospitals are contacted in order to check the data. The Register data are also compared with data from the Medical Birth Register, the Care Register, the Register on Induced Abortions and the Register of Visual Impairment, as well as the Cause of Death Statistics, maintained by Statistics Finland, whereby case-specific data are complemented, any missing cases with congenital anomalies are added to the Register, and diagnoses are confirmed by contacting the treating hospitals.

Connection to other databanks/data sources

Routine - As part of validation procedures
The Register on Congenital Malformations utilizes data from the Medical Birth Register, the Care Register, the Register on Induced Abortions, and the Register of Visual Impairment, all maintained by STAKES, as well as from the data provided by the National Authority for Medicolegal Affairs (TEO), and from the Cause of Death Statistics, maintained by Statistics Finland.

For research purposes
Register data are not disclosed regularly.
STAKES is authorised to disclose data in the Register of Congenital Malformations to researchers for scientific research purposes after consulting the Data Protection Ombudsman.

Access of stakeholders to not published datasets
Patients: The data subjects have no right of access to and no right to rectify the data entered into the register, because the Register of Congenital Malformations is a statutory statistical and research register and the personal data stored in it are not used in decision-making or care concerning the data subjects.

Evaluations

Indicators calculated:
The Statistical Summary of the Register of Congenital Malformations contains information on the number and prevalence rates (per 10,000 births) of congenital anomalies detected in stillbirths, and in live born infants before the age of one, on an annual basis, both nationally and by hospital

district. The national-level data gives the numbers of cases with congenital anomalies among perinatal deaths and infant deaths, as well as the percentages of such cases of all infant deaths at the same age. In addition, the Summary contains statistical data on major foetal malformations and other birth defects detected in terminations of pregnancy performed for foetal indications, and analyses the impact of such terminations on the national prevalence of cases with congenital anomalies. The annual numbers and prevalence rates of certain internationally monitored congenital anomalies are given at the national level, while a more detailed analysis is presented of neural tube defects, Down's syndrome and orofacial clefts.
The statistics begin from 1993, after which year the Register data have had an adequate coverage and reliability.

Statistical methods:

The Register of Congenital Malformations receives data on congenital anomalies from hospitals, health-care professionals and cytogenetic laboratories. It also draws data from the Medical Birth Register, the Care Register, the Register on Induced Abortions, and the Register of Visual Impairment, all maintained by STAKES, as well as from the data provided by the National Authority for Medicolegal Affairs (TEO), and from the Cause of Death Statistics, maintained by Statistics Finland. The diagnoses obtained from these data sources are confirmed by contacting the hospitals that have given treatment to the infant/foetus. Notification of congenital anomaly should be made as soon as possible after the detection of a congenital anomaly after birth or termination of pregnancy. Although the Register mainly collects data from the first year of the infant, it also collects data on subsequently detected congenital anomalies.
The Statistical Summary shows statistics on cases with congenital anomalies included into the Register of Congenital Malformations, i.e. live births, stillbirths or induced abortions in Finland with at least one detected major congenital anomaly and with a mother who has been resident in Finland at the time of the delivery and also during most of the pregnancy.
The Statistical Summary only gives information on major congenital anomalies as defined in the Register of Congenital Malformations, that is, structural anomalies, chromosomal defects and congenital hypothyroidism. Major congenital anomalies do not include hereditary diseases and other diseases not associated with congenital anomalies, dysfunction of organs or tissues, developmental disabilities, congenital infections, isolated minor dysmorphic features, normal variations and common less significant congenital anomalies included in the exclusion list of the Register. This practice complies largely with that of the European Surveillance of Congenital Anomalies EUROCAT.
From the notification forms and other sources, the data are stored in the Register electronically. The register is maintained by STAKES pursuant to the Act on Nation-wide Health Care Registers (566/1989) and Section 8 of the subsequent Statute (774/1989). Data check-ups are made regularly, missing cases and case-specific data are added from the Medical Birth Register, for instance, and any unclear cases and diagnoses are checked and ascertained by contacting the treating hospitals.

EUPHORIC INDICATORS

The EUPHORIC list of proposed indicators does not include any indicators relevant to congenital malformations.

4. Causes of death Register

REGISTER NAME	**Causes of Death Statistics** (Kuolemansyyt tilastot)
Address	Statistics Finland (Tilastokeskus) Postal address: FI 00022 Tilastokeskus Visiting address: Työpajankatu 13, Helsinki Tel.: +358 9 1734 2220 Fax: +358 9 1734 2279
Website	http://www.stat.fi/til/ksyyt/index_en.html
Main contact	Helena Korpi, +358-9-1734 3605 kuolemansyyt.tilasto@tilastokeskus.fi
Established	1936
Size	Total # of cases in the register: 1, 8 millions of deaths Annual case input: 48 000-49 000 deaths
Legal Status	Statutory

Registers' History

The cause of death statistics and the archive of death certificates have been operating since 1936. In the cause of death statistics statistical information is produced annually on the causes of death of persons permanently resident in Finland (i.e. persons who have died abroad while domiciled in Finland at the time of death are also included). The statistics are compiled on the basis of death certificates on deaths, and the data are supplemented with and verified against data from the Population Information System of the Population Register Centre. Death certificates are archived at Statistics Finland.

Cause of death data are used i.a. in health surveys, in allocating health promotion measures and monitoring health as well as in various medical examinations. By combining the data with other data files it is possible to study, for instance, differences in mortality between different population groups.

Legal Aspects

Legal framework

Establishing the cause of death and the related procedures are based on the Act (459/1973) and Decree (948/1973) on the Inquest into the Cause of Death.

Patient consent

- Single death certificates are given to the deceased person's next of kin, a pension institution or to the authorities
- Certificate data is give for scientific research or statistical surveys by application.

Ownership of data

Statistics Finland.

Budget

The collection, processing and making the statistics costs about 250 000 euros/year (wages, recoding, scanning).

Staff

About 6 man-years.

Data Collection

Starting point of documentation

The cause of death statistics data are total data including all deaths in Finland or abroad of persons permanently resident in Finland at the time of their death.

Death certificates are issued by physicians. If determining the cause of death requires an autopsy, the death certificate is issued by a forensic pathologist after the information acquired from the autopsy is complete. The data files on causes of death are verified and supplemented with also other demographic data from the Population Information System, which in practice makes the coverage of the cause of death statistics around 100 per cent

Statistics on stillbirths are made separately; cases of stillbirths are not included in deaths during the year. The coverage of statistics on stillbirths is supplemented with data from the birth register of the National Research and Development Centre for Welfare and Health (STAKES).

Comparability of data

The cause of death statistics are the only comprehensive statistics on causes of death in Finland. Statistics Finland's vital statistics are exhaustive statistics on the numbers of deaths.

Statistics on cause of death have been compiled since 1936; the years 1936 to 1968 exist only as copies of printed publications. The classification of causes of death has changed several times; the classifications used in different years and the available comparable shortened cause of death classifications are described on the homepage of the cause of death statistics under Classifications.

Causes of death are currently coded according to the ICD10 classification (International Statistical Classification of Diseases and Related Health Problems, Volume 1-3, WHO Geneva 1992, new edition 2004) at the level of 3-4 numbers. In some exceptional cases domestic specifications are used and in some cases the most accurate classification level cannot be attained in a reliable way. The statistics are compiled according to the rules of the classification in question and the relevant EU recommendations. The death certificate form is confirmed by the Ministry of Social Affairs and Health.

The longest comparable time series classification (54 categories) is from 1969 onwards. Statistics following this classification are available in Statistics Finland's StatFin database under the topic Health.

Other Statistics Finland's statistics describing the mortality rate and causes of death are v**ital statistics**, **statistics on road traffic accidents and occupational accident statistics**.

Data Management

Registers, but also their collaborating partners, need to address and agree on the processes and principles of data management to be applied.
Register data management can be distinguished to specific steps or phases, for each of which a corresponding method needs to be applied:

DATA MANAGEMENT STAGES	METHODS
Data collection at point of care	paper forms
Sending data to register	CD-ROM
Entry of data to register data base	manual entry, IT-enabled but necessary manual work also (coding, checking of data, cleansing etc.)
Disposal of data	physical destruction of material, complete deletion or encryption of ID information
Storage and data security	limited number of named persons with access to identifiable data, storage in locked or electronic-key-accessible locations, offline server or work station protected with passwords, encryption of identification information
Processing of data	Various statistical methods (Reported in evaluation section)
Reporting and dissemination	Various formats and channels (Reported under Publications - Supporting Actions)

Data collection at the setting of care

Death certificates are issued by physicians. If determining the cause of death requires an autopsy, the death certificate is issued by a forensic pathologist after the information acquired from the autopsy is complete.
The physician issuing the death certificate delivers the certificate to the Provincial State Office of the province where the deceased was a resident.

Sending data to the register

Provincial State Offices send the death certificates onwards to Statistics Finland. At Statistics Finland the death certificate data are compared with data on the deceased obtained from the Population Information System and lists of missing death certificates are sent to Provincial State Offices for monitoring purposes.

Entry of data to register data base - Accuracy check

Automated logicality and validation checks and manual check of all data.

Disposal of data

The data is stored permanently.

Storage and data security

Both in paper format and partly electronically, in a locked storage area.

Processing of data

Statistical tables are made available in paper publications and online, and it is possible to make tailored tabulation for customers, as well as prepare specific samples for researchers.

Reporting and dissemination

The data on Causes of Death statistics are produced annually and they are ready on October-November of the following year.

Participation supporting actions

The certifiers are asked about unclear codes and sequences during processing of the data.
The forensic pathologists receive the yearly paper publication.

Data Publication

Cause of death data are produced annually and they are completed in November of the following year. The data are final and describe the deaths during the previous calendar of persons permanently resident in Finland.

A publication is produced yearly on the cause of death statistics and data are released on Statistics Finland's StatFin database under the topic Health. Data are provided on the whole country, by region and by hospital district. The cause of death statistics are produced according to the basic cause of death.

Validation

Register coverage

The coverage of the Cause of Death register is in practice almost 100%, since data on deaths are cross-check also with the Population Register Center's information systems.

Validation history

Cross-check with the Population Register has been used since 1970’s.
The yearly coverage compared to the Population Register's data is published in the yearly publication.

Routine validation procedures

The data on deaths collected by the register is cross-checked with data from other registers, e.g. the Population Register Centre, the STAKES medical births register (for perinatal, neonatal and infant mortality), the information system of the police (for deaths occurring during traffic accidents).

Connection to other databanks/data sources

Routine - As part of validation procedures

See above

For research purposes

The cause of death data can also be combined with other data files, such as longitudinal data of population censuses and employment statistics.

The process for requesting data for research/statistical purposes and links to the necessary application forms can be found at:
http://www.stat.fi/meta/tietosuoja/kayttolupa_en.html

Access of stakeholders to not published datasets

Cause of death data are available since 1969 as time series in the database. The variables in the time series file are described on the homepages of the cause of death statistics under Tietoluettelot (In Finnish only). Tailored statistics and research data can be made from the file for customer needs. A license to use Statistics Finland's data files is required for research data and statistics produced by municipality. An application for a license to use the data can be found on Statistics Finland's homepage. The cause of death data can also be combined with other data files, such as longitudinal data of population censuses and employment statistics.

Statistics Finland maintains the Finnish Archive of death certificates. The archive contains the death certificates of Finnish residents since 1936. Copies of death certificates and unit level data on causes of death are released from the archives for the purposes specified in the Act on the Inquest into the Cause of Death (459/1973). These purposes cover the releasing of data

1. to the deceased person's next of kin, a pension institution or to the authorities
2. for scientific research or statistical surveys.

Instructions for requesting death certificates and on the procedures of requesting a license to use statistical data are available on the homepage of Statistics Finland's Archive of death certificates.

Extraordinary Reports on Demand

(The following information is provided on Statistics Finland web pages:
http://www.stat.fi/tup/hallinnolliset/index_en.html)

Service practices
In case you think you need statistical data, you should ask as early as possible whether suitable data are already available at Statistics Finland or whether your data needs can be connected to some project being planned here. A preliminary estimate is made without charge on the need for collecting new data or on the suitability of existing data for solving your organisation's research problem.

Pricing principles

Statistics Finland's pricing of services is governed by the Act on Criteria for Charges Payable to the State. Further information about the regulations related to pricing is available from Statistics Finland's legal services.

All prices mentioned on this page are tax-free and VAT is added to them. We are happy to make without charge a cost estimate, where it is specified in detail from which the price of the service is formed.

Research data

Compilation and processing of research data are priced at hourly rate according to the hours worked. The tax-free hourly rates vary between EUR 73 and 135 depending on the requirements of the assignment. Utilisation of existing data is usually less expensive than collection of new data. In addition to labour costs, the IT costs related to the assignment are taken into consideration in the price.

Interview and Survey Services

The price of data collections for the Interview and Survey Services is formed of costs from data collection and content design, from fieldwork of data collection and from processing and editing of data.

The most important factors influencing the costs are the mode of data collection (telephone interview, face-to-face interview, mail inquiry, online data collection or a combination of these), length and sample size of the inquiry, the amount of work required by the questionnaire and data collection design and the delivery mode of the data (file, tables, table report, survey report).

The prices of surveys may vary due to the matters mentioned above from a few thousand euros to even hundreds of thousands of euros.

Different survey implementation alternatives are always discussed beforehand concerning the most essential factors influencing the costs, after which a preliminary cost estimate can be given for the different alternatives. The final cost estimate is made when the alternative suitable for customer needs is found and the details of the survey are clear.

Research Laboratory

The services of the Research Laboratory are priced as follows:

Costs of establishing a research project: EUR 910

Renting of a workstation per hour: EUR 18

Price of research services per hour (primarily editing of the data): EUR 100

Statistical methods

Hourly rates are applied to the pricing of methodological services, where the tax-free price is EUR 73 to 135 depending on the nature of the assignment. In larger projects monthly rates can also be used.

Evaluations

Definition of Endpoint:

Parameters in regular reports:

Tables available online in the English version of the Statfin database on the subject area of: Health:

Deaths and age-specific death rates per 100 000 mean population by cause of death and sex 1969-2006 - updated 2007-11-05 11:22

Deaths and death rates: Total deaths, Age-standardized death rate, total population, ... *(n=4)*

Cause of death (short list in time series, 54-classes): 01-03 Certain infectious and parasitic diseases (A00-B99, J65), ... *(n=64)*
Gender: Total, Males, Females *(n=3)*
Year: 1969, 1970, 1971, 1972, 1973, 1974, 1975, 1976, ... *(n=38)*

The Finnish version of the Statfin-database contains 12 tables on causes of death statistics, by different classifications and variables.

Indicators calculated:

The statistics on causes of deaths contain data on deaths and mortality by cause of death, age, gender, marital status and other demographic variables. The statistics also contain data on the circumstances of death, as well as on perinatal, neonatal and infant mortality. The annual statistics are compiled by the so-called statistical underlying cause of death. Other causes of death (see list) are used in producing special compilation.
The data on causes of deaths are also combined with the longitudinal population census and employment data, and the formed time series are used to study the effect of socio-economic factors on mortality and connections between an occupation and mortality.

Statistical methods:

When using the cause of death statistics it should be noted that mortality and the frequency of causes of death are strongly dependent on age. For that reason age standardisation is used in the statistics when comparing mortality differences between different time periods and areas. In the cause of death statistics the age standardised mortality figure is calculated most often per 100,000 persons. Age standardisation is described in more detail in Statistics Finland's eCourse in Statistics in the course Demography and population statistics.

EUPHORIC INDICATORS

Cause of Death data can be utilized to calculate several of the mortality-related indicators of EUPHORIC:

- cardiovascular diseases section [numerator data of indicators A2 - A11, A13 and A14].

(clarify whether mortality data is available also from HILMO - probably it is) -

- Possible role in inverse calculation of cancer survival rates [numerator/denominator of indicators B1-B3]
- infectious diseases: C2 (numerator and denominator), C3 (numerator)
- diabetes: nothing relevant
- orthopaedics: E2 (numerator), E3 (numerator), E6 and E7 (numerator)
- Neonatal - maternal: H2, H3 and H4 (numerator)
- Miscellaneous: I1 (numerator)

Cross-checking of accuracy in reporting by contrasting data of CDR and HILMO or other relevant register.

Impact and external Auditing

The cause of death data is used, among others, in allocating health measure promoting, monitoring health politics and actions and researching treatment efficiency.
External auditing is not performed.

5. Cancer Register

REGISTER NAME	**Finnish Cancer Registry** (Syöpärekisteri)
Address	Finnish Cancer Registry, Institute for Epidemiological and Statistical Cancer Research, Pieni Roobertinkatu 9, 001300, Helsinki Tel.: +358-9-39 671 Fax: +358-9-3967 2324
Website	http://www.cancerregistry.fi
Main contact	Risto Sankinla, Chief Medical Officer registry@cancer.fi
Established	1953
Size	Total # of cases in the register: Annual case input: over 27000 incident cancer patients
Legal Status	Statutory

Registers' History

Cancer registration in Finland started in 1952. The first complete year of country-wide cancer registration was 1953. In the 1950s, the reporting of cancers and certain benign tumours was voluntary. In 1961 the National Board of Health issued a by-law making reporting compulsory.

The Cancer Register stores the information required by STAKES (as of January 1st 2009, National Institute of Health and Welfare - THL) in order to fulfil its statutory tasks regarding the incidence, mortality and prevalence of cancers as well as survival rates of cancer patients for planning of prevention, treatment and medical rehabilitation, as well as the data necessary from the perspective of health services utilization.
The data is processed only for scientific research and statistical analysis.

Validation process started in 1950, and for solid tumours completeness of the registration has been shown to be over 99%.

Validation publication:
Teppo, L., Pukkala, E., Lehtonen, M.: Data quality and quality control of a population-based cancer registry. Experience in Finland. Acta Oncol. 1994: 33: 365 369.
The first publication of the Registry came out in 1954, and it was the Register's Annual Report, titled Cancer Statistics in Finland (in Finnish).
Feedback mechanisms to collaborating partners had anyhow begun already in 1950.
The initial funding for setting up the Registry was provided by the Cancer Society of Finland.

Legal Aspects

Legal framework

Laws under which the register was established and laws regulating its operation are:

• Law on nation-wide healthcare registers	556/89) 3 §	STAKES registers
• Decree on nation-wide healthcare registers Modification 1993/1671	774/1989	STAKES registers

•	Law on the National Research and Development Centre for Welfare and Health	1073/92 2 and 6 §	STAKES registers
•	Public Health law	66/72	
•	Law on specialized hospital services	1062/89	
•	Personal data protection law	523/99	
•	Contract between the National Institute for Health and Welfare (the Register's legal controller) and the Cancer Society of Finland (the Register's technical management		

Patient consent

Due to the statutory nature of the Registry, patient consent is not required for the gathering of the respective data.

Ownership of data

The data is owned by the National Institute for Health and Welfare.

Budget

The global budget of the Registry is €2.5 million, of which 1 million is provided by the Cancer Society of Finland, another million by Finland's Slot Machine Association (RAY) and the final €0,5 comes from several research projects that are funded through external research contracts.

Staff

The Registry has a Supervisory Board, to which THL (the National Institute for Health and Welfare) and Cancer Society of Finland name members.

There are more than 20 permanent workers, among them experts, e.g., in medicine, epidemiology, statistics and information technology. In addition there are a number of researchers working on project-based funding.
There are 2 senior medical officers, plus 3 doctors-researchers, 7 statisticians, 19 administrative staff (of which 10 are occupied by the Cancer Registry and 9 by the mass screening register) and 5 IT- persons.

Data Collection

Starting point of documentation

Diagnosis - All physicians, all hospitals and other institutions in the country must send a notification to the Registry of all cancer cases that come to their attention. Pathological, cytological and haematological laboratories send the respective laboratory notification. Statistics Finland provides the registry annually with all death certificates where cancer is mentioned as well as all death certificates of registered cancer patients.

Follow up/Reference data collection

Information is also collected on death or emigration.

Data Management

Registers, but also their collaborating partners, need to address and agree on the processes and principles of data management to be applied.

Register data management can be distinguished to specific steps or phases, for each of which a corresponding method needs to be applied:

DATA MANAGEMENT STAGES	METHODS
Data collection at point of care	paper forms, downloaded and printed pdf., extract from ICT-system, online data collection (for data on colorectal cancer screening collected by the mass screening register) An increasing number of notifications, especially from the pathological laboratories, but also from hospitals, are currently sent in machine readable format. The automatic reporting contains the same information as the manual reporting forms, including in the free text fields detailed descriptions of the tumour site and histology.
Sending data to register	paper, CD-ROM; secured online collection
Entry of data to register data base	manual entry, IT-enabled but necessary manual work also (coding, checking of data, cleansing etc.) - First coding of cancer data is performed by qualified secretaries and supervised by the Register's physician
Disposal of data	physical destruction of material
Storage and data security	limited number of named persons with access to identifiable data (Chief medical officer, IT staff, data entry and coding personnel, as well as personnel responsible for data quality control). All of these persons have signed a contract of life-long obligation to confidentiality, storage in locked premises, offline server protected with passwords, separate passwords required for access to the database providing each member staff only with the rights absolutely necessary for carrying out his/her tasks, encryption of identification information, The daily and weekly back up copies of the database, as well as the CDs and data tapes are stored in fire-proof safety boxes, the keys to which are in the possession of only the person responsible for electronic materials. The annual back up copies of the database, as well as the back up copies of microfilms are stored in a bank safety box.
Processing of data	Various statistical methods (Reported in evaluation section)
Reporting and dissemination	Various formats and channels (Reported under Publications - Supporting Actions)

Data collection at point of care

Data is collected upon admission to hospital, before and after surgery and upon discharge.
Following cancer diagnosis, several clinical notifications on each patient are received during diagnostics and primary treatment, as well as data from pathological laboratories.

Sending data to register

See Data Management Table.

Entry of data to register data base - Accuracy check

All data are checked for accuracy before entering them into the database.
See for further details under Data management.

Disposal of data

Paper data collection forms are destroyed in a paper shredder once data entry and storage has been completed. Electronic data transfer devices (such as CD-ROMs) are also physically destroyed.

Storage and data security

The personally identifiable information stored in the Cancer Registry is confidential, in accordance with the law on nation-wide healthcare registers (556/89).
Data in the Cancer Register is stored in three formats:
1) electronic data in the central (offline) server, on CDs and tapes
2) data on microfilm and
3) data on the paper cancer and mass screening reporting forms.

Processing of data

See under Data management

Reporting and dissemination

See under 'Participation Supporting actions' and 'Publications'

Participation supporting actions

Participation to the Registry is mandatory.
Both public and private institutions are very cooperative. The Finnish Cancer Registry and its staff are highly recognised both among the scientific community and the health care sector in Finland. The output of the Registry is widely used in research, administration, and health education on all levels.
All this improves the quality of the registration activity and is likely to contribute towards complete coverage and high data accuracy in the Registry.

Data collection forms are available online in .pdf format for download.

The newest cancer statistics (incidence, mortality and prevalence) can always be found at the home pages of the Finnish Cancer Registry (www.cancerregistry.fi).

Data Publication

The newest cancer statistics (incidence, mortality and prevalence) can always be found at the home pages of the Finnish Cancer Registry (www.cancerregistry.fi).

Finnish Cancer Registry publishes regularly tabulations on cancer incidence, mortality and prevalence, added with tabulations on cancer survival and screening activity statistics. A traditional bi-annual report is printed every second year (also in English), but the same tabulations (and many others) are updated about every two months and published on the register's web pages.

NORDCAN is a data base providing data on incidence and mortality concerning 41 major cancer diseases in Denmark, Finland, Iceland, Norway and Sweden
http://www-dep.iarc.fr/nordcan.htm

The International Agency for Research on Cancer (WHO) has several different cancer databases (see www-dep.iarc.fr) where tabulated data from the Finnish Cancer registry can be found.

Scientific Publications
During the more than 50 years of the Finnish Cancer Registry, some 1500 scientific articles and about 100 doctoral dissertations have been published where Registry's scientists or the data have had a central role.
All publications can be found at http://www.cancerregistry.fi/eng/research/

A list of the register's personnel, with each person's publication list is available at:
http://www.cancerregistry.fi/eng/general/JID28.html

Validation

Register coverage

Number of departments in collaboration with the Registry: **781**

% of Departments included: 100 %

% of Market covered (Number of Cases of the specific medical service): 99 %

% of clinicians reporting to the Register / total number of physicians performing relevant procedures: 50%, but data from other sources adds to completeness

Validation history

(See in the history section)

Routine validation procedures

Everyone residing in Finland since 1967 has been assigned a unique 11-digit personal identifier (PID), which is widely used in a number of different everyday events (including health care), and in all important person registers. The PID of the patient is indicated on all cancer registry notifications, and it is stored in the Registry database. It is the key in all practical registration procedures: *e.g.*, in coding, searching from the file, and combining notifications for one patient received at different times and from different sources. For example, duplicate registration can thus be effectively avoided. PIDs have greatly facilitated record linkage operations in Finland, and large and complicated computer runs can be executed very rapidly and in a reliable way.

Connection to other databanks/data sources

Routine - As part of validation procedures

The Registry file is annually matched, through computerised record linkage (based on PIDs), with the Cause of Death Register located at Statistics Finland, so that the dates and causes of death (also non-cancerous causes, both underlying and contributory causes of death) can be added to the records in the Registry.

The Registry file is also regularly linked with Central Population Register where the correctness of the PIDs is checked, and the complete name, vital status, possible date of death or emigration as well as the official place of residence prior to the date of diagnosis are obtained.

For research purposes

Linking to the data of the Discharge Register is possible, but it is not utilized as a routine data source. Rather, the linkage is part of different research projects. The same applies to economical data. Generally, all important registries in Finland have been linked with the cancer registry files in different research projects.

Access of stakeholders to not published datasets

Extraordinary Reports on Demand

If needed, the Cancer Registry is able to produce special tabulations using any of the variables recorded in its data base, such as stage at diagnosis or morphology. Discussion with the director of statistics or chief medical officer in advance often helps in reaching the optimal definition of ad hoc tabulations.
Most data provisions in tabulated format are free. In case of complicated processes, a nominal fee is charged.

Public Institutions, such as the Ministry of Health, Regional Public Health Institutions and Public Health Insurance do not have any direct access to personal health records, but the Registry provides all necessary data in tabulated format after request.

The same applies to Private Health Insurances, manufacturers and patients.

Physicians do not have access to the data of their own department, not even for revisions. In the case of access needed for research purposes, access can be granted only after appropriate permissions from the National Institute of Health and Welfare and the Ministry of Health.
The same procedure applies also to other researchers whishing to access Registry data.

Evaluations

Definition of Endpoint:

- cancer incidence (cases)
- cancer mortality (deaths)

Indicators calculated:

- trends over time
- percentage of histologically verified cases
- proportions of cancers registered with death certificate only (DCO) information
- mortality/incidence ratios
- proportions with unknown primary site or histology

- practically 100% follow-up for death or emigration of registered patients

Statistical methods:

- descriptive epidemiology
- survival analysis
- analytical epidemiology
- prediction methods

EUPHORIC INDICATORS

The list below indicates which of the EUPHORIC indicators are calculated regularly or are possible to calculate on the basis of the register's data:

- cancer mortality (deaths) - EUPHORIC INDICATOR for breast, lung, colon Ca.
- mortality/incidence ratios - EUPHORIC CANCER INDICATORS
- survival analysis - EUPHORIC CANCER INDICATORS

Impact and external Auditing

The impact of the Cancer Registry on its sponsors, quality control and feedback activities, as well as on Public Health is invaluable.
For physicians, the impact of the Registry is limited with respect to direct clinical work, but the Registry is remarkable as a data source and partner in research activities
Patients benefit mostly through public health actions.

The Registry's staff holds regular meetings, while international collaborative studies on cancer incidence and survival, as well as scientific peer review of publications provide sources of external auditing and quality control.

6. Implant Register

REGISTER NAME	**Implant Register: Endoprothesis Register** (Implanttirekisteri: Endoproteesirekisteri)
Address	National Agency for Medicines PL 55 , Mannerheimintie 103b 00301 HELSINKI Phone: +358-9 4733 4246 Fax: +358-9 4733 4266
Website	http://www.nam.fihtm
Established	1980
Legal Status	Statutory

Registers' History

The register is maintained by the National Agency for Medicines, Division of Medical Devices. The initiative for setting up the register started in 1980, when also the first national collection of data was undertaken.

The register is outcome-research oriented. The data of the register is used in order to monitor and evaluate the endurance, suitability and safety of artificial joint protheses implanted in humans. Along the years, the register and the information that is published on the basis of its data have developed further in order to serve better the needs of the register's users. Annual statistics are published regularly, as well as research data for supporting clinical use and product develoment. The experiences of the National Agency for Medicines in maintaining the register and on the benefits of long term follow up have also been brought forward in several international work contexts.

Legal Aspects

Legal framework

Laws under which the register was established and laws regulating its operation.

• Law on nation-wide healthcare registers	556/89 3 §	STAKES registers, implant register, Visual impairments
• Law on Personal Data Protection	523/1999	all registers

Patient consent

The register is statutory, hence no patient consent is needed for collection and use of the data for research purposes.

Ownership of data

NAM

Budget

Part of the NAM-Budget

Staff

Head of the Register is Prof. Tomi Kauppinen, Head of the Medical Devices Department. At present there is no clear picture of the staff resources of the Register.

Data Collection

Starting point of documentation

Regular sources of data are healthcare authorities, institutions and healthcare professionals, as well as the Population Register Center.

The register collects data on various types of implanted orthopedic endoprothesis. By orthopaedic endoprothesis is understood as a replacement joint or part of a joint composed of artificial materials that is permanently placed within a person's body through surgery.

Follow up/Reference data collection

In addition, data on complications that may appear after hospital discharge is collected to the Register.

Data Management

Data collection at setting of care

Data is collected through paper forms (available for download on the website of the National Agency for Medicines), as well as electronically (sent to the register on CDs).

Storage and data security

Manually processed data are stored in a locked space. Data that is stored electronically is protected by passwords and user names.

Data Publication

The National Agency of Medicines publishes annual reports on endoprotheses. The reports are delivered free of charge to all departments that have submitted to the Agency's implant register a report concerning orthopaedic endoprothesis.
Also manufacturers get from this publication valuable information regarding the longevity of implants, in order to improve their quality.

Access of stakeholders to not published datasets

The register's identifiable data is defined as confidential accoding to the law on nation-wide healthcare registers (556/1989 4§).
The National Agency for Medicines can, however, after approval by the Data Protection Ombudsman, grant permission for release of its data for scientific research purposes. The release of data must fulfil the requirements set by the Personal Data Protection Law (523/1999) 12§:n 1 momentin 6).

In addition, it is agreed that each hospital has the right to access its own data stored in the register, if so it is desired.

Evaluations

Definition of Endpoint:
Revision Surgery with Revision of at least a part of the implant

Indicators calculated:
Revision Rate, Revision Burden, Probabilities, Incidences

Statistical methods:
Kaplan Maier Kurves

EUPHORIC INDICATORS
Revision Rate (E8), Revision Burden (E9)

7. Register on Visual Impairments

REGISTER NAME	**Finnish Register of Visual Impairment** (**Näkövammarekisteri**)
Address	National Research and Development Centre for Welfare and Health (STAKES) Postal address: PO Box 220 Postcode: FI-00531 Helsinki Visiting address: Lintulahdenkuja 4, 00530 Helsinki Tel.: +358-9-39 671 Fax: +358-9-3967 2324 Technical Maintainance Näkövammaisten Keskusliitto ry. Postal address: PO Box 30 (Marjaniementie 74) Postcode: 00030 IIRIS Tel: +358-9-396 041 Fax: +358-9-3960 4345
Website	http://www.nkl.fi/tietoa/nvrek/index.htm
Main contact	Sirkka-Liisa Rudanko, Chief Physician Address: Näkövammaisten Keskusliitto ry., PL 63 (Marjaniementie 74), 00030 IIRIS Tel: +358-9-396 041 Fax: +358-9-4720 E-mail: sl.rudanko[at]nkl.fi
Established	1983
Size	Total # of cases in the register: 34,257 (end 2006) Annual case input: 1,500 - 2,200 new registrations
Legal Status	Statutory

Registers' History

The Finnish Visual Impairments Register is a statutory register, operating in a collaboration between the National Researcher and Development Center on Welfare and Health and the Finnish Federation of the Visually Impaired. The National Board of Health established the Register in 1983. The purpose of the Finnish Register of Visual Impairment is to study the incidence of visual impairment in Finland. The Register serves as a basis for preventive measures and treatment of visual impairment, as well as for planning of rehabilitation and other special services for persons with visual impairment. In addition, the Register provides research material on ophthalmological diseases and visual impairment. It also aims to promote and support research in the field.

A central goal of the Register is to compile as comprehensive as possible a data base on visual impairment in order to serve those interested. Special statistics are drawn up on the basis of records compiled in the Register.

The register has gathered information about the visually handicapped for 24 years (1.1.1983-).

Received > 90% compliance:
It is estimated that there are roughly 80,000 visually impaired people in Finland (the population is 5,2 millions). The register contains information on 34,257 v.i. persons, of whom 15 892 are alive

(31.12.2006). 1,500 - 2,200 new registrations are made annually. New entries received in the past few years have not changed the profile of visual impairment formed on the basis of the register. It can be assumed that the register contains a representative sample of those v.i's using ophthalmological services in Finland.

Since the register is not complete, the main distributions describing the registered persons are presented as relative frequencies (%-distributions).

Legal Aspects

Legal framework

Laws under which the register was established and laws regulating its operation.

• Law on nation-wide healthcare registers	556/89) 3 §	STAKES registers, implant register, Visual impairments
• Decree on nation-wide healthcare registers Modification 1993/1671	774/1989	STAKES registers, Visual impairments
• Law on the National Research and Development Centre for Welfare and Health	1073/92 2 and 6 §	STAKES registers

Patient consent

Patient consent for data collection is not mandatory, due to the statutory nature of the Register.

Staff

The Register has a Supervisory Board the Members of which are named by STAKES and the Association of Visually Impaired Persons (NKL).

In addition, the Register employs one physician, one statistician and two administrative staff members.

Data Collection

Starting point of documentation

The operation of the Register is regulated by the Act (556/89) and Decree (774/89) on National Personal Records kept under the Health Care System.
Health care authorities, institutions and personnel subject to the National Research and Development Centre for Welfare and Health are, under the above-mentioned Act, responsible to forward to the Register such information on persons with visual impairment as is specified in the Decree.

Notification must be made by a specialist in ophthalmology or the ophthalmological unit of a hospital. Notification must be made if the corrected visual acuity is permanently less than 0.3 in the better eye of the patient, or if the person must for some other reason be considered comparable with a person with permanent visual impairment as described above.

Data Management

Registers, but also their collaborating partners, need to address and agree on the processes and principles of data management to be applied.
Register data management can be distinguished to specific steps or phases, for each of which a corresponding method needs to be applied:

DATA MANAGEMENT STAGES	METHODS
Data collection at point of care	paper forms, downloaded and printed pdf
Processing of data	Various statistical methods (Reported in evaluation section)
Reporting and dissemination	Various formats and channels (Reported under Publications - Supporting Actions)

Data collection at point of care

The information is collected on paper forms, and it is redundant data collection (data that is not extracted from the hospital's IT system).

Storage and data security

Both paper and electronic forms that are individually identifiable (through the personal ID number) are gathered by persons named by the register.

The forms are stored during processing in a locked space and after that in the archive. Material in electronic format is protected with user codes and passwords. The intention is to transfer in the near future the register's data to the relational database of STAKES, where the use of data can be monitored more systematically.

Reporting and dissemination

See under 'Participation Supporting actions' and 'Data Publication'

Participation supporting actions

Participation to the Register is mandatory for ophthalmologists and other healthcare officials and institutions.

Information service

The register operates an information service which:
- maintains a reference database containing about 10000 relevant entries;
- maintains a library with variety of materials relevant to visual impairment from both the professional and patient viewpoints, in Finnish, English and Swedish language. There is the possibility to lend books in collaboration with one's local library or to have them delivered through post. At the library's premises it is possible to view handbooks and relevant periodical publications.

The Register releases information leaflets on the main causes of visual impairment. It also publishes current studies and articles on visual impairment in its series of publications and annual report.

Promotion of research on visual impairment

The Register promotes research on visual impairment by providing special statistics based on its records, and bibliographical references to researchers and students. In addition, the Register surveys study subjects related to visual impairment, maintains contacts with researchers in the field, takes part in joint research projects and international activities, and organizes research seminars.

Data Publication

A summative report of the Registers activities and statistics is published once every five years.

The most important task of the Register is to process and print out data obtained from notification of a visual impairment. Central statistics illustrating the profile of visual impairment can be found in the statistical section of the annual report released by the Register.

The Register also maintains a bibliographical data base relating to studies, articles, congress reports etc. on visual impairment. The material is mainly Finnish or foreign non-medical literature available in Finland.

The Register releases information leaflets on the main causes of visual impairment. It also publishes current studies and articles on visual impairment in its series of publications and annual report.

Connection to other databanks/data sources

For research purposes

Connection is possible to the register of the Population Register Center, as well as to the Causes of Death statistics.

Access of stakeholders to not published datasets

Information compiled in the Finnish Register of Visual Impairment is confidential. Information concerning an individual with a visual impairment is not released to an outsider without the approval of the National Research and Development Centre for Welfare and Health.

Evaluations

Indicators calculated:

Distribution of visual impairment by age and gender
Principal diagnoses of visual impairments by age groups
Categories of visual impairment based on WHO definitions
Etiology of visual impairment
Multiple impairment and diabetes
Age at onset of visual impairment
Family status of visually impaired persons by age groups
Level of education of visually impaired persons
Main type of activity
Most common occupations (by frequency)

Statistical methods:

Presentation of relative frequencies (%-distributions).

In the statistics tables in addition to each variable's distribution throughout the register, also the distribution of newly registered cases is displayed. Throughout the tables displaying the basic data of the register, the following are presented: numbers, %-distribution, un-standardized and age- and gender-standardized prevalence, as well as number of new registered cases, %-distribution and un-standardized incidence.
This data, as well as the analysis of statistically significant differences, are presented in the wider version of the annual report, which is issued in five year intervals. The previous version was published in 2005 and the next one will be produced on the basis of the 2010 data.

EUPHORIC INDICATORS

EUPHORIC indicators do not address specifically the area of visual impairment.

2. NATIONAL SPECIAL REGISTERS

1. Finnish Registry for Kidney Diseases

REGISTER NAME	**Finnish Registry for Kidney Diseases** (**Suomen Munuaistautirekisteri - SMTR**)
Address	Visiting address: Kumpulantie 1A, 6th floor, 00520, Helsinki, Finland
Website	http://www.musili.fi/fin/munuaistautirekisteri/finnish_registry_for_kidney_diseases/
Main contact	Patrik Finne, Chief Physician
Established	
Size	Total # of cases in the register: 10341 of which 3809 were living (end 2006) Annual case input: about 500 new cases each year
Legal Status	Statutory

Registers' History

The Finnish Registry for Kidney Diseases contains data on Finnish dialysis and kidney transplantation patients since 1964. During the first 25 years the Finnish hospitals sent their data directly to the central registry of EDTA (European Dialysis and Transplantation Association) in London. Since 1989, data collection has been handled by the Finnish Registry for Kidney Diseases. Prof. Carola Grönhagen-Riska collaborated in the 80's with the EDTA (European Dialysis and Transplantation Association) central registry in London, and promoted the transfer of data collection to Finland.
In 1992, the Finnish data from the EDTA registry was transferred to the Finnish registry.

Received > 90% compliance:
It is estimated (2006 Annual Report) that the register covers 97-99% of all active dialysis patients starting from 1964. At the end of 2006 the register contained information on 10 341 patients, of whom 3809 were still living.

The first scientific publication of the Registry appeared in the journal of the Finnish Medical Society Duodecim in 1995.

The first annual Report was published in 1992 and the versions from 2000 and onwards are also available for download online. Paper copies of the report can be send upon request.

Annual reports have been produced since 1992.
In additional, every hospital receives a separate three-page report, covering their activity from the start to the end of the year.
If so desired, each hospital can order a tailored report, where e.g. their data is compared with the general country-level situation.

The Register is outcome research-related. Its main goals are to:
- Map the treatment and care needs of patients suffering of renal failure and assist hospital official in the planning and follow up of resource needs;
- Undertake epidemiological studies on the prevalence of renal diseases and the factors that affect the emergence and progress of these diseases;

- Collect statistical data that can be utilized in studying renal diseases.
- Assessment and surveillance of outcome of renal replacement therapy

Legal Aspects

Legal framework

• Personal data protection law	523/99	

Patient consent

Patient consent is required for data collection and entry in the Register, since it is a quality control project of the Finnish Kidney and Liver Association.

Ownership of data

The Kidney and Liver Association

Budget

Global Budget :
79400€ (year 2007).

Covered by:
Supported by RAY (Finland's Slot Machine Association).

Staff

Chief physician appointed, who is also the person primarily responsible for the scientific quality of the register, as well as a supervisory board that oversees the activities and development of the register.
The register is part of The Finnish Kidney and Liver Association, who has two representatives on the Board of the Finnish Registry for Kidney Diseases. In addition, nephrologists from all University hospitals are also represented on the Board.

The Register of Kidney Diseases employs one part-time doctor, who is also responsible for the register's statistical analysis, one secretary and has no dedicated IT-staff at present, but rather receives support from the Kidney and Liver Association's IT-expert. The register's database is outsourced, and maintained by the provider company.

The Register has a Supervisory Board that monitors and develops the activities of the Finnish Registry for Renal Diseases.
The members of the Board are:
Carola Grönhagen-Riska, HUS
Sirpa Aalto
Eero Honkanen, HUS
Ilpo Ala-Houhala, TAYS
Patrik Finne
Eero Honkanen, HUS
Pauli Karhapää, KYS

Marjatta Linnanvuo, varalla, OYS
Risto Ikäheimo, OYS
Kaj Metsärinne, SNY
Maija Piitulainen
Kai Rönnholm, HUS
Kaija Salmela, HUS
Risto Tertti, TYKS
Rauni Jukkara

Data Collection

Starting point of documentation

Diagnosis - After RRT data collection happens annually

Follow up/Reference data collection

Information in the report is updated with information on renal transplant patients, made available by the national register of renal transplant patients that operates in the corresponding unit of HYKS (the Helsinki and Uusimaa University Hospital).

Data Management

Registers, but also their collaborating partners, need to address and agree on the processes and principles of data management to be applied.
Register data management can be distinguished to specific steps or phases, for each of which a corresponding method needs to be applied:

DATA MANAGEMENT STAGES	**METHODS**
Data collection at point of care	paper forms
Sending data to register	paper
Entry of data to register data base	manual entry
Storage and data security	limited number of named persons with access to identifiable data, storage in locked or electronic-key-accessible locations, offline server or work station protected with passwords, encryption of identification information
Processing of data	Various statistical methods (Reported in evaluation section)
Reporting and dissemination	Various formats and channels (Reported under Publications - Supporting Actions)

Data collection at setting of care

Data collection at hospitals is redundant, in the sense that it is a separate, paper-based form. There are plans to implement within the next 2 years a server that will allow filling and submitting of the form online.
In that context, ensuring data security is particularly important.

Much of the data collected, exists presently in the hospitals' patient information systems, however there is a need for additional work by the submitting physician. E.g. laboratory values are requested to be provided with the indication of time collection - before and after dialysis, something that systems cannot distinguish automatically, and the doctor needs to specify manually. Co-morbidity data in the Finnish Registry for Kidney Diseases are unique among renal registries world-wide. Data on the ten most important co-morbidities are collected at the start of renal replacement therapy using a “tick the correct box” system, which hardly can be automated.

Data is collected at at least four points in time:
- when a patient arrives for dialysis or (more rarely) directly for transplant
- when type of treatment or treating hospital changes
- at the end of each year for all living patients
- in case of death, the last data available, as well as information concerning the death are collected

There is data collected annually during check up visits of RRT patients.

Sending data to register

Paper forms are mailed from the hospitals to the registry. Within a year the reporting of data will be web-based.

Entry of data to register data base - Accuracy check

The database program into which the data is inserted has automatic accuracy check routines. The secretary of the registry also checks for inaccuracies and contacts the reporting hospitals if data are unclear.

Storage and data security

The Registers database resides on an offline computer. The computer is protected by password and not accessible to unauthorized individuals.

Paper forms are located in a locked space, to which only the register secretary and the doctor responsible for the register have access.

Processing of data

By the register's secretary.

Reporting and dissemination

See under Publications.

Participation supporting actions

Participation in the Register is voluntary.

Feedback is provided to participating hospitals, in the form of the annual and tailored reports. Both of these services are free of charge.
Since the data collection requires the consensus of the patient, the completeness of each hospital's data depends on the activity of the nephrologists. In turn, this is reflected in the statistics available for the hospital, which acts as a sort of incentive to guarantee clinicians' motivation for data collection.

Data Publication

The annual report has been published systematically since 1992. It is published in Finnish and English and sent to Finnish and Nordic hospitals, to the Ministry of Social Affairs and Health, to the Social and Health care Research and Development Centres and to the renal disease registers of other countries.

The report provides current data on incidence and prevalence of RRT, mortality of RRT patients, laboratory variables, diagnoses and types of treatments.

Scientific Publications

Original Papers

[1] Couchoud C, Kooman J, Finne P, Leivestad T, Stojceva-Taneva O, Ponikvar JB, Collart F, Kramar R, De Francisco A, Jager KJ. From registry data collection to international comparisons: examples of haemodialysis duration and frequency *Nephrol Dial Transplant* 2008.

[2] Immonen K, Finne P, Hakala M, Kautiainen H, Pettersson T, Grönhagen-Riska C. No improvement in survival of patients with amyloidosis associated with inflammatory rheumatic diseases -- Data from the Finnish national registry for kidney diseases. *J Rheumatol* 2008;35:1334-1338.

[3] Stewart JH, McCredie MRE, Williams SM, Jager KJ, Trpeski L, McDonald SP, The ESRD Incidence Study Group (jossa Patrik Finne mukana). Trends in incidence of treated end-stage renal disease, overall and by primary renal disease, in persons aged 20-64 years in Europe, Canada and the Asia-Pacific region, 1998-2002. *Nephrology* 2007;12:520-527.

[4] van Dijk PC, Zwinderman AH, Dekker FW, Schon S, Stel VS, Finne P, Jager KJ. Effect of general population mortality on the north-south mortality gradient in patients on replacement therapy in Europe. *Kidney Int* 2007;71:53-39.

[5] The ESRD Incidence Study Group (jossa Patrik Finne mukana). Geographic, ethnic, age-related and temporal variation in the incidence of end-stage renal disease in Europe, Canada and the Asia-Pacific region, 1998-2002. *Nephrol Dial Transplant* 2006;21:2178-2183.

[6] The ESRD Incidence Study Group (jossa Patrik Finne mukana). Divergent trends in the incidence of end-stage renal disease due to type 1 and type 2 diabetes in Europe, Canada and Australia during 1998-2002. *Diabetic Medicine* 2006;23:1364-1369.

[7] Yoshino M, Kuhlmann MK, Kotanko P, Greenwood RN, Pisoni RL, Port FK, Jager KJ, Homel P, Augustijn H, de Charro FT, Collart F, Erek E, Finne P, Garcia-Garcia G, Gronhagen-Riska C, Ioannidis GA, Ivis F, Leivestad T, Lokkegaard H, Lopot F, Jin DC, Kramar R, Nakao T, Nandakumar M, Ramirez S, van der Sande FM, Schon S, Simpson K, Walker RG, Zaluska W, Levin NW. International differences in dialysis mortality reflect background general population atherosclerotic cardiovascular mortality. *J Am Soc Nephrol* 2006;17:3510-3519.

[8] Stewart JH, McCredie MR, Williams SM, Fenton SS, Trpeski L, McDonald SP, Jager KJ, van Dijk PC, Finne P, Schön S, Leivestad T, Lokkegaard H, Billiouw JM, Kramar R, Magaz A, Vela E, Garcia-Blasco MJ, Ioannidis GA, Lim YN. The enigma of hypertensive ESRD: observations on incidence and trends in 18 European, Canadian, and Asian-Pacific populations, 1998 to 2002. *Am J Kidney Dis* 2006:48;183-191.

[9] Finne P, Reunanen A, Stenman S, Groop P-H, Grönhagen-Riska C. Cumulative incidence of end-stage renal disease in patients with type 1 diabetes. *JAMA* 2005;294:1782-1787.
[10] van Dijk PC, Jager KJ, Stengel B, Grönhagen-Riska C, Feest TG, Briggs JD. Renal replacement therapy for diabetic end-stage renal disease: data from 10 registries in Europe (1991-2000). *Kidney Int* 2005;67:1489-1499.
[11] van Dijk PC, Jager KJ, de Charro F, Collart F, Cornet R, Dekker FW, Grönhagen-Riska C, Kramar R, Leivestad T, Simpson K, Briggs JD: ERA-EDTA registry. Renal replacement therapy in Europe: the results of a collaborative effort by the ERA-EDTA registry and six national or regional registries. *Nephrol Dial Transplant* 2001;16:1120-1129.

Reviews and Editorials

[12] Finne P, Grönhagen-Riska C. Dialyysipotilaiden ennuste on parantunut viime vuosina. Suomen lääkärilehti 2007;35:3039-3040, pääkirjoitus.
[13] Finne P, Grönhagen-Riska C. Tyypin 1 diabetes ja krooninen munuaistauti. Duodecim 2006;122:1415-6, pääkirjoitus.
[14] Finne P, Honkanen E, Grönhagen-Riska, C. Munuaisten vajaatoiminnan hoidon tulevaisuuden haasteet. Duodecim 2006;122:193-5, Nefrologia-teemanumeron pääkirjoitus.
[15] Stenman S, Grönhagen-Riska C. Munuaistautien aktiivihoito Suomessa. Duodecim 1995;111:1497-1504.

Validation

Register coverage

Number of Departments in cooperation with the Register: 29 hospitals
% of Departments included: 100% coverage
% of Market covered (Number of Cases of the specific medical service): 97-99% of all active dialysis patients starting from 1964.

Validation history

Validation process started in (year): 1992

Routine validation procedures

Every year the data in the register is compared against the information available in the transplant registers of surgical departments, to guarantee coverage.
Also once a year, a review is performed with regard to the laboratory values used in different care settings.
The register's secretary who is responsible for data entry, checks back with hospitals when necessary, to clarify accuracy of provided information and data.

The results of the validation processes are not published.

Requests for corrections of erroneous data must be done in writing. The request must be addressed to the register's responsible physician. The person submitting the request may be asked to verify his/her identity.

Connection to other databanks/data sources

Routine - As part of validation procedures

Transplant registers of surgical departments.

For research purposes

Discharge Register: Linking would be interesting in order to extract, e.g. other co-existing diagnoses, but does not take place at the moment.

Inhabitants Register /Deceased persons: information of deaths is received and cross-checked against hospital reporting

Causes of death: Yes, from Statistics Finland.
In addition, and in the context of a separate research project, information on employability had been extracted, through anonymized data (since there was no explicit consent provided by the patients).

Economical data: no

Others: Registry of renal transplant patients (operates in the corresponding unit of HYKS - the Helsinki and Uusimaa University Hospital).

Access of stakeholders to not published datasets

- The annual report, which does not contain personal information, is delivered to the nephrologists of the central hospital and to the EDTA-register (European Dialysis and Transplant Association Registry
- Identifiable data can be released with the consent of the respective person to researchers of kidney diseases, if the Supervisory Board of the Kidney Diseases Register has approved the research and has confirmed the legal processing of identifiable data.
- Data can be released to an X hospital for research (on kidney diseases) purposes, with the consent of the respective person.
- The patients who are included in the registry have the right to review their personal information.
  The request for review is either done in person or by self-signed letter or by a document verified through some other reliable means. The request is addressed to the register's responsible doctor. He/She is also the one who decides for the provision of data or actually provides the data. The review right is available for free. The person submitting a request for review may be asked to verify his/her identity

Extraordinary Reports on Demand:

- Pharmaceutical Industry: information is provided at general statistical level, against a fee.
- Dialysis-related companies: information on number of patients in dialysis (e.g.); however, the register does not have any information on specific devices, products etc.
- EDTA Central Registry, receives an annual report for inclusion in their European level overview.
- USRDS (US Renal Data System) - American Registry; utilizing statistics for international comparisons

Evaluations

Definition of Endpoint:

Focus on patients in active uraemia treatment.

Survival curves and analysis, to identify which are the determining factors for survival.

Indicators calculated:

Incidence of dialysis patients: how many per million inhabitants
Prevalence at the end of year (in dialysis)
Mortality: how many per thousand patients per year

Statistical methods:

Incidence and prevalence (half-standardized)
Survival rates
Kaplan-Meier curve and Cox regression model

Data can be analysed per hospital, and per diagnosis, comparisons are possible within the country and internationally.

EUPHORIC INDICATORS

Indicator F5 (Kidney Survival - 5 year survival rate) can most likely be calculated on the basis of the Kidney Diseases Register data.

Impact and external Auditing:

Sponsors

The primary sponsor is the Finnish Slot Machine Association, which has the mandate to promote and support activities such as the register.
In turn, the state - to which RAY is subordinate, also benefits from the registers activity. On the one hand, the collection and analysis of long-term register data can lead to improved healthcare service quality and better outcomes for patients. On the other hand, utilization of register data can also promote the better and more cost-effective use of healthcare resources, an aspect particularly relevant for a costly treatment as dialysis (estimated annual cost per dialysis patient is 60000€).

Public Health

The aspects explained above essentially relate to and apply also in Public Health.

Physicians

The register allows physician's to compare the results of their own patients' to the rest of the country, and in that sense it partly functions as a quality register.
Through the register data is also possible to follow whether the provided treatments actually follow the current treatment guidelines (see last annual report for details), which also is important quality feedback to doctors.

Patients

Registry data can also be used to assess the effects of various variables on RRT patients' survival. This is important for improving treatments.

Quality control activities / feedback
On the basis of the registry data, prognoses can be made about future incidence and prevalence of RRT, which helps hospitals to properly allocate their resources.

Regular meetings:
The Steering Group meets once a year. The Chairman of the Steering Group and the Chief physician meet once a month.

External auditing
There isn't any.

2. Register of Vascular Procedures

Registers' History

FinnVasc

The Finnish Register for vascular surgery was established in 1989. Its pilot use started in the same year in the University Hospitals of Tampere (TAYS), Oulu (OYKS) and Kuopio (KYS), as well as in the IV surgery clinic of the Helsinki University Central Hospital (HYKS).
The actual wider registration began in 1991, with the participation of all university and central hospitals, as well as several regional hospitals.
One of the main motivations for the establishment of the surgery was the possibility it offers in studying cost-effectiveness of vascular surgery procedures.

Main goals of the register were:
- statistics (numbers of vascular surgery procedures in the country)
- quality control
- national benchmarking
- comparisons to international recommendations
- follow up of various and recently introduced treatment approaches
- management of healthcare resources
- education follow up
- material for retrospective research studies

Validation process started in (year) 1991, 1997 (?)

Validation published in (year): 1998

Data Collection

Starting point of documentation - Follow up/Reference data collection

Data for the register were collected on paper forms.
Data collection took place upon hospitalization, before and after surgery, upon discharge and also at a follow-up examination up to 30 days post-surgery.

Data collection at point of care

The hospitals filled in a form for every vascular surgery and endovascular procedure they performed, and send it forward to the main unit in the Tampere University Hospital.

Main parameter (main target):
Patient's age, gender, possible risk factors, performed procedure and possible material used for by-pass. In addition, possible complications, re-operations, and follow up data of 30 days after surgery. Angle-shoulder pressure index is measured before the procedure, upon discharge and in the context of the follow up visit.

The ankle/arm pressure index was measured before any procedures, upon discharge and in the context of the follow up visit. Each hospital had its own Minivasc-register, for its own vascular

surgery procedures. In Finnvasc there were no patient identification data. They resided exclusively in each hospital's Minivasc register.
In the first four years of its operation, the procedures reported to Finnvasc were 17465.

In the Finnvasc-register information on vascular surgery, as well as on angioradiological procedures was collected from 1991 to 1999. The operations of the national register ended at the turn of the millennium, among other reasons because of data protection problems.

HUSVasc

In the place of Finnvasc developed the HUSVasc register, as one of the leading projects of the vascular surgery clinic. The development targets included among others the following:

- in terms of data entry and reporting, the register should be -at least for the largest part- real-time;
- the register must employ continuous entry of follow-up data
- the data content must be adequately detailed.

The HUSVasc procedures registry is understood as a database of both the healthcare services delivery unit and of the education and product development unit.
The specific goals of the register are:

- to have a positive influence on the quality improvement and maintenance of good quality care in vascular surgery in HUS
- to produce high quality reports for the administrative planning and development of the clinic
- to act as a log book for doctors in training and as a source of feedback on the work performed by the unit's surgeons
- to act as a source of clinical data as appropriate (patient-specific report view, procedure print outs and procedural blue prints)
- to act as a source of data for scientific research (data is released on the same premises as patient records are).

Data Management

Data collection at setting of care

In principle, data is entered to HUSVasc by all data producers (at present, due to the absence of links there may be partially overlapping entry), ie. vascular surgeons and hospital doctors (possibly also operating room supervisors), angioradiologists (possibly also the nurses of the angiolaboratory), vascular laboratory nurses and representative of the dialysis unit.

Processing of data

The production of reports is primarily done by research nurses, ,but the production of individual reports is so simple that also surgeons can study out of their own initiative the achieved results.

Validation

Register coverage

The goal is good quality and coverage of the Register's data. During the introduction of the register, data content was checked repeatedly and found good - on average, only approx. 5% of procedures were missing, thanks to all parties who have fulfilled their share of responsibility.

By 2005, the use of HUSVasc had become standard practice and the report generators are prepared to check data content regularly: research nurses take care of reminder, so the coverage is expected to reach 100% of procedures.

The Finnvasc data of Helsinki (IV surgery clinic) has been to a large extend adapted to fit HUSVasc and it has been agreed that they will be joined with HUSVasc, in which case the database will contain by the end of 2004 at least 14000 procedures.

3. OTHER REGISTERS - RELEVANT PROJECTS

1. Register of Induced Abortions and Sterilisations

In Finland, the Act on Induced Abortion, the first ever piece of legislation on abortion, came into force on 1 July 1950, whilst statistics on induced abortions have been published since 1951. The current Act on Induced Abortions originates from 1970. Since 1987, data on induced abortions and sterilisations have been kept in a STAKES database. Official statistical publications by the National Board of Health (one of STAKES' predecessors) have been used as a source of information for earlier years. The Register has been established for the purposes of statistics and research.

The Register of Induced Abortions and Sterilisations contains data on the annual numbers of induced abortions and sterilisations. In addition, data on induced abortions are provided by age group and hospital district per 1000 women of the same age, and data on sterilisations by gender and age group per 1000 women or men aged 25–54.
The Statistical Summary also gives numbers concerning grounds for induced abortions and sterilisations, the gestational stage at which induced abortions are performed, previous abortions and deliveries among abortion patients, methods of abortion used, and the contraceptive methods that abortion patients have used or that have been planned for them.

The collection of data is based on the Act on the Statistical Service of the National Research and Development Centre for Welfare and Health (409/2001), as well as on the Act (556/1989) and the Decree (774/1989) on National Personal Records Kept under the Health Care System.
Data on induced abortions and sterilisations are collected from all hospitals in Finland that perform induced abortions and sterilisations. The statistical population consists of all persons who have undergone induced abortion or sterilisation. In accordance with the current legislation (Act (238/1970) and Decree (359/1970) on Induced Abortion; Act (283/1970) and Decree (427/1985) on Sterilisation), the physician performing the procedure is required to report the case to the National Research and Development Centre for Welfare and Health (STAKES) within one month using a specific data collection form approved by the Ministry of Social Affairs and Health.
The data in the forms are stored electronically in the Register of Induced Abortions and Sterilisations, a statutory register maintained by STAKES pursuant to the Act on National Personal Records Kept under the Health Care System (566/1989), and Section 6 of the subsequent Decree (774/1989). Data check-ups are made regularly and any unclear cases and diagnoses are checked and ascertained by contacting the hospitals that have performed the procedure concerned. The statistics almost invariably have a coverage of 100%.

The Statistical Summary aims to provide up-to-date information on induced abortions and sterilisations to health-care professionals, administrators, planning officials and researchers working in the area of reproductive health and thus in need of this type of information. In addition to being published at the STAKES website at http://www.stakes.fi/statistics/abortions and http://www.stakes.fi/statistics/sterilisations. The Statistical Summary is sent to all hospitals that perform abortions and sterilisations.

The statistics on induced abortions and sterilisations are produced by STAKES biannually, and published in April and September. The April statistics consist of the previous year's preliminary statistics, while the September statistics consist of the previous year's final statistics. In addition, half-year preliminary statistics are published each autumn concerning induced abortions performed during the ongoing year's first six months. Estimates made on the basis of the preliminary statistics have found to be very close to the real figures. The numbers of cases given in the preliminary

statistics are usually somewhat lower than those in the final statistics as a few notification forms from the hospitals may arrive with a delay. Any errors identified in the statistics will be corrected.

2. Mass Screening Registry

The Mass Screening Registry is a department of the Finnish Cancer Registry and was founded in 1968. It is responsible of planning and evaluating national cancer screening programs in Finland. Data concerning invitations and screening tests are centrally collected and registered in the registry. Screening data are used to evaluate and control the programs and to help political decisions concerning public health issues.

In Finland, the responsibility to organize cervical and breast cancer screening is given to local municipalities, more than 400 in total (Primary Health Care Act 1972 and Decree 1992). Screening is free of charge to those invited by the municipality. According to the Decree of Primary Health Care, population based screening is to be offered to women between 30-60 years of age for cervical cancer and to women between 50-59 years for breast cancer.
http://www.cancerregistry.fi/eng/screening/

3. The PERFECT Project

The PERFECT (PERFormance, Effectiveness and Cost of Treatment episodes, http://info.stakes.fi/perfect/EN/index.htm) project (since 2004) has adopted the so called disease-based approach and has developed protocols for eight diseases/health problems (AMI, revascularization procedures (PTCA CABG), hip fracture, breast cancer, hip and knee replacements, very low birth weight infants, schizophrenia, and stroke). The disease-based model of the health care system (also called a microeconomic approach) is based on individual patient records of the whole population. It starts by modelling the natural progress 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 of the approach is that it uses individual level data available from registers that allow us 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 the selected risk-adjusted and well-defined patient groups. The general aim of the PERFECT project is to develop methods for register-based measurement of the cost-effectiveness of treatment and to create a comparative database that allows the treatments given and their costs and effectiveness to be compared between hospitals, hospital districts, regions and population groups. More specifically the project:

- Produces comparative information on treatments and their costs and effectiveness for treatment monitoring and development.
- Creates indicators and models for monitoring the content, quality and cost-effectiveness of treatment episodes in specialised medical care.
- Assesses factors that influence cost-effectiveness.
- Develops methods for the register-based measurement of cost-effectiveness, and comes up with proposals concerning the data content of national level registers in order to improve the continuous monitoring of cost-effectiveness.
- Develops an approach and methodology that can be subsequently applied to other disease groups as well.

- Compares cost-effectiveness at an international level

The development has been done in seven separate expert groups, whose members (total of about 50) are leading clinical experts on the diseases concerned. At present, register-based indicators (both on the regional and hospital levels) on the content of care, costs and outcomes between 1998 and 2005 are available for seven health problems. The indicators are available on the Internet, and they will be routinely updated using more recent information. The development of indicators is based on the PERFECT data base, which as such is based on linking various registers such as hospital discharge register, registers of the Social Insurance Institute and Cause of Death Register. The PERFECT dataset includes all new cases for the selected health problems in the country after late 1990s (for schizophrenia since 1995). In comparison to the approach of the EUPHORIC project, PERFECT goes much deeper into selected diseases/health problems. In addition to short -period outcomes the project looks also at outcomes in the longer term and also includes costs and other performance indicators into the considerations. For example, in each of the selected health problems the basic reports includes various outcome indicators based on survival / mortality (i.e. how many days a patient has lived during the follow up), re-admission to hospital, complications, percentage of patients that have been institutionalised, the share of patients that have returned home within the specified follow-up. Each basic report includes 5-10 outcome indicators so that the total number of outcome measures reported is over 50.

The indicators published in the PERFECT project have been widely used in local decision-making and have also been discussed in the media. The project has given a new dimension to the benchmarking of care: data that directly help the local decision-makers since they can compare their own performance not only by using cost or process indicators, but also outcomes and information on the relationship between costs, process, and outcomes. An example of the practical effect of the project is an implementation of an auditing process in relation to the actions of one University hospital following receipt of data on the relatively high mortality of low birth weight infants. In addition, the Ministry of Social Affairs and Health uses the information in their strategic planning: the indicators developed in the project will be used to evaluate the development of regional differences in the effectiveness of specialised care, in the National Development Project for Social and Health services 2008–2011. The project researchers have produced several manuscripts of which some have already been published (Korvenranta et al. 2007, and Rautava et al. 2007).

The experience from PERFECT (Häkkinen 2008) indicates, for example, that among the AMI and Stroke patients, about 20–30% of costs can be contained if all regions (hospital districts) would have had the same cost as that of the cheapest region in terms of risk-adjusted measures. Similarly, a total of some 500 deaths (amounting to about 7000 additional life years) would have been avoided if all regions would have had the same outcome as the best region in the treatment of the two disease groups in a country with a comparatively small population. Since the regional differences in cost were not clearly correlated with regional differences in outcome (mortality) these figures point to a great potential for efficiency improvements i.e. cost can be contained without decreasing outcome , and outcome can be increased without increasing costs. In addition, it has been found that the centralization of care in the Neonatal Intensive Care Units in the five university hospitals will decrease one-year mortality of infants (Rautava et al. 2007). A preliminary analysis (not yet published) indicates clearly better outcomes for Stroke patients that have been treated in comprehensive stroke centers.

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Annex 1 - Variables collected by the studied registers

Data Content - Hospital Discharge Register (HILMO)

Data on the provider of the service:
Specialty (classification)
Information on the kind of service that is provided (classification)

Data on the patient:
Personal identity number
Place of residence (municipality)
Code of home country when living abroad

Information on admission:
Date of admission
Way of admission (classification)
Coming from where (classification)
Referred by (classification)
Ordering party of outsourcing service (classification)
Date when patient was placed on waiting list for treatment
Cause of admission (classification)
Need of care at the time of admission (classification)

Information of care:
Main and secondary diagnoses (ICD-10)
External causes
Type of accident
Type and diagnosis of complications
(Surgical) procedures (main, other), incl. possible reoperation because of complication
Date of main operation
Need of care upon discharge/upon data collection time (classification)
Decision of long-term care (y/n)
Number of days off

Information on discharge:
Date of discharge
Discharge to where
Appropriateness of the place of care (classification)

Data of high-demand cardiac patients:
Procedures (classification made for this data collection)
Is the procedure primary or re-operation (classification made for this data collection)
Urgency of the case
Performance (NYHA classification)
Euroscore and logistic Euroscore
Complications (classification made for this data collection)

Data content - Medical Births Register

Source: Register's Data file - (as of November 2005)
http://www.stakes.fi/EN/tilastot/filedescriptions/medicalbirthregister.htm

1. Personal data of mother
- personal identity code
- surname and forenames
- profession
- municipality of residence
- nationality
- marital status
- cohabiting

2. Previous pregnancies and deliveries
- previous pregnancies
- previous deliveries

3. Present pregnancy and its monitoring
- check-ups during pregnancy
- date of first check-up visit
- mother's weight and height before pregnancy
- mother's smoking habits during pregnancy
- risk factors and interventions relating to pregnancy
- diseases during pregnancy (ICD-10 codes)
- hospital care during pregnancy

4. Delivery
- maternity hospital
- place of birth
- best estimate of gestational age at the time of delivery
- onset of last period
- duration of delivery
- method of delivery
- pain relief in labour
- other procedures relating to delivery
- diagnoses relating to pregnancy and delivery
- mother's diagnoses during delivery (ICD-10 codes)

5. The infant
- date of birth, control character of the personal identity code, time of birth
- sex
- infant born alive or dead
- number of foetuses = number of infants born
- letter indicating the order of birth in multiple pregnancy

- weight at birth
- length at birth
- head circumference
- Apgar score at 1 minute and 5 minutes
- pH of umbilical blood

6. Data of the infant by the age of 7 days or at discharge
- care interventions relating to the infant by the age of 7 days
- infant's diagnoses by the age of 7 days
- infant at the age of 7 days or at discharge from hospital
- length of stay in hospital for mother

Data content of the data file Small Preterm Infants

1. Personal data of mother
- personal identity code
- surname and forenames

2. Personal data of infant
- date of birth, control character of the personal identity code, time of birth
- surname and forenames
- sex
- best estimate of gestational age at the time of delivery
- weight at birth
- length at birth
- head circumference
- number of foetuses = number of infants born
- letter indicating the order of birth in multiple pregnancy
- maternity hospital
- other basic data

3. Pregnancy
- mother's diseases and complications during the present pregnancy
- mother's medication before delivery

4. Delivery
- rupture of amniotic membrane (water breaking)
- diastolic flow in umbilical artery
- Apgar score at 1 minute, 5 minutes and 10 minutes
- pH and BE of umbilical artery blood
- pH and BE of umbilical vein blood
- method of delivery
- presentation at birth
- resuscitation procedures/treatment in delivery room

5. Treatment received by the infant up to 42 weeks' gestation
- breathing disorders
- breathing support
- surfactant treatment
- broncopulmonary dysplasia
- medication
- infusion routes
- necrotising enterocolitis
- procedures and other treatment
- sepsis
- ultrasonography of the brain
- examinations of the fundus of the eye
- auditory examination
- electroencephalogram (EEG)
- magnetic resonance imaging (MRI) of the brain

6. Diagnoses for the infant up to 42 weeks' gestation
- diagnoses
- death diagnoses

7. The infant's situation at 42 weeks' gestation
- the infant's situation when its age corresponds to 42 weeks' gestation
(discharged, in hospital, dead)
- diet at discharge or at 42 weeks' gestation
- weight, length and head circumference at discharge or at 42 weeks' gestation

8. All hospitals where the infant has been treated up to 42 weeks' gestation
- hospitals and wards where the infant has been treated
- transferred to the next hospital
- where the infant has been transferred
- date, and the name and position of the person who has filled in the form

Data content - Register of Congenital Malformations

Source: Register's Description File - (as of March 2006)
http://www.stakes.fi/EN/tilastot/filedescriptions/malformations.htm

1. Mother

- name
- personal identity code
- municipality of residence
- nationality (Finnish or other)
- previous pregnancies (number)
- previous deliveries (number)
- previous stillbirths (number)
- previous spontaneous abortions (number)
- previous abortions induced for foetal indications (number)

2. Data on present pregnancy

- mother's work / employment
- mother's diseases and pregnancy-related complications, week of gestation
- mother's medication and vaccinations, week of gestation
- other exposures, week of gestation
- foetal screenings and examinations during pregnancy, week of gestation and the original reason for foetal examinations (screening, an irregular course of the pregnancy, etc.)
- number of foetuses

3. Infant/foetus

- name
- personal identity code or date of birth
- duration of pregnancy
- delivery/abortion hospital
- type of birth (live birth or stillbirth, induced abortion, miscarriage)
- sex
- letter indicating the order of birth in multiple pregnancy
- weight at birth
- date of death, if applicable

4. Congenital anomalies

- diagnosis in words
- diagnosis with ICD codes
- time of detecting the anomaly (during pregnancy, neonatal period, etc.)
- detection of anomalies during pregnancy (method of examination, week of gestation)
- further testing after birth for anomaly detection
- chromosomal and DNA testing and test results
- X-ray and ultrasound examinations, etc.

- autopsy
- other examinations

5. Anomalies in family members (family members' personal identification not registered)

- type of family relationship (mother, father, brother, sister, etc.)
- diagnosis in words
- diagnosis with ICD codes

6. Data on the notification of anomaly

- type of notification (form, other notification etc.)
- notifying unit
- date of receiving and date of processing the notification

Data Content - Implant Register

The Finnish Implant Register contain the following data:

1. Patient information
   - personal identification number
   - municipality of residence
   - date of death
2. Surgical Data
   - hospital that performed the surgery
   - date of surgery
   - site of surgery
   - reason for operation
   - model of implanted prothesis
3. Revision surgery
   - reason for operation
   - replaced or removed model of endoprothesis
   - date of previous surgery
4. Prothesis attachment
   - attachment with/without cement
   - cementing technique
   - cement brand name
5. Bone transplant
6. Prophylactic antibiotic
   - brand name of antibiotic
7. Primary complication
   - after the surgery, before hospital discharge
8. Latter complications
   - date of complication confirmation
   - complication

Data content - Finnish Cancer Registry

The data collection forms have developed since 1952 and are revised every once and awhile. Final, formal decision is made by STAKES (as of January 1st 2009, National Institute for Health and Welfare - THL).

The full data collection form in .pdf format is available for download at:
http://www.cancerregistry.fi/eng/registration/JID35.html

Main parameter (main target):

The following coded items usually meet the needs of producing statistics and doing analytical research:
- name and PID,
- municipality of residence,
- primary site and date of diagnosis,
- basis of diagnosis,
- stage: localised, regional metastases, distant metastases,
- malignancy: malignant, microinvasive (cervix uteri), in situ, borderline (ovary), benign (intracranial, urinary tract), or to be excluded from basic statistics (basalioma, polycythaemia vera, myelofibrosis, etc.),
- histology/cell type,
- treatment: surgery, radiotherapy, cytotoxic drugs, hormones, other; specific codes for curative/palliative surgery or radiotherapy; specific codes for primary treatment and later treatment,
- follow-up: date of death or emigration, cause of death.

Additional present parameters

In addition to the items listed above, for instance names of the notifying hospitals or laboratories, specimen numbers, tumour grade, TNM classification, site of metastases, details of the treatment, or cause for not being treated can, if needed, be used for different purposes, e.g., for searching the histological slides for re-evaluation.

Parameters included in the regular reports:

- Cancer incidence, mortality and prevalence by primary site (ICD-10 codes) sex, age, (histological type - only some routinely) and hospital district.
- Cancer patients survival figures.
- Various parameters linked with the mass screening programmes

Data content - Finnish Register of Visual Impairment

The data collection form was decided by STAKES in 1998.
It is available in Finnish at the URL below: (parameters provided in this section are the product of an unofficial translation)
http://www.nkl.fi/tulosta/pdf/nvrilmoitus.pdf

Main parameter (main target):

1. **Personal information:**
   - Identification number
   - Family and first name (s)
2. **Diagnosis**
3. **Other disabilities or chronic diseases**
   - physical handicap/disability
   - CP-disability
   - hearing disability
   - development disability
   - Diabetes: insulin, other treatment, no information available on treatment
   - No information on multiple disability
   - Other disability or disease: (which)
4. **Etiology**
   - aging
   - hereditary
   - occurring during pregnancy
   - perinatal
   - pre-term birth-related
   - diabetic retinopathy: proliferating, non proliferating, no information available
   - myopia
   - tumour
   - MS-disease
   - Inflammation
   - Accident
   - No information on etiology
   - Other etiology: (which)

5. **Duration of disability**

Month and year of disability start

6. **Visual acuity**

For right and left eye separately or no information.

7. **Visual field**

For each eye separately: less than 20°, less than 10°, homonymous hemianopsia, no information available

8. **Reporter's information** (place, date, name, place of practice - hospital or private, etc).
9. **Additional information**