8

NFU
NEDERLANDSE FEDERATIE VAN
UNIVERSITAIR MEDISCHE CENTRA

European Parlement
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Betreft	proposal of the European Commission on the General Data Protection Regulation
Datum	26-3-2013
Ons kenmerk	13.2422/CB/GvE

Dear mister López Aguilar,

With this letter the Dutch Federation of University Medical Centers (NFU) would like to take the opportunity to welcome the proposal of the European Commission on the General Data Protection Regulation. The NFU represents the eight University Medical Centers (umc's) in the Netherlands. Together these eight umc's have thousands of researchers working in clinical, translational and basic research. The NFU supports privacy protection but is also happy with the fact that under the proposal of the Commission, health research can continue.
However, the NFU would also like to respond to the amendments proposed in the draft report on the General Data Protection Regulation by rapporteur MEP Jan Philipp Albrecht.

The NFU is of the opinion that privacy rules should not go so far that it makes health research impossible, which seems to be the case if the report by Albrecht would be adopted without any changes.
It is also the opinion of the NFU that the availability of health data is absolutely crucial to be able to conduct excellent health research and to deliver quality care.
The draft report by MEP Albrecht is unfavorable to clinical research because of the following reasons:

- amendments 328 and 337: Member States are given the opportunity to make legislation to allow the use of pseudonymised data concerning health without consent, but only in cases of "exceptionally high public interest";
- amendments 27, 327 and 334-336: health data could only be processed for research with the specific, informed and explicit consent of the data subject;

Based on these observations, the NFU firmly wants to make clear that if these amendments were to be adopted, this would be a catastrophe to European health research because an unworkable situation would be created for health researchers to carry out their research. Such amendments could seriously jeopardize the health and well-being of European citizens. To strengthen our argument, attachments 1 and 2 provide examples of the crucial importance of the availability of data for respectively routine care and perinatal health.

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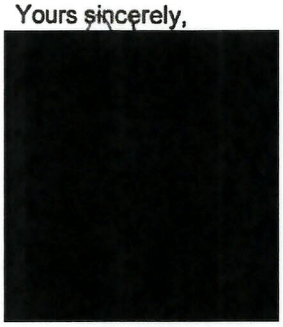
The NFU understands that there needs to be a balance between ensuring the privacy protection and carrying out health research which will contribute to improving the health of European citizens. However, if above amendments would be passed, it could have detrimental effects on the lives of European citizens.

We hope you understand our concerns regarding the consequences of these amendments.

Yours sincerely,



Annex:

Attachment 1: Example of the importance of the availability of anonymised data for routine care

Attachment 2: Example of the importance of data for enhancing knowledge about perinatal health outcomes and care in Europe.

Attachment 1

Example of the importance of the availability of anonymised data for routine care

Routine delivery of care is an important source of data that drives scientific research. Ideally, each time a patient is treated we learn. Data recorded in routine care is often referred to as "observational data". A number of research fields depend to a large degree to the availability of observational data from routine care. One of the domains in which observational data is critical is the domain of drug safety. Prior to introduction of a drug into the market, studies are performed to assess the safety of a newly developed drug. These pre-marketing studies, however, are limited in size, and often tailored to specific populations of patients. The limited size of these studies will prevent the recognition of infrequent side effects – the studies are simply not large enough. Moreover, as a drug enters the market, the type of patients taking the drug may differ from the pre-marketing trials. Groups of patients who were not included in the trial may start using the drug (e.g., patients with multiple diseases and drugs or children). As a result, post marketing surveillance, monitoring the effects of a drug after it has been placed on the market, is a critical component of drug safety research. Observational data used in post marketing surveillance is typically anonimised or pseudonimised and aggregated. From a practical perspective, informed consent cannot be obtained. For example, in my own department (the Department of Medical Informatics of the Erasmus Medical Center in Rotterdam), we use an observational database called IPCI from primary care involving nearly 2 million patients for drug safety research. Obtaining informed consent on this scale is simply not feasible. In IPCI, we work on the basis of "opt out" . Data are pseudonimised , and aggregated. The data base resulted in well over 200 scientific publications and dozens of PhD theses.

To illustrate the importance of the use of the data, just one example. At this very moment in Europe there is big concern regarding a number of side effects after the vaccinations for the so-called Mexican flue. In a number of countries, severe side-effects (such as narcolepsia) have been reported, albeit in a very low frequency. At present, this constitutes a major issue with significant attention in the lay press (with numerous articles in newspapers, especially in Scandinavia).

Using observational data from different European countries, a team of researchers is trying to fully understand the magnitude of the problem, resulting recent publications in leading journals (Narcolepsy as an adverse event following immunization. Vaccine. 2013 Jan 30;31(6):994-1007; The incidence of narcolepsy in Europe: Before, during, and after the influenza A(H1N1) pandemic and vaccination campaigns. Vaccine. 2013 Feb 6;31(8):1246-54; Current status and future directions of post-marketing vaccine safety monitoring with focus on USA and Europe. Biologicals. 2012 Sep;40(5):393-7; Safety of pandemic H1N1 vaccines in children and adolescents. Vaccine. 2011 Oct 6;29(43):7559-71; Guillain-Barre syndrome and adjuvanted pandemic influenza A (H1N1) 2009 vaccine: multinational case-control study in Europe. BMJ. 2011 Jul 12;343)

In the past years, there have been numerous drug and vaccine safety studies that are extremely relevant for the European population. We must make sure that this type of research is allowed to continue. Making the use of anonymised data no longer possible is, in my opinion, not in the interest of the European citizen.

[redacted]

Attachment 2

Example of the importance of data for enhancing knowledge about perinatal health outcomes and care in Europe.

Zeitlin J, Mohangoo A, Cuttini M. The European Perinatal Health Report: comparing the health and care of pregnant women and newborn babies in Europe. J Epidemiol Community Health2009;63:681-682 doi:10.1136/jech.2009.087296

In December 2008, the EURO-PERISTAT project launched the first European Perinatal Health Report. This presents and comments on indicators of perinatal health and care derived from routine statistical data in 25 EU member states and Norway.1 The report is part of the EU Health Programme for health surveillance and reporting. It also includes chapters from three other European projects with perinatal data: Surveillance of Cerebral Palsy in Europe (SCPE), European Surveillance of Congenital Anomalies (Eurocat) and European Neonatal Information System (Euroneostat).

Maternal and infant mortality have reached historic lows in Europe, but pregnancy and delivery still represent significant risks for women and their babies. Mortality during birth and the first month is higher than in any other period of life excluding old age. Over the years, stillbirth rates have decreased to a lesser extent than neonatal and infant mortality, and their causes remain largely unknown.2 Maternal deaths are rare but tragic events, particularly because a significant proportion of these deaths are associated with substandard care.3

Preterm birth and low birthweight form a stable if not increasing proportion of all births, and the scope for prevention has lagged behind developments in care.4 Their adverse effects extend from increased mortality to long-term physical, neurological and cognitive impairment, representing significant burdens for the children and their families, and a challenge for health and social services.5 Even in the absence of overt impairments, there is growing evidence that health in the perinatal period affects adult health. Babies born too small because of fetal growth restriction are more likely to develop metabolic syndrome as adults.6 Other connections between perinatal and adult health are being explored, and this life course approach to epidemiology requires good data on pregnancy and infancy.

While medical and technological innovations have contributed to declines in maternal and perinatal mortality, they have also raised new risks and ethical issues. Babies born alive at 24 and 25 weeks of gestation now have a 50% or greater chance of survival, but with high rates of impairments.5 Medical procedures have made it possible for more couples to conceive, but the use of these procedures can increase the rate of multiple births and adverse pregnancy outcomes.7 European health professionals are faced with the task of using new technologies while minimising their negative effects, and avoiding inappropriate medicalisation for the vast majority of women who have uncomplicated pregnancies and deliveries.

A final reason to monitor perinatal health is its sensitivity as a measure of overall population well-being and quality of health care. Many European countries provide universal health care and enjoy similarly high standards of living. Within countries, however, poverty and low socioeconomic status are associated with worse pregnancy outcomes.8 Welfare regulations and access to health services may change over time, and monitoring perinatal health will provide an instrument for the timely detection of adverse consequences.

The European Perinatal Health Report builds on several years of work by the EURO-PERISTAT group, which has identified appropriate indicators for perinatal health and standardised definitions and reporting rules to improve comparability and facilitate interpretation of differences.910 Ten core and 24 recommended indicators were agreed upon. Most of them are not currently included in the existing international databases such as EUROSTAT, World Health Organization (WHO) Regional Office for Europe's Health for All, and Organization for Economic Co-operation and Development

(OECD) health data. Of the recommended indicators, 10 require further development before implementation.

Implementing the indicators was a challenging task in the participating countries. Only neonatal mortality was available in every country, and no country could meet the requirements for all indicators. Sometimes, differences in definitions or data quality were insurmountable, and these are described in the report. Indicators of fetal and neonatal mortality are sensitive to the way the data are collected, for instance, in some countries terminations of pregnancy at or after 22 weeks of gestation are reported as fetal deaths, whereas elsewhere they are recorded in separate systems or not recorded at all. Thresholds for the inclusion of fetal deaths and live births in routine databases vary across Europe, and this has implications for the counting of cases at borderline viability.11 These methodological shortcomings cannot always be solved without changes to birth and death registration legislation or processes. Data on maternal mortality illustrate this difficulty most acutely. Many countries with high or moderately high levels of maternal mortality are those where enhanced ascertainment procedures exist.

Despite these limitations, assembling the data currently available in a single volume in this report substantially improves our knowledge about perinatal health outcomes and care in Europe. It also raises important questions about the health care, social and other factors that contribute to differences in outcomes between countries. The proportion of very preterm births (before 32 weeks of gestation) appears rather stable at about 1% of live births in most countries, while that of total preterm births varies more widely from 5.5% to 11.4%. The rate of low birthweight (<2500 g) shows a north to south increasing trend, raising questions on the appropriateness of a single standard in different populations. Fetal mortality, including fetal deaths at 28 weeks of gestation or over, ranges from around 3.5 per 1000 total births in Slovakia, Spain and Finland to over 6 per 1000 births in France, the Netherlands, Latvia and Scotland (UK), while neonatal mortality varies from around 2 per 1000 live births in Norway and Sweden to over 4 per 1000 in Latvia, Lithuania, Poland and Estonia. No single country consistently occupies the best ranking position, which illustrates the importance of avoiding comparisons based on single indicators only (the "report card" or "league table" approach).

Health care practices vary widely across countries, revealing the lack of consensus among clinicians about many common procedures such as induction of labour, episiotomy and instrumental delivery. Rates of caesarean delivery most explicitly illustrate this issue. While a few countries (Slovenia, the Netherlands, Norway and the Czech Republic) still have national rates consistent with those suggested by WHO almost 25 years ago,12 most are in the range of 20–30% and two countries even above that (33% in Portugal and almost 38% in Italy). Variations of this magnitude are unlikely to be explained by different in the characteristics of child-bearing women.

In its future work, the EURO-PERISTAT group will use these data to explore the reasons for the variations in perinatal health and the consequences of differences in perinatal care. At the same time, we aim to carry on the project, encouraging the development and use of new indicators for longer term outcomes and in other key areas such as maternal morbidity, social inequalities and outcome indicators for women with uncomplicated pregnancies. These efforts are important steps towards a harmonised and ongoing system for monitoring maternal and child health and care in Europe.

Footnotes

**Report writing committee: S Alexander, H Barros, B Blondel, MH Bouvier-Colle, S Buitendijk, C Cans, S Correia, M Gissler, A Macfarlane, A Mohangoo, Ž Novak-Antolic, J Zeitlin, W H Zhang, M Zimbeck. All members of the EURO-PERISTAT scientific committee and data providers contributing to the report are listed in Appendix A of the report.*

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Competing interests None.
**Report writing committee: S Alexander, H Barros, B Blondel, MH Bouvier-Colle, S Buitendijk, C Cans, S Correia, M Gissler, A Macfarlane, A Mohangoo, Ž Novak-Antolic, J Zeitlin, W H Zhang, M Zimbeck. All members of the EURO-PERISTAT scientific committee and data providers contributing to the report are listed in Appendix A of the report.*

Materials and methods

Study population

Patient data was obtained from the Dutch Perinatal Registry (PRN), a linked professional database of all pregnancies, births and admissions after birth in the Netherlands, collected from midwives, obstetricians and paediatricians [20,21]. The registry information consists of detailed information of maternal demographic factors, pregnancy and delivery characteristics and neonatal outcomes on a personal level. Patient data in the PRN is anonymous. The national coverage is 96% near to complete as registration is compulsory (professional requirement to receive health insurance fees). The use of these patient data was with the explicit permission of the holder of the PRN.
For this study all singleton deliveries from 22.0 weeks of gestation onwards during a five year period (1 January 2002 until 31 December 2006) were enrolled. We excluded the deliveries with missing gestational age or a birth weight less than 500 gram. WHO [5]. Therefore, 877,816 (871,889 live born and 5927 still born) singleton births remained for further analysis.