

European Commission – Health Monitoring Program Health Information Systems in Europe: Structures and Processes

COUNTRY REPORT

SWEDEN

The Health District of Northern Stockholm (NSSO) with Centrum for Gerontology and Health Economics (CGH) as performing body has made an agreement with Office for International Public Health and Social Programmes, Regione del Veneto – Giunta Regionale, Italy, to contribute as a representative for Sweden in the EU-project described in the headline.

Objectives

The project's mandate is outlined in the title "Health Information Systems in Europe: Structures and Processes" and the objectives are delineated in the Community action program on Health Monitoring – Projects subsidized in 2001 by the European Commission, as follows:

- "A fully detailed organizational description in terms of structures, resources and processes of the different Member States' Health Information Systems (HIS) with particular reference to selected Surveillance Systems and Health Services Monitoring Systems
- A comparative analysis of the information collected as for point 1, in order to allow the identification of major differences and similarities in the information systems
- Operative, feasible, sustainable recommendations for the implementation of the European Information System."

Rationale

The central idea behind this project is that if we do not manage a system (in our case the HIS), it will not work properly. In order to understand how HIS work we need to study organizations managing those systems. Each organization faces two key issues, i.e., how to divide labour among different units and how to coordinate it. We are therefore interested in the study of how our MS divide labour concerning HIS and how they coordinate different organizations and steps. A management perspective entails the description, analysis and interpretation of HIS current state looking at structures, i.e. distribution of authority and responsibilities, and processes, i.e. ways tasks are carried out.

The purpose of our project is to study HIS management, more specifically to identify cumbersome processes, structures performing blurred or useless tasks, gaps and overlaps in key activities and lack of an overall design. The assumption is that this analysis will allow MS

to improve HIS performance in terms of data; information quality and availability will lead to enhanced decision-making processes and finally healthier populations.

Strategy

The project will concentrate on the regional and national levels and analyze both Surveillance and Health monitoring systems. Each MS will study at least mortality among Surveillance systems, hospital discharges among Health monitoring systems and examine at least data interpretation among HIS processes. MS will be free to consider additional systems and processes.

Expected results of the Project

- An individual inventory of Member States` selected Surveillance Systems and Health Services Monitoring Systems
- A quantitative and qualitative comparative analysis of Health information structures, resources and processes
- Recommendations to the Commission for the implementation of the European Monitoring System.

Utilisation and Dissemination of results

Results will be made available to all levels of decision-making according to the organisation of Public Health in each involved Member State.

The publication will also be disseminated to all political and technical health Commissions of the European Union.

Alignment of the Swedish country-report

The Swedish report follows the outline given for country-reports by the project-coordinator.

The report concentrates on the Swedish Health Data Registers, which covers all the nation and are the main basis for data collection in the country. According to the instructions the description contains:

- a) Policies and legislation
- b) Roles and responsibilities
- c) Organizational chart of the system
- d) Processes
- e) Coordination mechanisms, and

a final conclusion about lessons learned based on a SWOT analysis.

The report is based on information collected from the homepages of the responsible authorities, presentations in research articles, brochures etc. To get a closer picture of how the system works we have also made some interviews with key-informants.

System description and analysis

a. HIS Policies, including legislations, and plans

A well-developed information system is a necessity in a democratic society. The long tradition in Sweden of collecting information on health and social conditions of the population provides an excellent base for monitoring disease and social problems. A unique person identification number for every citizen enables linkage of exposure and outcome data from several decades.

What are the main laws and regulations on HIS?

Following laws are regulating the Swedish framework of health data registers.

SFS-number	SFS-titel
1998:543	Law (1998:543) concerning health data registers
2001:708	Regulation (2001:707) concerning patient registers (National Board of health and welfare)
2001:708	Regulation (2001:708) concerning child births (National Board of health and welfare)
2001:709	Regulation (2001:709) concerning cancer (National Board of health and welfare)
2001:710	Regulation (2001:710) concerning Adverse Reactions to Medicinal Products (The Medical products agency)

Law (1998:543) Health Data Registers

Health Data Registers are allowed to be kept by central authorities within Health Care for following purposes

1. Statistics
2. Evaluation and Quality Assurance of Health Care and for
3. Epidemiological and general research

The central authorities within the Health Care area whom are keeping registers with information regarding data on an individual level are The National Board of Health and Welfare and The Medical Products Agency.

Registers that contains information on an personal level are regulated by the above presented laws and regulations. The National Board of Health and welfare is responsible to follow this framework of laws and regulations especially for the following registers; The Cancer Register, The Medical Birth Register, The Congenital Malformation Register and the Hospital Discharge Register. For the Medical Products Agency it's the register of Adverse Reactions to Medicinal Products.

A Health Data Register is only allowed to contain information that is in accordance with the purpose of the register.

It's the duty of the Government to stipulate what a health data register is allowed to contain. Personal identification numbers (PIN) are allowed in health data registers. But allowance must be carefully considered at the start of a new register.

The identity of a single individual may not be revealed in reports made on the basis of data from the health data registers.

b. Roles and responsibilities

Ministry of Health and Social Affairs

It is the responsibility of the Ministry of Health and Social Affairs to assist the Government in carrying out their policy. None of the points describing the tasks of the Ministry specially names the Health Information System. The tasks are formulated more in general and highlight the responsibility to plan and lead developments within the Ministry's area and take initiatives for reform, formulate proposals for government bills to be presented to the Riksdag concerning budgetary and legislative matters, and to guide the work of authorities.

The National Board of Health and Welfare

The most important tasks of the National Board are

- supervision of medical care and social services as to quality, safety, and the rights of the individual
- evaluation and follow-up studies of social policy
- mediation of expertise
- development and training
- coordination of social services statistics
- epidemiologic surveying

The Board is responsible for official statistics on social services, public health, health care and medical services, and causes of death.

The National Board of Health and Welfare issues code of statutes on the application of specific acts of law. Furthermore, the Board is responsible for planning and supplies for health and medical services, environmental health, and social services in case of war or crises.

In addition the Board is the designated Competent Authority under European Community directives on mutual recognition of diplomas concerning health professions.

Organisational chart

An organisational chart of The National Board of Health and Welfare is enclosed.

National quality Registers in Health Care

The Federation of Swedish County Councils and the National Swedish Board of Health and Welfare collaborate at the national level and actively support the creation and the development of National Quality Registers. The Swedish Society of Medicine and its specialty sections also participate in this effort. Since 1990, the Swedish Government and the County Councils have allocated resources for supporting the development and operation of the registers. The administrative work at the national level is managed by the National Board of Health and Welfare.

Currently, over 40 quality registers exist which are, or will eventually become, national in scope. The registers generate information concerning healthcare quality from different perspectives. All of the quality registers have one thing in common, they were all initiated by representatives of the medical profession and constructed to support quality improvement at their own departments.

The quality registers contain individual-based data on diagnosis, interventions, and outcomes. The opportunity offered by the registers to compare findings - mainly against national data (benchmarking) - is an important tool for local quality improvement teams in monitoring the outcomes of care. The information is also useful for patients.

Beyond the fact that several quality registers can demonstrate concrete results such as fewer complications and greater efficiency, the registers have also had other, more general effects. For example:

- Increased interest for, and clarification of, quality-related issues
- Dissemination of information
 - treatment methods
 - highlight problem areas
- Increased collaboration at various levels
 - stimulate meetings, local collaboration, project elements, etc
- Basis for local, regional and national planning

The National Quality Registers are presented in Swedish and English on the Internet and on a MARS CD-ROM. The homepage provides updated information and annual reports from the National Quality Registers. All the quality registers are presented in the report "National Health Care Quality Registries in Sweden 1999".

The Centre for Epidemiology – at the National Board of Health and Welfare

The Centre for Epidemiology (EpC) is a part of the Swedish National Board of Health and Welfare. The EpC has its own executive board with representatives from The National Board of Health and Welfare, The National Institute of Public Health, The Federation of County Councils, The Swedish Council on Technology Assessment in Health Care, The Association of Local Authorities, The Swedish Council on Technology Assessment in Health Care and the research community.

The establishment of a Centre for Epidemiology is based on the idea that there are many interested parties within epidemiology and that the potentials for using the unique sources of information from the Swedish disease and population registers have not yet been fully explored.

Objective and target groups

The overall objective of the Centre for Epidemiology is to describe, analyse and report on the distribution and development of health, diseases, social problems, utilisation of health and social services and its determinants in different population groups within Sweden.

The Centre for Epidemiology provides this kind of information to the Parliament and the Government, other public authorities, county councils, municipalities, researchers, media and the general public.

Main responsibilities

The main responsibilities for the Centre for Epidemiology are

- Collect and maintain epidemiological registers of high quality
- Develop and adapt classification systems and co-ordinate national terminology work within the areas of health and social services
- Produce National public health and social reports
- Initiate and conduct research and development
- Co-ordinate statistics within the areas of health and social services

Epidemiological registers

The existence of accurate epidemiological registers is a basic prerequisite for monitoring and analysing health and social conditions in the population. The registers must be of high quality and up-to-date. Data from the registers should be easily accessible to users. The integrity of individuals must be protected. The Centre therefore focuses its work on uniform and appropriate classification of diseases, quality control, performs validity studies, develops systems for increased accessibility and ensures that data protection legislation is adhered to.

The Centre has a national responsibility for several registers.

- The Cancer Register
- The Medical Birth Register and The Congenital Malformation Register
- The Hospital Discharge Register
- The Cause of Death Register
- The Abortion statistics (no personal identification number)
- Registration of sterilizations
- Registration of breast-feeding
- Registration of assisted reproduction
- The Acute Myocardial Infarction Register
- The Injury statistics
- EHLASS - The Swedish part of European Home and Leisure Accident Surveillance System (not nation-wide, no personal identification number)

The registers are nation-wide and cover the whole Swedish population. Data has been collected for decades and include a unique personal identification number for all registered persons. The dropout rates are very low, usually less than 4-5%.

Organisation and resources

The EpC is organised in six units:

- Management and administration

- Terminology and classification systems
- Centre for patient classification system
- Cancer and reproduction registers
 - comprises The Cancer register, The Medical Birth Register and The Congenital Malformation Register, The Abortion Statistics, Registration of sterilizations, Registration of breast-feeding, Registration of assisted reproduction
- Causes of death and patient registers
 - comprises The Hospital Discharge Register, The Injury statistics, The Cause of Death Register, The Acute Myocardial Infarction Register
- analysis (R&D).

The Centre currently (2003) has approximately 50 full-time employees. Most of the staff resources are devoted to basic work with registers, e.g. contact with local data managers, quality control of registers, contacts with data users about requirements for their data sets and programming.

Classification and terminology

The development of uniform and accurate classification systems for diseases, injuries, functioning and procedures in medicine is of vital importance in an epidemiological context. Health care services are also dependent on such classifications in order to characterise their activities in a meaningful way. The classification and terminology unit of the Centre for Epidemiology is active both in the development of new classifications and in the revision of existing ones. The provision of service and information to the health care sector on matters of classification forms is an important part of the unit's work.

Swedish versions of ICD-10 and the Nordic NCSP (Nomesco Classification of Surgical Procedures) are in use since 1997. An adaptation of ICD-10 for primary care was also published 1997.

Analysis

In collaboration with the WHO Regional Office of Europe, the Centre has developed an epidemiological and social information database, including indicators on health, disease, social problems, and risk factors on national, regional, and municipality levels. Data are presented in a user-friendly PC programme, which is freely available on the Internet. The information system serves county councils, municipalities, and others responsible for health and social affairs, as well as other parties interested in monitoring the epidemiological situation in Sweden.

The Centre for Epidemiology is responsible for the National Public Health Reports and Social Reports. Commissioned by the government, the reports serve as a basis for national social and health policy considerations. They are published every four (earlier three) years. Public Health Reports have been published in 1987, 1991, 1994, 1997 and 2001. Social Reports were published in 1994, 1997 and 2001. The two 2001 reports have also been published in English as supplements to scientific journals.

The Centre conducts research in collaboration with national and international researchers as well as clinicians, planners, and other professionals in the health and social fields. The research programme has included studies on different subjects, such as cancer survival, equity in health care, social inequality in health, incidence, mortality and case fatality of AMI, the

social consequences of illness, forecasting public health status, socio-economic problems, and social exclusion.

The Centre runs a stipend program financed by research grant foundations such as the Social Research Council (SFR) and the Medical Research Council (MFR). Within this program, graduate students and others can learn the methods of registry epidemiology and develop new ideas on how epidemiological and social registers can be utilised for various research purposes.

Annual statistical reports

A traditional product of health reporting still in demand is the annual statistical reports from the health registers. Such reports are presented from the cancer register, the medical birth and congenital malformation register, and the causes of death register. Statistics are published about abortion, breast-feeding, in-vitro-fertilisation (IVF), home and leisure accidents and tobacco use among pregnant woman and parents of small children. The annual reports are published within the system of Swedish Official Statistics (SOU). A)

How are you Sweden? – a statistical presentation program

To facilitate health monitoring at all levels, a computer-based statistical program “How are you Sweden?” was developed by the EpC. The program is based on an idea developed by the WHO in their European Health for All program, but with program modifications and a more extensive set of indicators. Over 1.000 indicators on demographic and social conditions, mortality, morbidity, life styles, consumption of health-care, drug sales etc. are available at national level and for all 21 counties and 289 municipalities. The program was first presented in June 1995 and has since been further developed. Data are updated annually. From June 1998 the program has been available on the Internet at no cost. It has so far proved to be very useful. Many county councils, public health and health service organisations, municipalities and national bodies have used it for planning or epidemiological monitoring. Several local public health reports have extensively based their analyses on data from “How are you Sweden?”, supporting the notion that the availability of local data stimulates local health promotion. A)

Public Health in Figures – start of an interactive web-based statistical program

Data availability is a main preoccupation of the EpC, and the statistical program “How are you Sweden?” was therefore an important first step in this direction. However, the program is based on a large, but fixed, number of indicators and has to be downloaded from the Internet. To meet a need for increased flexibility, an interactive web-based application for health statistics, “Public Health in Figures” has been developed. This allows users to choose their own statistics, i.e. age-groups, sex, diagnoses, geographical areas etc. Five modules provide data on birth and prenatal outcomes, abortion, cancer, causes of deaths and hospital discharges. A web-based version of “How are you Sweden?” constitutes the sixth module of the application. Though recently introduced, the first version of “Public health in figures” already had 3.000 monthly visitors by November 2000. A)

Informing the general public

EpC annually receives more than 10.000 inquiries about health and health statistics from professionals and the general public, especially the mass-media. Processing these questions is one important general public-service task that lies within the responsibility of a governmental

body. The Centre's work is recognised to be of general interest to the public and is therefore often covered in the media.

To support the media and others interested in cancer, the EpC has collaborated with the Swedish Cancer Society in producing an easily-accessible report "Cancer in figures" covering the incidence, mortality, survival, causes, risk factors etc. for different cancer sites. This report has so far run to three editions.

The EpC recently edited a special theme issue "Public Health and Health Care" of the National Atlas of Sweden – an encyclopaedia series presenting aspects of Sweden in maps, text and pictures. A Swedish and an English version are available.

The number of visitors to the EpC home page has steadily grown, to over 21.000 per month in 2002.

Swedish Institute for Infectious Disease Control (SMI)

A main task of the SMI is surveillance of communicable diseases and analysis of the current epidemiological situation, in Sweden as well as internationally. The surveillance is carried out in close collaboration with the County Medical Officers of Communicable Disease Control. The basis of the surveillance is the registration of the 54 notifiable diseases (55 pathogens) according to the Communicable Disease Act. These pathogens are notifiable in parallel to the SMI and the County Medical Officers, both by the clinicians and the laboratories.

The SMI is as an example responsible for the surveillance of Creutzfeldt-Jakob disease (CJD), and report regularly to the EU commission and to the EU Nero CJD Network. Another task is the surveillance of the coverage of the national vaccination program and the influenza surveillance.

The international contacts and collaborations have become increasingly important as new and old networks for infectious disease control within the European Union now are rapidly developing. Sweden and the SMI also have a long tradition of active work within the frames of the WHO. In the last years, collaboration to promote reduction of infectious diseases within the Baltic Sea Area has become a growing concern of the institute.

Statistics Sweden (SCB)

SCB produce and coordinate official statistics.

The mission of Statistics Sweden is to produce and make available official statistics relating to different areas of society, which can serve as a basis for decisions, public debate and research. These statistics are to be objective, reliable, comparable, up-to-date and easily accessible.

In the health care area SCB cooperate with The National Board of Health and Welfare, that have statistical responsibilities and produce the official statistics on their behalf.

There is a distinction in Sweden between official statistics and other public statistics. Official statistics are produced according to the statistical act and ordinance and published as required by official regulations.

The Official Statistics Act states that official statistics are statistics for public information, planning and research purposes in specified areas produced by appointed public authorities in accordance with the provisions issued by the Government. Official statistics shall be objective and made available, free of charge, to the public. Further, they are to be produced and published in a manner that protects the privacy of individuals. All authorities responsible for official statistics should each year provide an updated description for every product for which they are responsible.

The Federation of County Councils

The Federation of County Councils represents the governmental, professional and employer-related interests of its members – the 18 county councils, the regions of Västra Götaland and Skåne and the municipality of Gotland.

The operational concept of the federation is to work together with its members in strengthening regional vitality and welfare and regional democracy.

The statistical unit of the Federation of County Councils offers data-service regarding:

- Consumption of inpatient health care, that is mostly taken from the Hospital Discharge Register (EpC)
- “Swedish Health Care in the 1990s. Trends 1992 – 2000.” The report is a part of the work of the Federation of Swedish County Councils to contribute to extending knowledge of developments during the last decade in the Swedish health care sector. The complete report may be downloaded (pdf).
- “Nya sjukvårdsdata i focus” which is an interactive web-based application for health statistics like “Public Health in Figures” at the EpC. Compared with “Public Health in Figures” this application more is aimed to serve managers on different levels as a target group. Nya sjukvårdsdata i focus, that was started in 1999, as a tool to compare and analyse development within the health care sector, also can be used by researchers or for education purposes.

Based on cooperation with the other Nordic countries within the Nordic Medico-Statistical Committee (NOMESCO), and Nordic Social Statistical Committee (NOSOSCO), the Federation of County Councils also offers access to a database of indicators concerning social and health statistics collected for the annual statistical publications in the Nordic countries. The database gives the users the opportunity to make their own analyses and presentations of the data. The database is internet-based and gives the users direct access to the latest updated version of the data.

The Medical Products Agency

The Medical Products Agency is the Swedish national authority responsible for regulation and surveillance of the development, manufacturing and sale of drugs and other medical products.

The task is to ensure that both the individual patient and healthcare professionals have access to safe and effective products and that these are used in a rational and cost-effective manner. In addition to the control of medicines, the MPA is responsible for providing information about medicines, giving permission to carry out clinical trials, approving licences and controlling natural remedies and other medicine-related products.

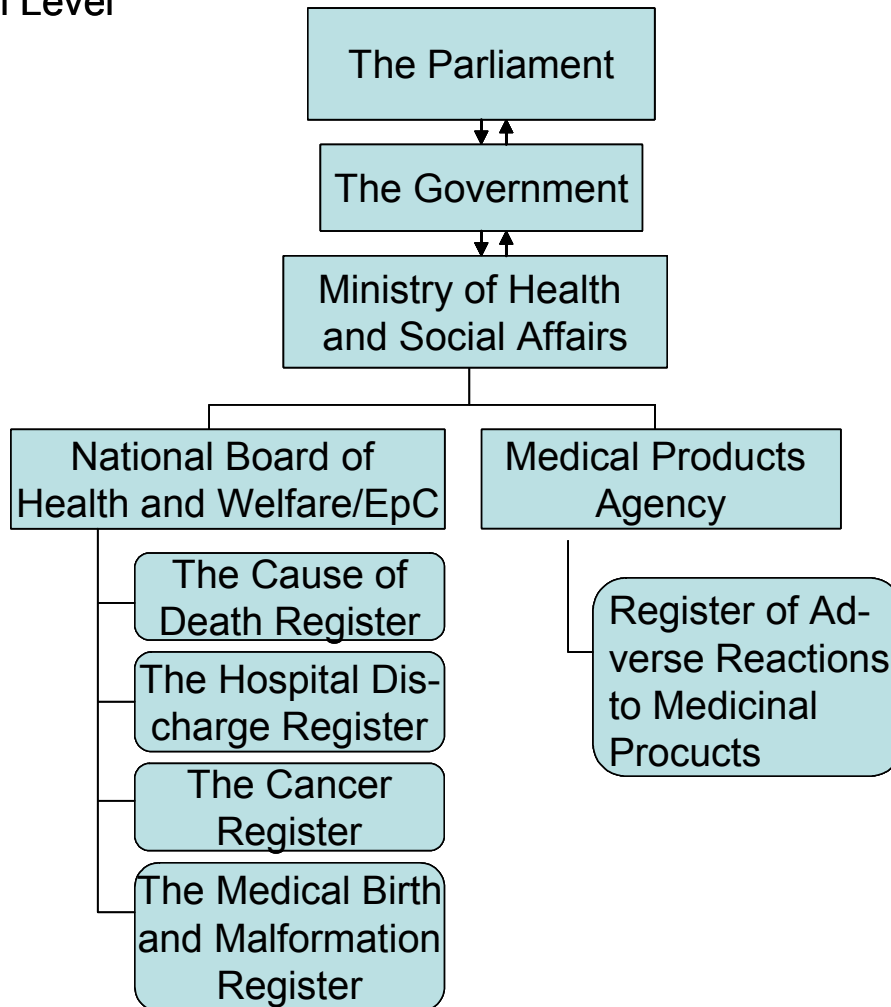
In carrying out their duties, MPA act both as a formal regulatory authority and as an informal promoter of the rational development and use of new and existing medicinal products.

The role of the MPA has changed to some extent since Sweden entered the EU. In addition to their national responsibility, they also investigate medicines for decisions at the EU-level, in close collaboration with national drug regulatory authorities in other European countries.

The Medical Products Agency is responsible for the register of Adverse Reactions to Medicinal Products.

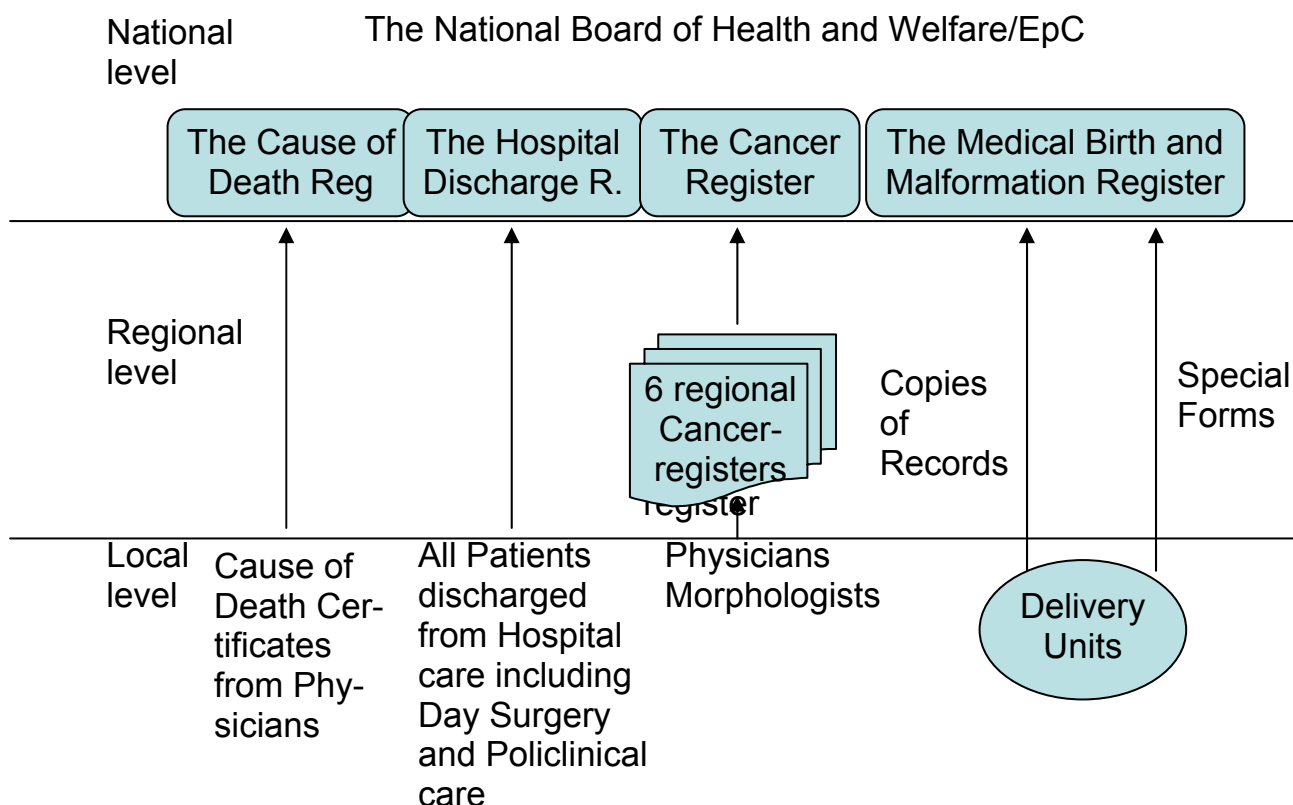
c. Organizational chart of the system

The National Health Data Registers and the Cause of Death Register
National Level



d. Processes

The law (1998:543) on health data registers and regulations to the law (SFS 2002:707-109) permits The National Board of Health and Welfare to run three health data registers. The information in the registers is only allowed to be used for statistics, some following up and evaluation, and for research. The Aim is to promote preventive care and treatment of diseases. In addition to these three registers, that contain data on living persons, the EpC also run the Cause of Death Register.



Confidentiality and safety-regulations.

The personal data in the health data registers are protected under the law of confidentiality (1990:100). According to this law the confidentiality is total, e.g. information can not be handed out. The confidentiality also includes other departments within the National Board of Health and Welfare. However there are some exceptions regarding data needed for research and statistics. For those purposes information can be handed over if it is definitively clear that it can be de-coded without harming the subjects of the registration.

Today the EpC hand out information for research only. The main role is that the use of data has to be approved by an Ethical Committee. To guarantee confidentiality the researcher has to sign a reservation that regulates how the information can be used.

The most important lines in the reservation are the following:

- The information is secret and can only be used for the purpose specified in the research application.

- The information has to be kept in a way that guarantee that no unauthorized users can see it
- Responsible doctor (head of department or corresponding) has to assess that the register data agree with data in the records and if there is a risk for negative consequences if registered people are contacted.
- When the research-project is finished the information has to be destroyed.

Results from research-projects or statistics may not be presented in such a manner that it is possible to identify individuals.

Just a few persons working with the registers have direct access to the information.

It is important to note that the health data registers only contain PIN-number and not names and addresses of the registered individuals. The only exception from that rule is the Cancer Register that contains both PIN-number and names.

How long is data kept in the registers?

All data in the registers are saved without time limits.

The right to be informed what data about yourself that's kept in the registers

A registered person has the right to be informed what data/information about him-/herself that exists in the registers. This kind of information is possible to get free of charge once a year.

Correction of data in the registers

A registered person has the right to claim correction of incorrect data in the registers.

Tabell 1 National Health Data Registers. Starting-year and method of Data collection (Rosén/Eriksson Journal of the Swedish Medical Association nr 35 1999)

Register	Starting year	Method of Data collection	Remark
The hospital Discharge Register	1962	Electronically transmitted from the regional level	Nation-wide from 1987
The Cancer Register	1958	Electronically transmitted from the regional registers	From the beginning transmitted via forms directly to the National Board of Health and Welfare
The Medical Birth Registry	1973	Copies of Records from Child Births	Integrated since 1980
The Registry of Congenital Malformations	1965	Special Forms	
The Cause of death Register (1850)	1952	Cause of Death Certificates from Physicians	Managed of the National Board of Health and Welfare since 1995 but produced by SCB

Use of the registers

The registers are frequently used for research, evaluation, planning and other purposes by a variety of users. Annually some 550 major orders and a large number of minor requests for data are processed from the registers.

Current projects at the Centre include the development of registration systems for injuries, outpatient visits and drugs.

Is there an absolute need for Personal identification numbers (PIN) (Rosén/Eriksson Journal of the Swedish Medical Association nr 35 1999)

Yes, it's necessary for research if you want to know if it is the same person that has been exposed for a special risk factor or has been given a special treatment that's five, ten or twenty years later has got a special disease or has died.

Rosén/Eriksson also discusses cost-efficiency of the health data registers and make the Statement that "It is un-ethical not to use collected data".

The Cause of Death Register

The aim of the register

To deliver the Official Cause of Death Statistics and to provide information for preventive care, evaluation of different methods within health care and for various research.

Extent

The statistics on causes of death comprise all deaths during a year, covering Swedish residents, whether the person in question was a Swedish citizen or not and irrespective of whether the deaths occurred in Sweden or not. Dead-born babies, people who died during a temporary stay in Sweden, or who ask for political asylum and have no residence permit are not included. Emigrated Swedes that no longer are registered in Sweden are also excluded.

The number of deaths in Sweden in 2000 amounted to 93 516 of which 47 806 were women and 45 710 men. As compared to 1999 the number of deceased persons increased by about 01.1 percent for the women and 2.5 percent for the men..

Content

The main variables included in the register are; social security number, home district, sex, date of death, underlying cause of death, nature of the injury, multiple causes of death, marked if autopsied or not and if so what kind, marked if operated within four weeks before death, marked if injury/poisoning, marked if alcoholic related, marked if narcotic related and code for diabetes.

Data collection

Every time a person dies in Sweden a Cause of Death Certificate has to be issued by a physician. The Certificate is normally issued by the doctor that has been responsible for the patient during his/her last care episode or by another doctor that has examined the dead body.

The most exhaustive way to establish the cause of death is autopsy. There are two different types, clinical and forensic. The clinical one is performed on the initiative of a doctor. The

forensic one is performed by the orders of the police authorities. A decrease in the number autopsies performed might lead to inaccurate statistics. Reasons for the decrease are new regulations that give relatives the right to deny autopsies, changed rules for financial compensation for clinical autopsies, and changed directions for forensic autopsies. The number of autopsies has decreased from about 50 percent at the beginning of the seventies to about 18 percent in 1998. The decrease varies for different ages. Among those above 85 years the number has decreased by about 77 percent, from 30 percent in 1970 to 7 percent in 1998. In the age-bracket 0-14 the frequency has dropped from 69 percent in 1970 to 48 percent in 1998 which constitutes a 30 percent decrease.

The main part of the data in the Cause of Death Register is collected by the Cause of Death Certificates from Physicians. Population data comes from Statistics Sweden.

At the end of World War II, the World Health Organization (WHO) took over responsibility for international co-ordination. The sixth revision of ICD was then widely accepted and gained great respect and support. This version contains definitions of important concepts as well as well-defined instructions for data collecting and data processing.

ICD-10 is described in detail in *International Statistical Classification of Diseases and Related Health Problems (10th revision, volume 3, Geneva 1993)*. Volume one consists of the systematic part of the classification of diseases. The second volume deals with regulations and guidelines on how to use ICD-10. There are also instructions as to how to code the underlying causes of deaths and a couple of supplementary classifications. Volume three consists of an alphabetical, detailed register.

Quality control

The quality of the statistics varies, due to the examinations made to define the underlying cause of death or the changes in the classification system or the processing methods. The main source of the statistical unreliability is the examinations made to define the underlying causes of death. According to WHO the underlying cause of death is to be taken from the death certificate to be shown in the statistics. The underlying cause of death is defined as a) the disease or injury that initiated the chain of diseases that finally resulted in death or b) the circumstances involving the accident or the act of violence that caused the lethal injury.

The dropout is small. Cause of Death information is missing for less than 0,5 percent of all deaths. Since 1997 there is no drop out in the totals. Data from the population statistics include even deaths who are not reported with cause of death certificates – but without data on cause of death (ICD-code R99.9).

Analysis

To facilitate comparison with other years and regions age standardizing is used.

The most common cause of death both for women and men is diseases of circulation organs. Almost half the deceased population had such a disease as the underlying cause of death (49 percent in women, 47 percent in men). The second most common cause of death is tumours where the figures are 22 percent for women and 25 percent for men. Breast cancer is the most common cause of cancer among women. Prostate cancer is the most common among men.

The development in Sweden during the period 1987-98 is favourable. The mortality trend for most of the causes of death is falling. The trend is the same for women and men, although the

level is higher for men than for women. As far as diseases of the circulation organs are concerned the mortality trend has decreased continuously during the actual period, that is from 133 deaths per 100 000 women in the age-bracket 15-74 in 1987 to 91 in 1998. For men the corresponding rate has decreased from 360 to 230.

The total tumour mortality trend is also falling. It is the same development for most of the different cancer sites even though the mortality trend in lung cancer for women has increased during the actual period.

The trends in "avoidable" mortality are decreased during the period 1987-98. About 10 percent of all deaths in the age-bracket 1-74 occurred in medical care indicators and about 10 percent in health policy indicators. However, the decreasing trend for both women and men has stagnated during the last couple of years for the medical care indicators as well as for the health policy indicators.

Reporting

Statistics on causes of death have annually been published between 1911 - 1993 by Statistics Sweden (SCB). The National Swedish Board of Health and Welfare has been responsible for publication since 1994. Statistics Sweden is however entrusted by the National Swedish Board of Health and Welfare with the actual compilation of the statistics.

The Hospital Discharge Register

The aim of the register

The Register aims to provide data on consumption of care as a basis for evaluation, planning and general health care-information.

Extent

The register includes about 1.34 million discharges annually corresponding to 845.000 patients.

From 1987 HDR covers all public, in-patient care in Sweden. The Centre for Epidemiology (EpC) also has data for earlier years, 1964-1986, for somatic care and 1973-1986 for psychiatric care. HDR for those periods does not cover the whole country.

Content

There are four different types of information in the Hospital Discharge Register:

Data on the patient

- personal identification number
- sex
- age
- place of residence

Data on the hospital

- county council
- hospital
- department

Administrative data

- date of admission
- date of discharge
- length of stay
- acute/planned admission
- admitted from
- discharged to

Medical data

- main diagnosis
- secondary diagnoses
- external cause of injury and poisoning
- surgical procedures

Data collection

In the 1960s, the National Board of Health and Welfare started to collect data on individuals treated as in-patients at public hospitals. During the 1970s more and more county councils joined the register system on a voluntary basis. In 1984, the Minister of Health and Welfare together with the Federation of County Councils decided to make the reporting compulsory.

Due to a debate in the media about integrity, personal identification numbers were withdrawn from the register for some years, making it anonymous and of no value for research. Together with other governmental authorities and the research community the EpC informed the Government of the advantages of a patient register with individual data. This led to reintroduction of personal identification numbers in the register in 1993.

Information to HDR is delivered once a year to EpC from each of the 21 county councils in Sweden. EpC gets a magnetic tape or disc with one data file for the whole county council. Every discharge during one year corresponds to one record in that file. With effect from 2001, the Government has empowered the National Board to collect information on out-patient hospital care as well.

Quality control

The very rapid changes of hospital organisation in Sweden makes estimations of underreporting hard to make. This is especially true for psychiatric and geriatric care. The total number of drop-outs for somatic short-time care for the period 1987-1991 has been estimated to less than 2 per cent.

For all records reported to HDR a data control is run. A check is made that compulsory variables are reported, e.g. personal identification number, hospital and main diagnosis. A check is also made that codes for different variables and dates have valid values.

Personal identification number

Some obviously incorrect data is corrected in connection with the quality controls. Number of stays with missing personal identification number (PIN) was 2001 0.4 per cent. Some counties are better than others in reporting PIN and some others are among the best every year.

Main diagnosis

In 2001 the main diagnosis was missing in 0.9 per cent of the hospital stays reported. The bad reporting from psychiatric is remarkable. The drop-outs in main diagnosis is concentrated to a few county councils.

E-code

The number of hospital stays with an injury or poisoning diagnosis where the E-code is missing has increased from 3.0 per cent in 1987 to 11.8 per cent in 1998. From then it has decreased to 3.7 per cent in 2001. One county council is responsible for a majority of the missing E-codes.

Discharged deceased or alive

The information in HDR for 1964-2000 whether the patient was deceased or alive at the discharge has been compared with the date of death from the Swedish Cause of Death Register (CDR). Of the total number of 42 million discharges during the years it has been possible to compare 95.5 per cent. For the remaining 4.5 either the personal identification number and the variable "discharged" or the date of death in CDR was missing. For 99.91 percent of the discharges, the information in HDR corresponded to that in CDR.

Reporting

Publications

- In-patient diseases in Sweden 1987-1996 (whole report in Swedish, with an English summary)
- Hospitalisation due to injuries and poisoning in Sweden 1987-1996 (whole report in Swedish, with an English summary)

The Cancer Register

The aim of the register

The Swedish Cancer Register was founded in 1958. The purpose of the register is to measure the prevalence of cancer and how it changes, and to create a basis for clinical and epidemiological research and international comparisons.

Extent

The Swedish Cancer Register covers the whole population of Sweden. About 42.000 malignant tumours are registered annually. In 2000 the register included 1.7 million tumours and over 1.5 million persons diagnosed with cancer.

Content

There are three different types of information in the Swedish Cancer Register

Data on the patient

- personal identification number
- sex
- age
- place of residence

Medical data

- site of tumour. For the years 1987-1992 the tumours has primarily been coded in ICD-9 and from 1993 and still in ICD-O/2. For the whole period 1958-w the codes are available as ICD-7 codes
- histological type. From 1993 according to SNOMED, ICD-O/2. For the whole period 1958-w the codes are available as the old histology code (WHO/HS/CANC/24.1)

- basis of diagnosis
- date of diagnosis
- reporting hospital and department
- reporting pathology/cytology department

Follow-up data

- date of death
- cause of death
- date of migration

Data collection

The registration of newly detected tumour cases is based upon compulsory reports from all physicians responsible for in- and outpatient departments in hospitals, in both public and private administration. Hospital and forensic pathologists give independent compulsory report for every cancer diagnosis made from surgical biopsies, cytological specimens and autopsies. Reporting is also compulsory for pathologists working in private laboratories.

Since the mid-80's there are six regional registries associated with the oncological centres in each medical region of Sweden where the registration, coding and major check-up and correction work is performed. The regionalization implies a close contact between the registry and the reporting physician, which in turn simplifies the task of correcting and checking the material.

The regional registries annually send information about newly registered cases and correction concerning those previously reported to the National Cancer Register.

Quality control

The material passes through the following controls:

- the identification number is checked against the register covering the total population of Sweden
- duplicates are subject to special checking
- the validity and logical contents of the codes are checked when the material is processed.

An estimation of the drop-out rate of cancers can be done by comparing the Cancer Register data with the Cause of Death Register, since the Swedish Cancer Register does not accept DCO's (death certificates only). The overall reporting to the registry is estimated to be 96 per cent of all diagnosed cases.

Reporting

Cancer Incidence in Sweden is published on the Internet annually. The Report highlights trends in cancer incidence and has recently been updated with prevalence data. Increasing trends in the incidence of malignant melanoma and lung cancer among women are examples of results that have created concern among policy makers.

The Medical Birth Registry and the Registry of Congenital Malformations – (integrated since 1980)

The aim of the Medical Birth registry

Data support to the analyses of risks during pregnancy and at delivery as well as public information.

Extent

Data contains all deliveries in Sweden from 1973. Data includes the previous gestation as well as the new-born child. About 85.000 – 120.000 deliveries a year.

Content

Individual data on previous gestation, smoking habits, medication, family situation, hospital, length of gestation, type of delivery, diagnoses of mother and child, operations, type of analgesia, sex, weight, length, size of head, birth-conditions, place of residence, nationality, etc.

Data collection

Data are provided continuously by all delivery units in Sweden.

Quality control

The total rate of drop-outs are estimated to 0.5 – 1.5 percent annually, but are slightly higher for children died during their first days.

Reporting/use

Since the early 1990s the importance of breast-feeding has been emphasised, especially in delivery and maternity wards, and statistics indicate that Swedish mothers are likely to have one of the highest breast-feeding frequencies in the developed nations. Between 1986 and 2000 the frequency of infants still breast-feeding at six months increased from 51 percent to 72 percent.

Annual reports are published within the system of Swedish Official Statistics (SOU). Some results are also published through scientific articles and in professional journals.

Data from the register also are available through the interactive web-based statistical program "Public Health in Figures" and from the Board of Health and Welfare information service.

The Registry of Congenital Malformations

The aim of the registry

To continuously follow the development of serious congenital malformations to be able to quickly discover changes in occurrence of different malformations.

Extent

Serious congenital malformations reported within six months after birth. About 1.700 reports a year.

Content

For infants with congenital malformation is the mothers identification number, delivery hospital, the infants date of birth, sex, weight, length, head circumference, gestational age and malformation diagnosis reported.

For terminated pregnancies is the woman's date of birth, hospital, date of termination, foetus weight, foetus length, gestational age, indication, method for prenatal diagnosis and malformation diagnosis reported.

Data collection

Data are collected on special forms from all departments of obstetrics and gynaecology, paediatrics, pathology, hand surgery and plastic surgery.

Quality control

Some lack of reporting may occur.

Reporting

Reports from the register are given every six month. Results including trends, prevalence etc are published in the annual reports. Special analyses can be made on request.

Publications:

- Registration of congenital malformations 2001
- Registration of congenital malformations 2000

e. Coordination mechanisms

The Centre for Epidemiology coordinates official statistics within the social sector. The task includes investigating consumer needs, ordering, and purchasing official statistics from the producers.

International collaboration

The EpC has the main responsibility to report Swedish health, etc, statistics to international organisations. The Nordic countries have long enjoyed close collaboration in health and social statistics, most comprehensively with the Nordic Medico Statistical Committee (NOMESCO) and the Nordic Social-Statistical Committee (NOSOSCO). There are also regular meetings and collaboration with e.g. the International Association of Cancer Registries (IACR), the European Network of Cancer Registries (ENCR), the International Clearinghouse for Birth Defects (ICBD), the Association of Nordic Cancer Registries (ANCR) and the Association of Nordic Medical Birth Registries (NOMBIR). The EpC is represented on the board of the Nordic WHO Centre for Classification of Diseases. An EpC representative is also chair and member of the WHO Mortality Reference Group. A)

Recent years have, as expected, seen increased involvement in European public health monitoring. Representatives of the EpC have been active in the Health Monitoring Programme and its projects or other EU or Euro stat health projects. However the need for collaboration to create comparative data by far exceeds the EpC's available resources. A)

Lessons learned using SWOT

What lessons can be learned from analyses of HIS both at the MS and EU level?

Is there any relationship between good management of HIS and health outcomes? Why?

Strengths

The Nordic countries have a long tradition of collecting data on deaths and diseases. They employ epidemiological registers of high quality covering the whole population. This report refers to the National Cancer Register, the Medical Birth Registry including the Registry of Congenital Malformations, the Hospital Discharge Register and the Causes of Death Register. The value of these registers grows continuously as time passes.

Using a unique personal identification number (PIN), it is possible to link data on exposure or treatment from other sources to outcomes in these health data registers. This Nordic system has created large databanks that are invaluable to the research community, giving our register researchers a huge competitive advantage since they do not have to start collecting data from scratch. Thousands of scientific articles have been published based on data from these registers. The knowledge derived has saved many lives and improved the quality of many more.

The National Board diary shows more than 500 requests annually for data from the Swedish health data registers. Over the years this has resulted in more than 1.000 peer-reviewed articles. Professor Måns Rosén, director for the Centre for Epidemiology (EpC), makes the following list of good examples. The Cancer Register has been an important source for analysing the association between residential radon exposure and lung cancer (1), the potential effects of magnetic fields (2), trends in cancer survival (3, 4) and the effects of cervical cancer screening (5, 6). The Medical Birth Register has also been used extensively, e.g. to analyse the risk of smoking during pregnancy (7-9), pregnancy outcome after the Chernobyl accident (10), associations between administration of vitamin K to newborns and childhood cancer (11), teenage pregnancy outcomes (12) and effects on children born after in vitro fertilization (13). Since 1994, data on maternal drug use has been collected in the medical Birth Register. This information has already resulted in some publications, but will evidently result in many more and increase our knowledge of the effects, both positive and negative, of drug use during pregnancy (14, 15).

The study of vitamin K and childhood cancer well illustrates the advantages of large national health registers. A case-control study by Golding et al. published in the British Medical Journal indicated that intramuscular vitamin K administration doubled the risk of childhood cancer compared with oral administration (16). Since intramuscular administration was recommended by the National Board of Health and Welfare, this result created much concern in Sweden, but also in other countries. In Sweden, a study based on the Medical Birth and Cancer registers was initiated. However, the Swedish study, also published in the British Medical Journal, showed no increased risk of childhood cancer (11). Later studies have confirmed the Swedish results. There were several differences between the British case-control study and the Swedish register-based study. One was sample size: the case-control study included 195 cases and 558 controls while the register-based study included more than 2.300 childhood cancers and 1.3 million controls. In the register-based study, data were already available in the registers and data from two registers were record linked. Supplemented with data on maternity hospital routines for vitamin K administration, the study

was completed within a few months. This example well illustrates both the reliability advantages of using large national registers and the cost-effectiveness of such an approach.

The quality of health data registers are crucial for their usefulness for research. Many validity studies of the registers have been conducted, indicating variations in diagnostic procedures. However, the studies indicate mostly good data quality provided the data are analysed with care.

Weaknesses

There are, of course, also disadvantages with national health data registers. For example, data are collected without specifying diagnostic criteria in advance. Focus is on outcomes and the number of variables collected is also strictly limited. Consequently, it is harder to control for confounders and patient characteristics. Some of these disadvantages can be handled in cohort and case-control studies by combining data collection from specific research projects with national health data registers.

An important topic is the risk of violating individual integrity. This risk of doing harm may be twofold: the risk of unlawful trespass/encroachment of data on individual diseases, and the perceived uneasiness/discomfort at just being registered. No system could guarantee 100% security, but after more than four decades of administrating health data registers in Sweden, there is no known case of misuse or data leakage to unauthorized persons. The risk of data trespass is very small. E)

That some people feel discomfort at just being registered is a negative aspect that has to be considered seriously. Public confidence in health data registers is influenced by mass media debate and knowledge of how the registers are being handled. In surveys, about 9% of the Swedish population feel registration is a threat to personal integrity. Dissemination of the purposes and the usefulness, and the careful administration of these registers are therefore important and never-ending responsibilities for administrators and users. E)

Opportunities

Though many researchers do use the registers, they are still an under-used "goldmine". Perhaps the biggest potential can be found on a local or regional level to make researchers in the County Councils and Municipalities to use local registers more frequently.

Many studies, not least in the field of cardiovascular epidemiology, are criticized for focusing on men, or on a limited age-group or a specific geographical area, etc. This kind of limitation can be disregarded when using national registers, since they include both sexes, all age groups, and all parts of a country – an important advantage when assessing health services.

Many studies could be done without national health data registers, by collecting new data sets. In that case, however, one would have to accept the use of far greater resources and more time before answers to the research questions were available. In some cases, it is not even realistic to conduct a study without national registers.

Another option is to create new registers through linking existing ones. For example, severe injuries and myocardial infarctions can be followed by continuous linking of the Hospital Discharge and Causes of Death registers.

Threats

Måns Rosén cannot see that there are any conflicts within Sweden as it comes to the national health data registers. The cooperation is good between the EpC and the Ministry of Health and Social Affairs and with other Boards and Organisations on the national level. The process of data collection and quality control in cooperation with the local registers and the County Councils also works very well. But of course there is a legitimate concern about the confidentiality of these registers. From time to time debates flare up on the ethics of administering these registers that contain much sensitive data on individuals.

Sometimes there is a tension between the member countries and the European authorities concerning influence in different matters. The European strive to harmonize statistics can be a problem if it leads to reduced quality for countries with well functioning registers. If the Ministry of Health and Social Affairs cut down their allowances with regard to stimulation money from the EU there can be a troublesome economical situation to.

References

given by Professor Måns Rosén at page 23.

1. Pershagen G, Åkerblom G, Axelsson O, Clavensjö B, Damber L, Lagarde F, et al. Residential radon exposure and lung cancer in Sweden. *N Engl J Med* 1994; 33: 159-64.
2. Feychting M, Ahlbom A. Magnetic fields and cancer in children residing near Swedish high voltage power lines. *Am J Epidemiol* 1993; 138: 467-81
3. Adami HO, Sparén P, Bergström R, Holmberg L, Krusemo UB, Pontén J. Increasing survival trend after cancer diagnosis in Sweden: 1960-1984. *J Natl Cancer Inst* 1989; 81: 1640-7
4. Stenbeck M, Rosén M, editors. Cancer survival in Sweden in 1961-1991. *Acta Oncol* 1995; suppl. 4.
5. Adami HO, Pontén J, Sparén P, Bergström R, Gustafsson L, Friberg LG. Survival trend after invasive cervical cancer diagnosis in Sweden before and after cytological screening, 1960-1984. *Cancer* 1994; 73: 140-7.
6. Bergström R, Sparén P, Adami HO. Trends in cancer of the cervix uteri in Sweden following cytological screening. *Br J Cancer* 1999; 81: 159-66
7. Ericson A, Gunnarskog J, Källén B, Otterblad Olausson P. Surveillance of smoking during pregnancy in Sweden 1983-1987. *Acta Obstet Gynaecol Scand* 1991; 70: 111-17.
8. Norström M-L, Cnattingius S. Smoking habits and birthweight in two successive birth cohorts in Sweden. *Early Hum Dev* 1994; 37: 195-204.
9. Cnattingius S, Haglund B. Decreasing smoking prevalence during pregnancy in Sweden: the effect for small-for-gestational-age birth. *Am J Public Health* 1997; 87: 410-13.
10. Ericson A, Källén B. Pregnancy outcome in Sweden after the Chernobyl Accident. *Environ Res* 1994; 67: 149-59.
11. Ekelund H, Finnström O, Gunnarskog J, Källén B, Larsson Y. Administration of vitamin K to newborn infants and childhood cancer. *Br Med J* 1993; 307: 89-91.
12. Otterblad Olausson P, Cnattingius S, Haglund B. Teenage pregnancies and risk of late fetal death and infant mortality. *Br J Obstet Gynaecol* 1999; 106: 116-21.

13. Bergh T, Ericson A, Hillensjö T, Nygren K-G, Wennerholm. Deliveries and children born after in-vitro fertilization in Sweden 1982-1995: a retrospective cohort study. *Lancet* 1999; 354: 1597-85.
14. Källén B. The teratogenicity of antireheumatic drugs – what is the evidence? *Scand J Rheumatol* 1998; 27 (suppl. 107): 119-24.
15. Ericson A, Källén B, Wiholm B-E. Delivery outcome after the use of antidepressants in early pregnancy. *Eur J Clin Pharmacol* 1999; 55: 503-8.
16. Golding J, Greenwood R, Birmingham K, Mott M. Childhood cancer, intramuscular vitamin K, and pethidine given during labour. *Br Med J* 1992; 305: 341-6.

Other References

- A) Måns Rosén. A finger on the pulse. Monitoring Public Health and Social Conditions in Sweden 1992-2002. (Draft)
- E) Måns Rosén. National Health Data Registers: A Nordic heritage to public health. *Scand J Public Health* 2002; 30: 81-85.

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