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european surveillance of congenital anomalies

EUROCATs Position on the Commission's proposed EU Regulation on Data Protection (EU Directive 95/46/EC on data protection)

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Introduction

The EU Directive 95/46/EC on data protection is under revision and there are several implications for congenital anomaly registries. EUROCAT Member Registry Leaders are going to contact their local Members of the European Parliament to raise awareness of this issue. This document:

- details how the proposed revision has the potential to affect the work of congenital anomaly registries
- details the EUROCAT Network's collective position on the proposed revisions
- acts as an explanatory document that EUROCAT Member Registry Leaders can provide to their local MEPs, to accompany relevant local examples highlighting how EUROCAT Member Registry data has been used effectively to date.

The Proposed Changes

The existing Directive is changing to a Regulation (REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) - http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf).

Once adopted by the European Parliament, this will become law in all EU countries.

The main principles of the new Regulation are:

- Explicit consent will be needed to process personal data relating to health (article 9)
- There will be a right for all patients not to be included (e.g. this could mean deletion from a registry database)
- Coded ID numbers will be considered identifiable data

The proposed Regulation currently includes three articles (81, 82 and 83) exempting the type of research conducted with congenital anomaly registry data and linkages to auxiliary files. It is imperative that articles 81 and 83 remain in the regulation once adopted.

Article 81 - Processing of personal data concerning health

1. Within the limits of this Regulation and in accordance with point (h) of Article 9(2), processing of personal data concerning health must be on the basis of Union law or Member State law which shall provide for suitable and specific measures to safeguard the data subject's legitimate interests, and be necessary for:

(a) the purposes of preventive or occupational medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject to the obligation of professional secrecy or another person also subject to an equivalent obligation of confidentiality under Member State law or rules established by national competent bodies; or (b) reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety, inter alia for medicinal products or medical devices; or (c) other reasons of public interest in areas such as social protection, 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.

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 for therapies, is subject to the conditions and safeguards referred to in Article 83.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying other reasons of public interest in the area of public health as referred to in point (b) of paragraph 1, as well as criteria and requirements for the safeguards for the processing of personal data for the purposes referred to in paragraph 1.

Article 83 - Processing for historical, statistical and scientific research purposes

1. Within the limits of this Regulation, personal data may be processed for historical, statistical or scientific research purposes only if: (a) these purposes cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject; (b) data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information as long as these purposes can be fulfilled in this manner.

2. Bodies conducting historical, statistical or scientific research may publish or otherwise publicly disclose personal data only if: (a) the data subject has given consent, subject to the conditions laid down in Article 7; (b) the publication of personal data is necessary to present research findings or to facilitate research insofar as the interests or the fundamental rights or freedoms of the data subject do not override these interests; or (c) the data subject has made the data public.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for the processing of personal data for the purposes referred to in paragraph 1 and 2 as well as any necessary limitations on the rights of information to and access by the data subject and detailing the conditions and safeguards for the rights of the data subject under these circumstances.

Why does this matter for EUROCAT?

EUROCAT is the European network of population-based congenital anomaly registries for the epidemiologic surveillance of congenital anomalies. EUROCAT started in 1979 and currently surveys over 1.7 million births per year in Europe (covering 31% of the EU birth population via 38 congenital anomaly registries in 21 countries). EUROCAT is comprised of high quality multiple source registries, ascertaining terminations of pregnancy as well as births. EUROCAT member registries send anonymised individual case data (full members) or summary data (associate members) to the EUROCAT Central Registry database. EUROCAT Central Registry is also a WHO Collaborating Centre for the Surveillance of Congenital Anomalies.

Congenital anomaly registries achieve high levels of ascertainment and completeness by collecting information from multiple sources. For data validation purposes, and to prevent cases being counted more than once, which is vitally important where rare anomalies and small numbers are involved, personal information about both the mother and baby is required. This allows further public health investigation, for example in the event of a cluster. Without such data there would also be unique and irreconcilable difficulties in matching anonymised antenatal diagnoses in a fetus with similarly anonymised postnatal notifications of a child, often received some months or even years after delivery.

Understanding the causes of anomalies and monitoring their occurrence (e.g. investigating trends and clusters and potential new teratogenic exposures) requires data relating to geographical location, maternal age, birth weight, gestational age at delivery etc. and increasingly requires data linkage (e.g. linkage to prescription data for postmarketing pharmacovigilance of medication use in pregnancy). Evaluating the success of screening programmes and auditing maternity care, and the planning for future care requirements, requires accurate outcome data together with knowledge about how and when anomalies were diagnosed.

International passage of pseudonymised data is essential for the work of EUROCAT.

Key examples of EUROCAT Surveillance;

- assessing the impact of health threats such as environmental incidents (e.g. Chernobyl and the swine flu epidemic) on congenital anomalies
- post-marketing drug safety surveillance (pharmacovigilance)
- assessing differences between countries in prenatal screening and diagnosis
- assessing the impact of folic acid policy on primary prevention

The issue of consent

EUROCAT acknowledges that patients provide information about themselves in confidence and where information is held in confidence informed consent from the patient is normally required for use of that information in a way that could identify the patient. However, there are certain situations where it is not possible to obtain informed consent from patients and a way needs to be provided by which patient identifiable information, when needed to support essential healthcare activity could be used without the consent of patients. This can only be used in circumstances where the medical purpose is in the interests of patients or the wider public, where consent is not a practicable alternative, and where anonymised information is not available or cannot suffice. Such an arrangement is essential for the operation of both Cancer and Congenital Anomaly/Rare Disease Registries.

EUROCAT registries aim to provide timely, accurate and easily accessible information for health professionals and the public, to help them make informed decisions. Ongoing surveillance and the monitoring of anomaly occurrence to check for varying trends or changing patterns of distribution are also very important public health activities.

Identifiers are required to avoid double counting and for the validation of cases, ensuring accurate matching between antenatally diagnosed anomalies and postnatal notifications. It is currently impractical

to obtain explicit parental consent for the inclusion of a case in most EUROCAT registries for a number of reasons;

1. Many reliable and valuable notification sources used by registries involve little or no contact with parents; for instance cytogenetic laboratories and pathology departments
2. Parents understandably may become distressed when asked for consent from multiple notifiers
3. Discussions of congenital anomaly notification may not be appropriate during the period when parents have first been informed about a potential problem, especially prenatally. Assessing the likely outcome of an affected pregnancy is usually very difficult, and properly 'informed' consent is therefore difficult to obtain
4. The potential for sensitivities surrounding terminations of pregnancy for congenital anomalies may prevent discussions for notification to a registry, however consent is not always required in the case of a death
5. It is the experience of many registries that health professionals do not prioritise requesting consent for notification of cases during consultation and that this leads to long delays in notification or failure to notify.

Any emphasis on individual healthcare professionals having to weigh the public health benefits of each disclosure is a cause for concern for registries. Such an approach would lead to variation in practice as different healthcare professionals reach different conclusions. Data-reporting rates would vary unpredictably, and moreover be susceptible to changes in the data protection environment. This could result in the presence of damaging artefacts in the statistics derived from registry data. It is questionable whether many doctors have the skills, information, time or interest to make appropriate judgements about benefit to the public health of each and every disclosure. The concern for registries is that in such situations it may be much easier, quicker and safer for doctors to judge there was no benefit rather than disclose when unsure.

In 2003-2004 EUROCAT conducted a survey of 29 of its congenital anomaly registries in 15 countries (Busby et al. 2005 (Appended)), and the EUROCAT experience shows that the logistical difficulties in obtaining informed consent (even despite extremely low parental refusal) is a serious threat to the operation of registries that rely on multiple sources of information such as clinician notification or access to medical records.

Debate about the right of the individual to be adequately informed and to give consent has eclipsed discussion about research governance and confidentiality procedures that might obviate the need for individual consent.

Key Message

The EUROCAT Network urges MEPs to ensure the inclusion of articles 81 and 83 in the proposed regulation once adopted in parliament.

Survey of informed consent for registration of congenital anomalies in Europe

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Eurocat is a network of population based registers of congenital anomalies in Europe covering about a quarter of the birth population in 19 countries (www.eurocat.ulster.ac.uk). We surveyed registries with regard to the requirement for informed consent and its implementation.[1]

Participants, methods, and results

We sent a questionnaire on ethics and confidentiality developed by the Eurocat Working Group to 35 registries in 2003 and updated June 2004; 29 registries from 15 countries replied (table). Eight registries reported experience of opt-in informed consent.

Five registries depend on medical records and notification from clinicians. One experienced a fall in registration (less than 10 written consents in the entire year in which opt-in consent was instituted, compared with 249 cases in the year before opt-in) such that an exemption was negotiated enabling a switch to opt-out consent. Currently 0.1% of parents opt out. A second registry, in which notifying clinicians ask for consent by post, is permitted to keep a reduced, anonymous set of documentation on cases without consent (about 18%). A third registry gives administrative help for clinicians obtaining consent by post (amounting to 1-3 hours a case) but still estimates 15-20% loss of cases through non-response, although only 0.5% of parents actively refuse to participate. A fourth registry is not fully operational because of low notification levels related to the consent requirement. All these registries reported difficulties persuading busy clinicians to undertake the additional work of obtaining consent for the registry, or convincing clinicians of the value of collecting registry data. Healthcare professionals have also to coordinate consent procedures to avoid parents being approached multiple times. A fifth registry does not yet know how ascertainment is affected but reports less than 1% parental refusal.

Of the other three registries operating opt-in consent, one registry covering a small population has research paediatric staff who examine all babies (malformed or not) born in participating hospitals, for which consent is obtained at booking. This registry reports only two parental refusals since 1990. One registry is based on interviews of cases and controls shortly after birth by clinicians who then notify the case to the registry; this registry is not aware of problems, although it has little information from clinicians on parental refusals. One registry is a voluntary association of clinicians who obtain verbal consent from their patients when registering the case and is not aware of serious problems, although this has not been formally evaluated.

Comment

Eurocat experience shows that informed consent is a serious threat to the operation of registries relying on clinician notification or access to medical records. Despite extremely low parental refusal, opt-in informed consent poses logistical problems, as other types of registry have found.[2–4] Although much has been written about the right of the individual to be adequately informed and to give consent (the parents in the cases of newborns), further research should evaluate parents' desire to participate in activities that may lead to the protection of the health of children in the community and the subsequent ethical duty on the part of the clinician to inform and to request consent. However, this places a further burden on clinical workload.[5]

Discussion about opt-in informed consent seems to have eclipsed discussion about effective forms of opt-out

National legislation on informed consent for congenital anomaly and other clinical registers

Country	National legislation regarding informed consent as of June 2004*
Austria	Has not yet enacted new legislation which may lead to a consent requirement, but does not currently require consent
Malta	
Finland	Exemption from informed consent for health care registers
Italy	Exemption from informed consent for healthcare or disease registers the data from which are officially included in regional health statistics
Belgium	The relevant supervisory body can provide an exemption from the requirement for consent for individual registries on a case by case basis for a specified period. In Belgium, France, and England and Wales this exemption requires some level of "opt-out" consent
Denmark	
England and Wales	
France	
Spain	
Ireland	Consent is required depending on the statutory position of the organisation from which data is sought; a total restructuring of the health services in 2005 will likely further change the requirement for consent
Germany	National legislation requires informed consent without exemptions for registries
Luxembourg	
Poland	
Netherlands	
Portugal	One registry is able to operate without consent since they do not hold name and address†

*For those registries operating consent procedures we define "opt-in consent" as the situation in which parents of children with a congenital anomaly are specifically asked for consent to place their children on the register. We define "opt-out consent" as the situation in which information is generally available to all parents to advise them of the existence of the register and the option to remove their child from the register.
†In some countries—for example, Germany—informed consent is required even if name and address are not retained by the register.

What is already known on this topic

Although European Directive 95/46/EC allows national law (or a national supervisory body) to exempt healthcare or disease registries from the requirement to obtain informed consent for the processing of personal medical data, many countries have not legislated for any exemptions and there is much debate about the effect of the consent requirement on epidemiological research and surveillance

What this study adds

The logistical difficulties in obtaining informed consent is a serious threat to the operation of registries that rely on clinician notification or access to medical records, despite extremely low parental refusal

Debate about the right of the individual to be adequately informed and to give consent has eclipsed discussion about research governance and confidentiality procedures that might obviate the need for individual consent

consent and also about data confidentiality and research ethics procedures that would be acceptable to the public. The primary concern of most patients is not the use of their data for research but inappropriate access to medical data, and there is insufficient debate about what safeguards to ensuring confidentiality and the appropriate use of personal data would be sufficient to replace the requirement for individual consent.

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Lifetime intellectual function and satisfaction with life in old age: longitudinal cohort study

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What is successful ageing? Current opinion is that "cognitive vitality is essential to quality of life . . . in old age."[1] This depends substantially on people's cognitive ability from early life,[2] and on how much they decline from their cognitive peak in young adulthood. Early cognitive ability also affects physical health and even survival to old age.[2] But surely happiness and satisfaction with life are also key indices of successful ageing. Happiness was described as "the highest good and ultimate motivation for human action"[3]; this does not seem to be related to current cognitive ability.[3] Cognitive level in youth and the amount of cognitive change across the lifespan are important indicators of cognitive vitality in old age. We examined a unique data set to investigate whether these factors are associated with people being happier.

Participants, methods, and results

The Lothian birth cohort 1921 is a relatively healthy group of 550 older people (mean mini-mental state examination 28.2 (standard deviation 1.7), range 18-30). They were given the same test of mental ability (a version of the Moray House test number 12) at mean ages 10.9 (0.3) and 79.1 (0.6) years old,[2] giving three cognitive measures: early life ability, late life ability, and lifetime cognitive change. Moray House test scores were converted to IQs (standardised to a mean of 100 (15) and adjusted for age at testing. To compute lifetime cognitive change we used the following process. IQ at age 11 was the independent variable in a linear regression with IQ at age 79 as the dependent variable; the standardised residual produced from this equation was used as the measure of lifetime cognitive change.

Participants were mailed[4] the widely validated satisfaction with life scale.[5] This scale has five statements requiring a response from strongly disagree (score 1) to strongly agree (score 7), which we summed to give a

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