



Danish Cancer Society



27 February 2013

Proposal of the Danish Cancer Society (DCS), European Network of Cancer Registries (ENCR), and Association of the Nordic Cancer Registries (ANCR) on the proposed General Data Protection Regulation (GDRP) of the European Parliament and of the Council of the European Union.

With reference to text of the GDRP as proposed by the European Commission (COM(2012) 11 final) dated 25.1.2012 and to the Draft Report by the Committee on Civil Liberties, Justice and Home Affairs of the European Parliament (LIBE) dated 16.1.2013 DCS, ENCR and ANCR observes that:

The amendment proposals from the LIBE-Committee can seriously hamper the capacity of research done to protect public health, monitoring of health care and safety of health interventions. This seems quite contradicting, because the LIBE-Committee emphasizes that public health is both urgent and compelling (justification to proposed amendment 27).

European citizens and policy makers face concrete requirements for more accountability and performance assessment in healthcare, requirements for effective health protection, and efficient administration of the healthcare systems. In sum there is an increasing need for more and better information on public health and quality of the health care provided.

Research in public health is a fundamental pillar for the planning, management and evaluation of healthcare, as well as for disease prevention. Due to important results from register-based epidemiological research it has been possible to protect human lives and to avoid premature deaths.

Amendments proposed below.

**Amendment 1
(LIBE Amendment 27)**

Recital 42	
<i>Text proposed by the Commission</i>	<i>Amendment proposed by LIBE</i>
<p>(42) Derogating from the prohibition on processing sensitive categories of data should also be allowed if done by a law, and subject to suitable safeguards, so as to protect personal data and other fundamental rights, where grounds of public interest so justify and in particular for health purposes, including public health and social protection and the management of health-care services, especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system, or for historical, statistical and scientific research purposes.</p>	<p>(42) Derogating from the prohibition on processing sensitive categories of data should also be allowed if done by a law, and subject to suitable safeguards, so as to protect personal data and other fundamental rights, where grounds of public interest so justify and in particular for health purposes, including public health and social protection and the management of health-care services, especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system, or for historical, statistical and scientific research purposes.</p>

Recital 42
<i>Amendment proposed by DCS, ENCR & ANCR</i>
<p>(42) Derogating from the prohibition on processing sensitive categories of data should also be allowed if done by a law, and subject to suitable safeguards, so as to protect personal data and other fundamental rights, where grounds of public interest so justify and in particular for health purposes, including public health and social research, protection and the management of health-care services, especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system, or for historical, statistical and scientific research purposes.</p>

Justification

Public health is urgent and compelling, not least for those who depend on advances in healthcare. During the last 50 years the benefits of collecting and using complete records on morbidity and mortality have been shown repeatedly. The importance of health registries is increasing in both planning and quality assessment of healthcare, and further with the European initiative to create large scale biobanking facilities in countries where data from biobanks can be combined with data from population registries for public health research purposes.

It is important that research into public health issues such as prevention is exempted explicitly. Many health registries are set up for quality assurance (providing bench marks on aggregate data). However, once the data are in the registry, they can be used for scientific register-based research and linked to other relevant registries for health such as education. Linkage of records of population census, cancer registry and population registry does as an example enable researchers to assess occupational and environmental health threats and to study the effect of risk factors for cancer over long follow-up periods.

Challenges of designing effective and sustainable health care systems, and of protecting an aging population from preventable diseases requires that health policies are based on sound evidence. In the absence of sound population based epidemiological research, actions would be founded on anecdotes, small trials and stakeholder interests.

**Amendment 2
(LIBE Amendment 327)**

Article 81 - paragraph 2 a (new)	
<i>Text proposed by the Commission</i>	<i>Amendment proposed by LIBE</i>
	<i>2a. Member States law may provide for exceptions to the requirement of consent for research, as referred to in paragraph 2, with regard to research that serves an exceptionally high public interests, if that research cannot possibly be carried out otherwise. The data in question shall be anonymised, or if that is not possible for the research purposes, pseudonymised under the highest technical standards, and all necessary measures shall be taken to prevent re-identification of the data subjects. Such processing shall be subject to prior authorisation of the competent supervisory authority, in accordance with Article 34(1).</i>

Article 81 - paragraph 2 a (new)
<i>Amendment proposed by DCS, ENCR & ANCR</i>
[DELETION OF LIBE AMENDMENT]

Justification

*Epidemiological research is –as noted above- a fundamental pillar for the planning, management and evaluation of healthcare, as well as for disease prevention. For this reason epidemiological research must be regarded **research of the highest public interest**. Health data are to be considered as extremely sensitive and all necessary measures shall be taken to prevent the identification of any data subject.*

However, DCS, ENCR and ANCR agree with the International Epidemiological Association, that making access to health data without the explicit consent of the data subject possible only as an ‘exception’ granted by a Member State for research serving “exceptionally high public interests” poses as exceptional and extra-ordinary.

Explicit consent

For the following reasons it would be virtually impossible to use registry data if there were no exemptions to the principle of explicit consent.

- a) Studies based on health registry data often involve analysis of tens or hundreds of thousands of cases in order to gain coverage and statistical power. Database projects may therefore face considerable costs, difficulties and delay in reaching data subjects, likely many years after the data was originally collected and people have moved, changed names or doctors or died. The practical burden of seeking consent in this context would therefore be disproportionate and lead to inefficient use of public funds for research and in long-term be deleterious to the public's health.*
- b) Systematic exclusion of deceased data subjects would introduce a significant selection bias abolishing the chances for objective scientific studies, while inclusion of the data cannot do impose harm on the data subject.*
- c) The repeated burden for patients or their relatives of being asked to consent to the use of their data for research is of concern.*
- d) Low response rates leads to biased research results. Public health surveillance must be both reliable and sufficiently comprehensive that changes can be tracked over time. Robust research depends on access to samples and data from as many people as possible.*
- e) Incompleteness of registration would vary between registries as a result of differences in the manner in which consent is sought or given. This would invalidate international comparisons of cancer incidence.*
- f) It is a well documented fact, that there are differences between individuals who consent to participation in research and those who do not. This entails a potential for selection bias threatening the validity of research results, since the missing of data leads to biased results.*

In addition Member States may vary in their appreciation of “exceptions” to the requirement of consent and legislate differently in this respect, hindering the flow of data across borders within in the EU and the conduct of joint research projects.

In some Member States disease registration is mandatory by law reflecting an ethical paradigm that allows for the use of information gained in the course of individual medical treatment for the benefit of others who develop, or are at risk of developing a similar disease.

The LIBE amendment leaves room for substantial discretion by Data Protection Agencies who have never done empirical research and are not trusted an ethical responsibility relating to the aims of research. In a free society scientific research, which aims to bring its results into the public domain, must be able to shed light on and document social and medical practices, risk factors etc.

Pseudonymisation

Some groups claim that all health research can be performed with anonymised or pseudo-mised data, using constructions by Trusted Third Parties (TTP). Though the Working Party endorses Privacy Enhancing Technologies (PET) as a way to further privacy and data security, we strongly warn against the following aspects of this trend.

The anonymisation of data before they reach the research domain only leads to an effective erosion of the data quality. Data must be sufficiently detailed to find the delicate patterns

which might predict what can keep us healthy and what not. Instead of on anonymisation techniques before data reach the research domain, the emphasis should be on how safety and confidentiality of data within the research domain can be assured. Medical scientific researchers should not be seen as aliens and potential adversaries of patient confidentiality, but as how they see themselves: part of the collective endeavor of health care to protect health and improve health care.

First of all it is an illusion that all good public health research can be performed with anonymised or pseudomised data. Since encryption algorithms rely on gender, date of birth, and name, and can be supplemented by place of residence, one may assume such a system to be rather robust. However, people change names, misspellings occur, residence may change and small errors in the name, date and year of birth used by the encryption software may result in linkage to previous data is missed by the registration office, and duplicate entries may be introduced into the cancer registry. The linkage to death certification is one of the pillars in proper cancer registration, and missing a link to an already reported case may have impact not only on the overall incidence but also on the estimation of survival. In the study of impact of occupational risk factors for cancer, which often is determined on relatively few cases, a missed link between a worker and a rare cancer like leukaemia may completely change conclusions and refute a true risk. On the other hand reporting bias exaggerating a risk may be the result of interview studies not based on data from proper population based monitoring.

The second aspect of this trend is that it often ignores that source data (such as from electronic health care records) are sometimes inaccurate and therefore need to be checked. This can only be done by allowing researchers to interact with the data sources about particular patients. One way pseudonymisation can create highly unreliable research databases.

The third aspect is that of costs. These TTP constructions are very costly and consume funds which otherwise could have been dedicated to proper research. Again, data security is of paramount importance. However, no breaches of data security have been reported from countries which have held diseases registries over a very long time without using TTP constructions.

One of the first commandments of monitoring is that the data must be correct (Council of Europe, Convention no 108). Introduction of expensive and complex procedures for research into public health, may lead to more data sharing across Europe, but also to lesser data to be shared because of undue hindrances to collect and link data.

If confidentiality regulation and security procedures lead to less correct data and in turn to erroneous conclusions on analysed data, more harm than benefit for the societies and for the individual will be the result. False conclusion may can potentially harm large populations or at least change the life of thousands of people in vain.

**Amendment 3
(LIBE Amendment 328)**

Article 81 - paragraph 2	
<i>Text proposed by the Commission</i>	<i>Amendment proposed by LIBE</i>
<p>Processing of personal data concerning health which is necessary for historical, statistical or scientific research purposes, such as patient registries set up for improving diagnoses and differentiating between similar types of diseases and preparing studies of therapies, is subject to the conditions and safeguards referred to in Article 83.</p>	<p>2. Processing of personal data concerning health which is necessary for historical, statistical or scientific research purposes, such as patient registries set up for improving diagnoses and differentiating between similar types of diseases and preparing studies of therapies, is <i>shall be permitted only with the consent of the data subject, and shall be</i> subject to the conditions and safeguards referred to in Article 83.</p>

Article 81 - paragraph 2
<i>Amendment proposed by DCS, ENCR & ANCR</i>
<p>Processing of personal data concerning health which is necessary for historical, statistical or scientific research purposes of the highest public interest, such as patient registries set up for improving diagnoses, investigating disease causes and differentiating between similar types of diseases and preparing studies of therapies, is subject to the conditions and safeguards referred to in Article 83.</p>

Justification

Described above

**Amendment 4
(LIBE Amendment 334)**

Article 83 – paragraph 1	
<i>Text proposed by the Commission</i>	<i>Amendment proposed by LIBE</i>
1. Within the limits of this Regulation, personal data may be processed for historical, statistical or scientific research purposes only if:	1. Within the limits of this Regulation, personal data <i>not falling within the categories of data covered by Articles 8 and 9</i> may be processed for historical, statistical or scientific research purposes only if:

Article 83 – paragraph 1
<i>Amendment proposed by DCS, ENCR & ANCR</i>
1. Within the limits of this Regulation, personal data <i>not falling within the categories of data covered by Articles 8 and 9</i> may be processed for historical, statistical or scientific research purposes only if:

Justification

Population registry data will lose scientific value if data concerning children (Article 8) cannot be processed for scientific research purposes. Children below the age of thirteen account for a considerable part of the population. Further it must be possible to conduct long term studies and long term follow-up studies - as for example a study relating childhood residence and adult health status or a study of the long term health consequences of cancer in children.

Likewise the exclusion of special categories of personal data (Article 9) will reduce the possibility of collecting data for population registries and terminate linking of registry data for research purposes. This trend would only be strengthened as the special categories of personal data (Article 9 paragraph 1) are proposed broadened by LIBE.

**Amendment 5
(LIBE Amendment 336)**

Article 83 – paragraph 1 a (new)	
<i>Text proposed by the Commission</i>	<i>Amendment proposed by LIBE</i>
	<i>1a. Subject to the exception in paragraph 1b, data falling within the categories of data covered by Articles 8 and 9 may be processed for historical, statistical or scientific research only with the consent of the data subjects.</i>

Article 83 – paragraph 1 a (new)
<i>Amendment proposed by DCS, ENCR & ANCR</i>
<i>1a. Subject to the exception in paragraph 1b, data falling within the categories of data covered by Articles 8 and 9 may be processed for historical, statistical or scientific research only with the consent of the data subjects if these purposes are of the highest public interest and cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject.</i>

Justification

The amendment is proposed for strict consistency with the proposal of deletion of LIBE Amendment 327 and proposed amendment to Article 81 paragraph 2 (LIBE Amendment 328).

**Amendment 6
(LIBE Amendment 337)**

Article 83 – paragraph 1 b (new)	
<i>Text proposed by the Commission</i>	<i>Amendment proposed by LIBR</i>
	1b. Member States law may provide for exceptions to the requirement of consent for research, as referred to in paragraph 1a, with regard to research that serves an exceptionally high public interests, if that research cannot possibly be carried out otherwise. The data in question shall be anonymised, or if that is not possible for the research purposes, pseudonymised under the highest technical standards, and all necessary measures shall be taken to prevent re-identification of the data subjects. Such processing shall be subject to prior authorisation of the competent supervisory authority, in accordance with Article 34(1).

Article 83 – paragraph 1 b (new)
<i>Amendment proposed by Danish Cancer Society</i>
[DELETION OF LIBE AMENDMENT]

Justification

The deletion is proposed for strict consistency with the proposal of deletion of LIBE Amendment 327 and proposed amendment to Article 81 paragraph 2 (LIBE Amendment 328).