Reform of EU legal framework for the protection of personal data. Possible detrimental consequences for public health research and epidemiology.

Work on the proposals for personal data protection legislation is in progress in Europe.

The progress of the regulation

Since initial consultations in early 2009, the Commission of the European Union has worked on proposals for 'the protection of citizens with regard to the processing of personal data and on the free movement of such data'. The Commission's proposal of January 2012 ultimately took the form not of a directive under which the member states' own national laws would have to be adapted but of a 'regulation', a Union law, legally binding on all member states (see Commission's proposal[i]). A regulation was seen as an appropriate instrument to bring harmonization and coherence to areas which were major concerns of businesses, for example, legal certainty. Even so, in accordance with the principles of subsidiarity and proportionality there are aspects of data protection and movement for which the regulation would allow member states to enact their own law with consequential cross-border variation in those aspects.

The proposal would have brought about the opportunity of using identifiable personal data for scientific purposes which under the current EU directive of 1995 (see current directive[ii]) is restricted by the obligation to obtain the consent of every data subject. After lengthy discussions within European Parliamentary committees, the Parliamentary Committee for Civil Liberties, Justice and Home Affairs (LIBE), the leading parliamentary committee for this regulation, passed a proposal in October 2013 making amendments to the Commission's proposal which could seriously impede the advancement of public health research and epidemiology (see LIBE proposed amendment[iii] [iv]).

Meanwhile, the proposal is languishing in the third of the EU's legislative bodies, the Council of the EU. The Council must put forward its own proposals for amendments to the Commission's regulation. It has been debating for many months and has, so far, put forward amendments for 40 articles[v]. Last December, at its meeting of member states' Justice Ministers, also attended by a resolute Commissioner for Justice, there was a clash of opinion of the Council's and the Commission's respective legal counsels regarding the legality of some of the proposals concerning processes around the so-called one-stop shop approach, the consistency mechanism and the proposed EU Data Protection Board in cases of cross-border litigation between an EU citizen and a business[vi]. There is a fear that what would be a one-stop shop for the corporation could be a multi-stop shop for the citizen. The Council does not envisage resolving the differences before March. Only then can the three bodies hammer out final legislation. However, this year there will be a newly elected Parliament and newly appointed Commission - it could be some time before we see an enacted regulation.

The problems for public health research and epidemiology

The problems for public health research and epidemiology lie in articles 81 and 83 (see[iv]). The difficulties foreseen with reference to the amendments to these articles have been outlined by many public health and epidemiological associations, among which are EUPHA and IEA, who have observed that limiting the use, without explicit, informed consent, of personal health data for public health monitoring and research only to cases of 'high public interest' would make impossible large sections of research that actually are 'an ordinary and indispensable tool for the identification of causal factors of diseases and for the evaluation of the performance and value of health services' and are the bases for public health policies and health services governance in any society that has

a care for the health of its citizens. The routine epidemiological work of a cancer registry, for example, would be hampered and degraded if it did not have complete data at individual level for incidence, relapse, mortality, type of medical or surgical treatment, and screening participation. A proposal to abolish these amendments was sent on past February 2013 to Jan Philippe Albrecht – member of the "Committee on Civil Liberties, Justice and Home Affairs" (LIBE) and to Juan Fernandez Lopez Aguilar president of the LIBE- by the IEA (available at the website of the IEA-EEF[vii])

This January in Brussels, Sophie in 't Veld, a member of the European Parliament and LIBE vice-chair, hosted a session at the 7th International Conference for Computer, Privacy, & Data Protection (CPDP) which was entitled, 'Secure Science: Research and Data Protection: Will the proposals for new EU data protection legislation impede medical, social or historical research?' The session was attended by a representative of the IEA. Two facts stood out above others. Firstly, the Commission is driven by a desire to have the regulation approved before the end of its term but there is not agreement among the member states. Secondly, it is envisaged that whatever the wording of the regulation some freedom will be granted to member states which will bring negative consequences to cross-border research. If decisions on what is 'high public interest' vary between countries, in effect creating legal *uncertainty* (contrary to the Commission's intention) cross-border research could become impossible.

How to proceed

There is still time, although limited, for public health researchers and epidemiologists to lobby parliamentarians and the Justice Ministers of their respective countries. Key issues are:

1. The potential consequences that could follow from the LIBE amendments stressing that adequate technical means exist which would guarantee data security whilst both safeguarding the rights of individuals and the benefits which ensue from research.

2. The lack of use of available data to improve knowledge about health threats and efficacious treatments conflicts with one of the fundamental human rights: the 'right to health'. A citizen enjoying the fruits of public health research and epidemiology should not have the right of denying information which would benefit the next generation.

Rodolfo Saracci, Adele Seniori Costantini

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[i] The Commission's proposal for a General Data Protection Regulation http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf
[ii] The current EU Directive http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:NOT
[iii] Articles 1 to 29 of the LIBE amended proposal http://www.europarl.europa.eu/meetdocs/2009_2014/documents/libe/dv/comp_am_art_01-29/comp_am_art_01-29en.pdf
[iv] Articles 30 to 91 of the LIBE amended proposal http://www.europarl.europa.eu/meetdocs/2009_2014/documents/libe/dv/comp_am_art_30-91/comp_am_art_30-91en.pdf
[v] Council's amended text for articles 1 to 39 & 80 http://register.consilium.europa.eu/pdf/en/13/st10/st10227-ad01.en13.pdf
[vi] Webcast of Council meeting of Dec 6th http://video.consilium.europa.eu/webcast.aspx?ticket=775-979-13755
[vii] http://iea-europe.org