Revision of the European Data Protection Directive: opportunity or threat for public health monitoring?

The link between public health monitoring on one hand and data protection legislation on the other may not be immediately clear to all. Nevertheless, it has a strong relation with the conditions required to build and correctly operate high quality, sustainable public health information systems.

The following public health goals are directly influenced by the data protection legislative framework:

- optimizing efficiency, through a detailed analysis of health services provided to specific categories of individuals;
- monitoring appropriateness, safety and quality of care, through a systematic assessment of processes and outcomes across different categories of users in the intermediate and long term;
- targeting equity, through the analysis of deprived individuals that otherwise would have been difficult to track in relation to specific interventions;
- ensuring the sustainability of systems of health indicators, through the intelligent use of the information available in large administrative databases;
- enhancing data completeness for evidence-based policy making, identifying ways to extend the secondary use of health data;
- enhancing data quality, through linkage of different databases at the subject level, which will prevent that events are missed or double counted; and
- enhancing the competitiveness of the European Union, through an increased ability in using health data and the routine performance assessment of health services and systems to support research and development for innovation.

Maintaining systems of EU health indicators is central to achieving these goals and can only be realized by integrating data sources in all Member States (MS). However, as a consequence of an uneven implementation of the EU Data Protection Directive (DPD), access to individual (micro) data appears to be still limited and heterogeneous, jeopardizing the comparability of results across Europe. A comprehensive framework for data protection is fundamental to create the best conditions to harmonize access to accurate, complete and up-to-date data.

Results of an ad hoc survey conducted by a Work Group of the Network of Competent Authorities [an advisory body in the field of health information for the European Commission (EC) under the second Public Health Programme] showed that substantial divergences exist on the way sensitive data are processed for public health purposes across Europe.

The EC 'Communication on a Comprehensive Approach to Data Protection' acknowledges that the DPD has been sometimes incorrectly implemented by MS. Furthermore, the Directive leaves MS some room for 'manoeuvre' in certain areas and the authority to maintain/introduce particular rules under specific conditions. As a result, there have been divergences between national laws on how to implement the DPD in many contexts, including public health. The DPD includes two possible exemptions to the general prohibition of processing sensitive data, including health data that are relevant for public health: Article 8(3), for which data can be disclosed for preventive medicine, medical diagnosis, care provision/treatment or management of health-care services; and Article 8(4), for which MS may lay down additional exemptions for reasons of substantial public interest. Recital 34, which is related to Article 8(4), mentions public health as a possible reason of substantial public interest.

However, only few MS, in particular UK and France, passed laws concerning the processing of sensitive data for important public interests. A revision of the DPD has been recently proposed by the EC. However, the proposed text, although recognizing a lack of harmonization across MS, fails to address the key points for public health that may overcome the above limitations.

A dedicated workshop tackled this issue at the EUPHA Conference 2010, inspiring a collective response to the open consultation launched by the EC to gather input for the DPD revision. The scarcity of responses received from the public health field seems to indicate that experts may be not completely aware of the relevance that privacy legislation in general, and the EU Directive in particular, have for their work.

The response generated by the workshop requested a specific normative provision that would specify under which conditions the processing of health data is legitimate, without patient consent, for public health purposes. Processing of sensitive data should be considered legitimate when the following conditions apply: (i) processing is performed for public health governance and research; (ii) the study is approved by a competent ethical committee; and (iii) data processing occurs in a secure and privacy protective environment implementing the concept of 'privacy by design', including privacy impact assessment.

In our opinion, public health would greatly benefit from the inclusion of such a norm in the new DPD planned for 2011. While better prevention strategies can be identified for subgroups at risk, each subject will directly benefit from tailored approaches identified to protect his/her health as a result of finely tuned epidemiological investigations.

A directive that would allow the application of modern protection practices, expanding the classical thinking of infection control to the prevention of clustered risk factors in specific subgroups of citizens, would be beneficial for both the public interest and the individual.

Our proposal duly considers novel solutions, including trusted third parties for data linkage and privacy-enhancing technologies (PETs), as necessary to reconcile interests of privacy protection with the individuals’ right to health and health care.

The homogeneous implementation of this norm across MS should be accurately monitored at both national and international levels.

On one hand, MS should provide uniform specifications in relation to the content, management and the precise conditions under which health databases can be made available for public
health, establishing central resources, e.g. National Registries of Health Databases. Common rules would foster the application of secure procedures, e.g. designating unique data custodians and trusted third parties for data management. On the other hand, the EC should undertake three targeted actions.

First, the EU should provide citizens with a unified framework through which public health monitoring can be properly conducted and easily evaluated, promoting activities, e.g. the creation of a European Registry of Public Health Databases, to standardize and link all documentation provided by MS for the usage of individual data for public health. Secondly, the EC should clarify the conditions for the legitimate cross-border flow of health data for public health. Currently, the transfer of individual data for secondary uses, without patient consent, is practically forbidden under the current legal framework. In this context, it is crucial that the free flow of health information is not hampered, provided that appropriate safeguards are put in place to protect privacy and data protection rights.

Therefore, a revision of the EU DPD should also specify rules for the legitimate exchange of health information across MS for public health, through the preparation of targeted European codes of conduct. Thirdly, the EC should monitor the correct application of privacy legislation, through a permanent entity, e.g. an ‘EU observatory on the implementation of the DPD’, established through specific tasks included in its work programmes (FP7, Public Health Programme).

In conclusion, a targeted revision of the EU DPD taking duly into account the above rules and recommendations, would turn a potential threat for public health monitoring, into an opportunity to ensure both the respect of data protection rights and better health for all across Europe.

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References


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