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Quality Registries in Sweden, Healthcare Improvements and Elderly Persons with Cognitive Impairments

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Abstract

Policy-makers, the medical industry and researchers are demonstrating a keen interest in the potential of large registries of patient data, both nationally and internationally. The registries offer promising ways to measure and develop operational quality within health and medical care services. As a result of certain favourable patient data regulations and government funding, the development of quality registries is advanced in Sweden. The combination of increasing demand for more cost-efficient healthcare that can accommodate the demographic development of a rapidly ageing population, and the emergence of eHealth with an increasing digitalisation of patient data, calls attention to quality registries as a possible way for healthcare improvements. However, even if the use of registries has many advantages, there are some drawbacks from a patient privacy point of view. This article aims to analyse this growing interdependence of quality registries for the healthcare sector. It discusses some lessons from the Swedish case, with particular focus on the collection of data from elderly persons with cognitive impairments.

Keywords

privacy – data protection – quality registries – demographic development – patient data – elderly people – cognitive impairments – eHealth

1 Introduction

All healthcare systems need effective ways to measure and develop operational quality of the services they provide.[1] In several countries, such as Sweden, national and regional quality registries play an increasingly important role in fulfilling this aim. These government-administered quality registries collect information on individual patients' problems, interventions, and outcomes of interventions in a way that allows the medical and personal data to be compiled for all patients and analysed at the unit level. Thus the registries allow researchers and others to follow patients and their relatives throughout their lives and obtain information about birth, hospital-based inpatient and outpatient care, dental care, prescribed medication, cancer and other diagnoses and, ultimately, death.[2] The purpose is to develop and ensure the quality of care. The registries are considered to be a promising approach to achieving quality improvement.[3] The registries are also used for certain other purposes, such as clinical research and public quality reporting. These and similar registers are sometimes also called clinical databases, patient registers or disease registers.

Thanks to certain favourable patient data regulations and significant government funding, the development of quality registries is quite advanced in Sweden. Other countries, like the United States, have more complex data regulations and uncertain funding, which limit the development of such registries.[4] These two factors — regulation and funding — seem to play a large part in shaping the development of the quality registers in different countries.[5] Policymakers, the medical industry and researchers have shown a keen interest in

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1 The author's research involves legal issues related to bioethics, research regulation, children's rights and rights of the elderly. Financial support from the Swedish Research Council, Ragnar Söderberg Foundation and the Marianne and Marcus Wallenberg Foundation is gratefully acknowledged. This article was presented at the 21st Annual World Congress on Medical Law, Coimbra at the EAHL/EJHL Joint Seminar, 3 August 2015. The article has benefitted from comments from Professor Henriette Roscam Abbing. The background provided in the article about the Swedish legislation and the registry system is partly derived from T. Mattsson, 'Collecting data for quality improvement and research in Swedish healthcare, and the individual patient's right and ability to protect their privacy', *The Int. J. Technology Policy and Law* 2(2-4) (2016) 160-168.

2 L. Emilsson, B. Lindahl, M. Koster, M. Lambe, and J.F. Ludvigsson, 'Review of 103 Swedish Healthcare Quality Registries', *Journal of Internal Medicine* (2014), doi: 10.1111/joim.12303, 1.

3 C. Levay, 'Policies to foster quality improvement registries: lessons from the Swedish case', *Journal of Internal Medicine* (2015), 10.1111/joim.12438.

4 *Ibid.*

5 *Ibid.*

the potential of large registries of patient data, both nationally and internationally; the EU, for example, is promoting different registries in several health areas. Many consider patient registries and databases to constitute key instruments for developing clinical research, improving patient care and enhancing healthcare planning. For instance, registries are considered the only way to collect data so that a sufficient sample size can be created for epidemiological and/or clinical research in the field of rare diseases.[6]

Two current trends seem to highlight quality registries as a particularly valuable tool for future health and medical care. One is the current *demographic development*. The ageing population worldwide and the falling birth rate have led to intensive discussions about the urgency of increasingly cost-efficient and tailor-made healthcare adapted to meet the rapidly changing and growing needs of the population.[7] The main argument in this case is that the rising number of older people translates into increasing dependency on the whole healthcare system. In the coming decades, the impact of the demographic development will be at least partly reflected in rising healthcare costs. Spending on health is already substantial in EU, accounting for 6-10 per cent of GDP in the EU Member States and around 8 per cent of GDP in most countries in the OECD countries.[8] Most countries in the EU are concerned about planning future healthcare in accordance with this demographic development, for economic as well as quality reasons. This naturally includes estimating not only the overall demand of healthcare but also the types of healthcare services that will be needed. Predictions are difficult and yet necessary. However, there are strong indications in research and reports that healthcare services face

6 For example, the EU has recommended that Member States should consider supporting specific disease information networks at all appropriate levels for epidemiological purposes, registries and databases (Council Recommendation on an action in the field of rare diseases (2009/C 151/02), online at http://ec.europa.eu/health/rare_diseases/policy/registries/index_en.htm, retrieved 2 April 2016.

7 T. Mattsson, M. Axmin and E. Holm, 'Perspectives on Solidarity, Social Security, Healthcare and Medical Research', in A. Numhauser-Henning (ed.), *Elder Law: Evolving European Perspectives* (Chelterham: Edward Elgar Publishing, forthcoming).

8 The share of healthcare expenditure 2012 exceeded 10.0% of gross domestic product (GDP) in six EU Member States (the Netherlands, France, Belgium, Germany, Denmark and Austria), compared to GDP recorded in Latvia (2010 data), Estonia and Romania (6.0% or less), see Eurostat health care statistics, http://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_statistics, accessed 10 May 2016. For OECD statistics, see OECD Health Statistics, http://www.oecd.org/els/health-systems/health-data.htm (accessed 10 May 2016). In 2013, health spending (excluding investment) as a share of GDP was 8.9%, ranging from 5.1% in Turkey to 16.4% in the United States.

many challenges in the near future due to the ageing population. For example, it is probable that in the near future people will live not only longer but also in better health.[9] On the other hand, it is also expected that falling mortality will be accompanied by an increase in morbidity and disability. So, while health may continue to improve, different causes of morbidity and disability may at the same time become more common, demanding increasing efforts from the healthcare sector. Registries are seen as one way to find suitable solutions to this challenge. Collecting data from regular monitoring of accidents or successful treatments involving older patients or patients with cognitive impairments at regional health units is considered as an important tool for increasing the quality and efficiency of care for patients with similar health problems in the coming years.

However, even if the use of registries has many advantages for research and quality assessment in most areas of healthcare, there are some legal and ethical problems as well, specifically in cases where non-anonymous data are needed to be included in the registries. From a patient privacy point of view, collecting data for dementia registries or other registries using data gathered on incapacitated persons is problematic. These individuals often have limited or no decision-making capacity; therefore, the information must sometimes be retrieved on other grounds than their individual informed consent. The problem will not vanish by excluding such groups totally, because their information is invaluable for certain kinds of studies. For example, to develop successful healthcare for dementia, related healthcare needs to be evaluated regularly, and this requires the participation of patients with dementia. However, the use of data from people with limited or no decision-making capacity raises concern about the limitations inherent in applying the right to refuse to those lacking the cognitive capacity to do so personally.[10]

The other trend that highlights quality registries as a particularly valuable tool for future health and medical care is *eHealth*. Governments at all levels are increasingly seeking to improve their governing capabilities by developing and

9 European Commission, 'The 2015 Ageing Report European Economy, Economic and budgetary projections for the 28 EU Member States (2013-2060)', *European Economy* 3 (2015) 118-119.

10 Reporting to the Swedish Social Welfare Board's (*Socialstyrelsen*) five national health data registers (the Patient Register, the Medical Birth Registry, the Cancer Registry, the Drugs Registry and the Dental Health Registry) is mandatory according to law. Registration in the national and regional quality registers, however, is optional for healthcare entities and is not a mandatory duty for the patients. The Patient Data Act Ch 7 Sec 2 gives the individual the possibility to avoid being registered in a quality registry and this right also applies after the processing of personal data has commenced.

implementing strategic information and communication technologies (ICTs) in different ways in their healthcare system. This is often referred to as the eHealth development. The concept of eHealth encompasses all forms of electronic healthcare that are delivered through the Internet. It may be information, education, commercial products or direct health services, including clinical activities. The application may comprise computerized healthcare systems which provide users with information, mobile healthcare which enables users to communicate widely through wired networks, and health portals which provide reliable health information. The connection and interdependence of eHealth and quality registries is a least twofold. First, some parts of eHealth — such as electronic health records and healthcare "big data" — expand the possibility of collecting, analysing and displaying registry data. During recent years, Swedish and European public authorities and entities have developed public platforms and infrastructures that provide access to large amounts of healthcare information, including data from clinical trials and patient information. In addition, other actors such as pharmaceutical companies, healthcare providers, laboratories and insurance companies have accumulated years of health data in medical databases and have digitized their patient records. Thus, there is a large potential for research and quality assessment based on this vast amount of healthcare information that has been compiled as a result of the eHealth development. Secondly, healthcare providers can use the registries directly in new and innovative ways for the healthcare system. For example, several Swedish registries offer interactive data analysis to participating providers, and others offer online healthcare to the general public.[11] Personal data may also be used by both clinicians and patients to provide assistance on health-related issues (see for example the use of health apps in healthcare).

Thus, increasing demands for more cost-effective healthcare that can also meet demographic and other societal challenges, in combination with the faith in eHealth for fulfilling these and other requirements, call attention to national and regional registries as central tools for healthcare improvements in Sweden and many other countries. This article aims to analyse this growing interdependence of quality registries for the healthcare sector, and vice versa, and discuss some lessons from the case of Sweden, with particular focus on the collection of data from persons with cognitive impairments.

11 C. Levay, 'Clinical quality registers as e-health', in: G. Erlingsdotter and H. Sandberg (eds.), *White Paper eHealth* (Lund:Media-Tryck 2016).

2 Quality Registries in Sweden

2.1 *Background*

According to Section 31 of the Health and Medical Services Act (1982:763), the quality of Swedish health and medical care should be systematically and continuously improved and assured. Working with quality registries is an effective way of fulfilling this legislative requirement. These registries contain a variety of patient-related data gathered from several care givers about diagnoses, measures taken, results of treatment and so on. The collected health data is processed, compared and analysed, and used to increase the quality of health and medical care on different levels. For example, with the data, a successful treatment or procedure for a particular patient group — say, dementia patients — may be found, and this knowledge can be used to change routines and procedures at health clinics in Sweden to create better and safer healthcare for dementia patients. The current coverage of the quality registries is impressive. According to a study from 2014, many quality registries have attained a near-total national completeness for their diagnostic or therapeutic categories, with almost 100 per cent of the target population registered.[12] About 60 per cent of the quality registries report a completeness of 80 per cent or more. The geographical coverage is also high; for almost one third of the registries, all Swedish healthcare units and hospitals that treat a specific disorder report continually to the relevant quality registry.[13]

Sweden has unique opportunities for using quality registries owing to its comprehensive population registries and unique personal identification number system. Sweden has a tradition of maintaining national, individual-based registries. The population registry dates as far back as the 18th century. Since the 1970s, Sweden has worked continuously to develop nationwide quality registries to assess healthcare in Sweden. The first quality registry, the Swedish Knee Arthroplasty Registry, started in 1975. There are currently around 100 national quality registries funded by the state and the county councils, and more are under development.[14] These registries have various origins and purposes. For example, some registries have been developed to describe geographic variations in the use of different treatment methods. Other records are designed to highlight differences in healthcare utilisation and medical practice. There are also records based on individual procedures (such as knee replacement or hip

12 *Supra* note 2, pp. 32-38.

13 *Ibid.*

14 See Kvalitetsregister.se, retrieved 25 April 2016.

surgery), specific diagnoses (such as diabetes or cancer) and particular areas where there are known risks (such as fall risks for the elderly).

2.2 *Regulation and Organisation of Patient-data Collection*

Since 2008, national and regional quality registries are regulated by the Patient Data Act (2008:355). According to the Act, care givers are allowed to collect and process personal data in a registry for the primary purpose of developing and securing the quality of health and medical care. Since some years back, the expansion and addition of quality registries has been promoted by the government, which pushes the development forward through economic incentives to care givers.

In the Patient Data Act, quality registries are defined as automatic and structured collections of personal data with the purpose of systematically and regularly developing and ensuring the quality of healthcare (Chapter 7 Section 1). The aim of the regulation is both to facilitate enhanced patient safety and maintain a strong protection of privacy.[15] The registries are developed through collection of patients' personal data from several care givers in order to make comparisons of healthcare on a national and regional level.[16] The data is often retrieved from the patients' medical records.[17] The Patient Data Act regulates the processing and use of this data. In addition, there are some general provisions in the Personal Data Act (1998:204); this means that when the Patient Data Act does not contain any relevant rules, the provision of the Personal Data Act shall apply.[18]

In Swedish healthcare, the presumption is that secrecy and confidentiality of the medical records and other personal data of the patients shall be maintained.[19] However, under certain conditions the data can be disclosed. The regulation may be designed as a duty or a possibility to disclose data.[20] Reporting to quality registries is voluntary for the care giver. According to the

15 Prop. 2007/08:126 Patientdatalag m m 177.

16 *Supra* note 15, 176.

17 *Ibid*., 195.

18 The Personal Data Act will be replaced by the coming European General Data Protection Regulation in 2018.

19 Public Access to Information and Secrecy Act (2009:400), Ch 25 Sec 1.

20 There are numerous statutes in Sweden issued by the government and the parliament that require data to be disclosed. This situation is criticised in legal doctrine; see U. Sandén, *Sekretess och tystnadsplikt inom offentlig och privat hälso- och sjukvård. Ett skydd för patientens personliga integritet*, (Umeå: Skrifter från juridiska institutionen vid Umeå University, 2012) p. 27. She argues that the situation is unacceptable from the perspective of patient privacy. It is impossible for a patient in Sweden to know what personal

Public Access to Information and Secrecy Act (2009:400), a public care giver is allowed to disclose data to a national or regional quality registry for the purpose of quality assurance of care.[21] This regulation applies to private care givers as well. Every registry must have a national or regional healthcare authority within the health sector which is responsible for the use of personal data that is collected in the registry. Often it is a county council or a national authority that has this responsibility. Each hospital, or other local care giver, that collects data for a registry is responsible for its local register process. For example, the party who is the personal data controller has the duty to ensure that the person who is being registered receives information about the processing of personal data.

A national strategic group makes decisions concerning the overall development of quality registries in Sweden. The group consists of representatives from the government and the municipalities.[22] In addition to the strategic group, there is an operative unit and an expert group with more practical duties, such as managing funding of the registry centres.[23] In 2012 the National Registry Service at the National Social Welfare Board (*Socialstyrelsen*) was established. The aim is to contribute to and maintain the high quality of the registries and make them useful for the clinical community and researchers. This board is also supposed to assist when researchers need to merge or cross-check data in registries, for example between a national quality registry and one of the Social Welfare Board's national registries, such as the National Health Data Registry or the National Patient Registry.

3 The Need for Collecting Data for Future Healthcare versus the Need for Patient Privacy

3.1 *The Solidarity Principle Applied*

For research and quality assessment to be possible in healthcare, many patient groups need to be involved in the collection of data. The principle of solidarity

data has been disclosed without his or her consent or knowledge to other persons or authorities.

21 Ch 25 Sec 11.

22 Handbok för kvalitetsregister med SLL som huvudman, Karolinska institutet and Stockholms läns landsting, Stockholm 2012 4.

23 There are eight registry centres: QRC Stockholm, EyeNet Sweden, Registercentrum Syd, KCP (Kompetenscentrum för psykiatriska och andra kvalitetsregister Örebro Uppsala), UCR (Uppsala Clinical Research Center), Registercentrum norr, Registercentrum Västra Götaland and RCSO (Registercentrum Sydost), online at http://www.kvalitetsregister.se/om_kvalitetsregister/quality_registries, retrieved 20 January 2016.

plays a significant role in this context and is also a fundamental reason for allowing research on patients or patient data with the purpose of developing healthcare for the common good and future generations. Medical research is a necessary component of helping others with diseases, pain and suffering, and therefore, it is argued, participating in research becomes a moral obligation.[24] In addition, the obligation stems from the advantages we gain from the existence of the social practice of medical research. We continually benefit from others being part of research and should therefore not be "free riders" in this system.[25] We all benefit from living in societies where research is carried out and which uses the benefits of past research. Since we readily accept these advantages that have been given to us, we have a moral obligation to contribute to this social practice that continuously advances our society.

Solidarity is a term that usually refers to the feeling of unity and belonging between people or a unity of a group or a nation that is based on community of interests, objectives, and standards.[26] The principle of solidarity is essential to the notion of a social Europe and has also been central to the EU legislation in many areas. It is referred to in various objectives of the EU, such as the goal of promoting solidarity among Member States and among generations. The principle of solidarity is reflected in the European Charter of Fundamental Rights as well.[27] The same principle is also a concept that is well known in the context of national welfare models in general. Although several welfare models may be distinguished in Europe, in most national systems there are several benefits based on the principle of solidarity and not related to any form of earnings through previous employment. A prime example of such benefits is healthcare.[28]

The solidarity principle is currently at issue due to rapidly approaching and significant demographic challenges in the near future. As mentioned, European societies today are facing considerable pressures on healthcare systems due

24 H. Harris, 'Scientific research is a moral duty', *Journal of Medial Ethics* 31 (2005) 242-248, 242.

25 *Ibid.*

26 See for example *Merriam-Webster Dictionary*, online at http://www.merriam-webster.com/dictionary/solidarity, retrieved 8 March 2016.

27 Particularly this is to be found in Chapter IV of the Charter, which is even titled 'Solidarity'. The chapter includes provisions for entitlement to social security benefits and social assistance in accordance with Union.

28 Lately, legal systems and the courts have struggled with the question of how, and the extent to which, the solidarity principle should apply within the European social welfare systems for certain groups with important effects, for example for retired and elderly persons and for EU migrants. It seems as if the integration process in Europe challenges the traditional conception of solidarity, see for example *supra* note 7.

to decreasing financial resources, and demographic shifts with increasing proportions of persons above 65 years of age.[29] For older people to be able to obtain assured care of good quality in the near future, research is needed on specific geriatric diseases and injuries, how older people react to drugs and how they experience the care. In addition, the expected growing pressure on health and medical care in general calls for new measures to increase the efficiency in care systems and decrease the cost per patient. This situation demands increased medical research on older people and people with age-related disorders, such as persons with cognitive impairments. At the same time, the most influential international documents on medical research — such as The World Medical Association's Declaration of Helsinki and The Council for International Organizations of Medical Sciences' International Ethical Guidelines for Biomedical Research Involving Human Subjects — limit participation for persons who are unable to give their consent to being part of a research study. The limitation rules are based on the principle that the well-being of the person should take precedence over the interests of science and society.[30] For example, justifying research on persons with dementia or other cognitive impairments demands major considerations. Seeing medical research as a public good cannot by itself justify research based on reasons of solidarity. Therefore, gathering information for research purposes should only be pursued if it can be done in a research-ethically acceptable manner. It involves an examination of the balance between the risks to the subject and the scientific value of the study. As a consequence, medical research in Europe needs to pass through an ethical review process. In all European countries, the ethics review legislation demands minimally invasive and minimally risky research procedures on vulnerable groups and safeguards against wrongful use. Under such circumstances, and if all conditions are met, research also on these groups may be justified.[31]

3.2 *The Privacy Principle Applied*

As discussed earlier, many national and regional quality registries in Sweden provide central information that helps healthcare workers identify risks and proactive working methods to prevent health damage in the healthcare

29 K. Scott, 'Demographic developments and economic challenges in an ageing Europe', in: Numhauser-Henning (ed.), *supra* note 7.

30 See for example World Medical Association, Declaration of Helsinki, para. 5.

31 The research participation in in these cases often based on the solidarity principle, i.e. that there is a moral obligation to help others and a moral obligation to be just and do one's share; compare Harris, *supra* note 25, 247.

system. The contents of the registries are the basis for the open reporting of content and outcomes of care. However, a prerequisite for this is that current data is available and can be followed over time. In addition, national quality registries need to have a significant range to be useful for systematic improvement in healthcare. If, for example, data from persons with impaired decision-making capacity is missing in the records, the data may become less reliable. Then there is a risk that the effect on improving patient safety will be diminished. Therefore, participation of all groups is considered necessary, including incapacitated persons.

Many quality registries focus on specialised care and specific treatments, but during the last ten years they have also started to address a broader patient population, including people with multiple diseases and people with cognitive impairments. Such national registries collecting data for older persons with cognitive impairments include, among several others, the Swedish Dementia Registry and the Swedish Stroke Registry. The aim of the Dementia Registry is to improve the quality of diagnostics, treatment and care of patients who suffer from dementia disorders. All patients diagnosed with such disorders are registered and are then followed up every year.[32] The other registry, the Stroke Registry started in 1994 and is one of the world's largest stroke registries. All hospitals in Sweden with acute stroke patients participate in the registry. The aim of the registry is to support high-quality care for stroke patients throughout the country.[33]

As mentioned above, participation in national and regional quality registries in Sweden is voluntary. Before personal data is treated in a registry, the responsible authority must inform the patient. Information is to be provided in accordance with the Patient Data Act, Chapter 8, Section 6. This includes information such as which national or regional health care authority is responsible for the use of the personal data, the aim of the registry, which data will be stored and the possibility to refuse to provide data to the registry. In addition, according to Chapter 7 Section 3, patients must also be informed about their right to request at any time that all personal data be erased. For cases in which it is not possible to provide the information before personal data processing is started, it must be provided as soon as is practicable thereafter, in accordance with the same section. The patient always has the right to oppose the registration. The law imposes no requirement on any consent from the individual. Instead, the patient is given an opportunity to object to the processing of the

32 See http://www.ucr.uu.se/svedem/index.php/about-svedem, retrieved 20 April 2016.

33 See http://www.riks-stroke.org/?content=&lang=eng&text, retrieved 20 April 2016.

data. This is sometimes referred to as "opting out"; the person's privacy is protected by his or her right to refuse registration of the information provided.

How, then, does the system of registering incapacitated persons work in order to include these groups? The rights to information and to oppose registration presuppose personal capacity to understand the information provided and to be able to form an opinion about whether or not to participate.[34] Only a small number of incapacitated persons in Sweden have a legal representative for these types of situations and the possibility for a consent by a legally recognised representative is thus limited. Therefore, the practical situation has been problematic in respect to the registries which include incapacitated persons. The legal framework did not regulate this situation for long. The situation became very troublesome and led to regulation in 2015. According to this new regulation, in chapter 7 Section 2a in the Patient Data Act, the conditions for data registration of an incapacitated person is that the person's attitude has been elucidated as far as possible, and there is no reason to believe that he or she would have opposed the registration if he or she had been mentally competent. Thus the decision is up to the health personnel to make, based on the information about the person's wishes and demands, if any. In terms of the health personnel's investigative work on this issue, there is little guidance in the preparatory works.[35] The difficult question — how the delicate balance is to be maintained between the desire to register data for the future quality of care and the importance of the individual's right to privacy in each individual case — remains for the individual care giver to resolve. This legal construction is problematic from a privacy rights perspective, because it does not give any guarantees that the person will receive information or gain knowledge of his or her own participation. The practice is particularly problematic because there is an economic incentive for care givers to collect personal data, as the national government remunerates the collecting units for this service.[36]

34 If legal representatives exist, for example custodians for children or trustees for incapacitated individuals, these representatives decide on behalf of the person according to the Child and Parental Code (1949:381). Few persons with cognitive impairments in Sweden have a legal representative, because relatives do not automatically acquire this role, and instead a power of attorney is often used.

35 Prop 2013/14:202, p. 45.

36 To encourage the development of the national and regional registries, care givers receive financial compensation for each registration. As mentioned above, it is not mandatory for a care giver to report data to a quality registry. (For other kinds of registries, there may be a statutory duty to report health data in Sweden. According to Section 6 of the Health Data Registry Act (1998:543), public and private care givers have a duty to report certain health data to the Swedish Social Welfare Board.) The quality registries are therefore dependent

Currently, there is a governmental discussion on how to improve the legal situation of the lack of substitute decision-making options for many incapacitated persons in Sweden, which will most probably lead to a new legislation in the coming years.[37]

4 EU General Data Protection Regulation (GDPR)

As already discussed, Swedish registry policies are characterised by a soft and accommodating regulation through which health professionals' own activities in data collection are encouraged practically and financially. However, the EU data protection legislation, notably the General Data Protection Regulation (GDPR) which will govern the data protection of EU citizens from 2018 onwards may challenge Sweden's generous attitude towards collecting data. The background is that the new privacy regulation aims to create stronger data protection laws for EU. The GDPR will enable people to better control their personal data and put up legal barriers for using data without their individual consent. This may be a challenge to some Swedish registry policies on mandatory collection of data without individual consent. It may also be problematic for the registries that collect data for persons with cognitive impairments — that is, persons who cannot give informed consent to the collection of their personal data. Similar issues are also central to the future development of many eHealth services. eHealth tools and techniques need to be designed so that products and services can provide acceptable levels of privacy. Such development is crucial for eHealth development in general.[38]

The new data protection legislation includes two legislative instruments: the general data protection regulation[39] (GDPR) and the data protection regulation in the area of law enforcement.[40] This strengthened data protection

on the interest of the care giver in supplying the registries with data. The use of quality registries has increased significantly after the government approved high levels of compensation. In addition, the county councils have a separate reimbursement system for the regional registries.

37 In December 2015 a governmental report from a special Committee was published, suggesting certain changes in the regulation, see SOU 2015:80 Stöd och hjälp till vuxna vid ställningstaganden till vård, omsorg och forskning.

38 Privacy engineering is an emerging cross-disciplinary field within the software and information systems area with the aim of delivering electronic systems with an acceptable level of privacy.

39 This regulation will replace directive 95/46/EC.

40 This regulation will replace the 2008 data protection framework decision.

regulation is the outcome of several years of work to modernise the European data protection regulation, a product from the 1990s that is considered outdated due to the technological development in society and the increasing amount of personal data that is in circulation in society. The new regulation aims to strengthen the right to protection of personal data under these new circumstances,[41] relying on the protection of the processing of personal data as a fundamental right laid down in the Treaty on the Functioning of the European Union (Article 16)[42] and in the Charter of Fundamental Rights of the EU (Article 8).[43] The Data Protection Regulation contains (similar to the current Swedish Data Protection Act) a principle forbidding the processing of sensitive personal data (Article 9.1). Sensitive personal data is defined as data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data specifically addressed to uniquely identify individuals or data concerning health or sex life. The ban is associated with a number of important exceptions (Article 9.2-9.5). For some of the exceptions to be applicable, regulatory support for such treatments must be expressed in European Union law or national law. The possibility for Sweden to derogate from the ban is expected to come into national law largely through sector-specific legislation, which in the case of health data at present is primarily regulated in the Data Patient Act.

The new data protection regulation will provide the basis for the general processing of personal data within the EU. This means that the Swedish Personal Data Act and other regulations in connection with this regulation must be repealed. In addition to the EU regulation, there is a need to develop national complementary regulation, both where this is required (for example control systems including penalties and a supervisory authority), and where the regulation permits additional national rules on certain issues. In February 2016, the government appointed a national commission for the task of analysing

41 GDPR article 1.

42 According to the article, everyone has the right to the protection of personal data concerning them, and EU rules shall stipulate conditions relating to the protection of individuals with regard to the processing of personal data by Union institutions, bodies, offices and agencies, and by the Member States when carrying out activities which fall within the scope of EU law, and the rules relating to the free movement of such data.

43 The article states: 'Everyone has the right to the protection of personal data concerning him or her. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified. Compliance with these rules shall be subject to control by an independent authority.'

the need for revisions of the national legislations; this commission shall propose provisions on a general level that can complement the Data Protection Regulation.[44] It is clearly stated in the directive for the national commission from the Government that the legislative proposals must have an appropriate balance between the protection of privacy and the authorities', companies' and individuals' need to process personal data.[45]

The commission's investigative task does not include to analyse the data protection implications of the Regulation in sector-specific areas, such as the area related to health including the Patient Data Act. Thus, the question of the extent to which the EU regulation will be considered to collide with or affect the Patient Data Act is open for discussion. As mentioned, the EU Regulation contains rules stipulating when personal data processing may take place in healthcare. Further investigation is needed of the framework of Swedish legislative process to determine the extent to which the rules of the Patient Data Act must be further adapted to the rules of this regulation. In this process, it is likely that further investigations will be asked for by the government to make the necessary impact assessments of the sector-specific issues raised by data protection regulation. For example, when it comes to issues related to healthcare and research on adults with cognitive impairments, the Data Inspection Board — in a recent consultation response to the government regarding a legislative proposal on this issue[46] — stated that due to the upcoming data protection legislation, the proposed possibility for a deputy to agree to certain processing of personal data must be investigated further.[47]

5 Conclusions

In Swedish legislation there has traditionally been little protection of the right to privacy.[48] Instead, openness and transparency have long been trademarks of the national law-making powers. In recent decades, as a member of EU, Sweden has seen this openness successively challenged in several ways. One

44 Dir. 2016:15 Dataskyddsförordningen. The assignment is to be completed by May 2017.

45 *Ibid.*, p. 6.

46 *Supra* note 46.

47 The Data Inspectorate, 2016-04-04, case 2335-2015.

48 I. Österdahl, 'Transparency versus Secrecy in an International Context: a Swedish Dilemma', in: A.S. Lind, J. Reichel and I. Österdahl (eds.), *Information and Law in Transition — Freedom of Speech, the Internet, Privacy and Democracy in the 21st Century* (Malmö: Liber, 2015) 73-99, 77.

such challenge was the implementation of the EU Directive on the protection of personal data.[49] The latest challenge is the creation of a new regulation. During this process, Sweden has tried to retain some latitude in the regulation for national possibilities to be able to keep an open and transparent tradition, to the disadvantage of the protection of personal data. The potential tension between EU law and Swedish law in this regard tends to be even more explicit as the new data regulation will soon enter into force and override any potentially contrary legislation when it comes to collecting and processing personal data. This article has sought to explore this new situation in which Swedish openness — in terms of the extensive collection and use of medical and personal data in Sweden's many national and regional registries — is challenged.

Registries are considered to be one of the most important tools for healthcare providers in fulfilling requirements on patient care and safety and in developing the health sector in Sweden.[50] It is an understandable approach: registries serve as platforms for interorganisational professional collaboration to monitor and develop the quality of healthcare for many groups of patients. This data from the registries may be used for different tasks, such as clinical research, quality assurance, public quality reporting, research and information to stakeholders and policy-makers.

The legislation of national and regional quality registries aims to benefit different patient groups by using the data for research and quality assessment. However, one precondition is that people are willing to share their data for the sake of helping others. Patient data is considered to be the foundation of the continuous improvement of healthcare and patient safety. It is a distinguishing feature of many healthcare systems that they are solidarity-based, with access to high-quality, proven care that is possible only through the research based on previous patients' and research subjects' experiences. Demographic developments are already putting significant pressure on the healthcare system in Europe, and a precondition for cost-effective, tailor-made healthcare for the older population is continuous, relevant health and medical research. The availability of patient data has a central role in this progress.

One problem, however, is the risk of violating privacy rights for the very same group. The current legislation in Sweden is an example of the difficulty

49 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, O.J.95/L.281/31, 23 November 1995.

50 M.G. Hansson, 'Access to Health Data in Registries and the Cost of Privacy Concerns — Introducing a Privacy Ombudsman while Extending Access to Data', in: Lind et al. (eds.), *supra* note 48, pp. 326-338, 326.

of legislating generous methods of collecting data about all individuals — including incapacitated individuals — and at the same time finding ways to create protective legislation for the same group. There seems to be a problem owing to the fact that the legislation does not provide enough guidance for the health personnel on the registration of information about incapable persons. This is unfortunate in a situation where the care givers may have multiple interests in the management of information about a person.[51] At worst, incapacitated persons participate simply because they do not have the capacity to say no.

Thus, the handling of the tension between availability of good data for research purposes as a basis for patient safety and access to evidence based treatment on the one hand and patients right to privacy on the other is, once again, an issue for debate in Sweden. As discussed, with the new EU privacy requirements in the GDPR, the government is forced to re-examine the present legal protection level. According to the coming regulation, health research can be done without consent if it is of significant public interest. This raises the following question: who should decide what research is of such interest? One option is the appointment of a proxy to decide on the behalf of the incapacitated person. Another is the possibility of using advanced decisions, i.e. previously made decisions by the now incapacitated person.

European societies today are facing considerable and mounting pressure on their healthcare systems due to dwindling financial resources and demographic shift resulting in larger proportions of persons above 65 years of age. Medical research is closely connected to this demographic development in Europe. The ageing population in EU and worldwide and diminishing birth rates have an urgent need of increasingly cost-efficient and tailored healthcare adapted to meet these changing and expanding needs. One part of those discussions involves demands for increased medical research to find ways of decreasing morbidity and easing disability among older people. As a consequence, the new data protection regulation will most probably give rise to a necessary but difficult discussion of the elderly patients' right to good quality care on the one hand and their right to data protection on the other in cases where non-anonymous data are needed to be included in the registries.

51 L. Broström, M. Johansson and T. Mattsson, 'Registrering av beslutsoförmögna för forskning, statistik och systematiskt förbättringsarbete', *Förvaltningsrättslig tidskrift* 3 (2014) 369-380.