The position of the European Public Health Experts Workshop on Privacy Protection on the revision of the EU Data Protection Directive

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1. PREAMBLE

The current document has been prepared as an official response of the "European Public Health Expert Workshop on Privacy Protection" (EUPHEX) to the public consultation opened by the European Commission on the Communication: "A comprehensive approach on personal data protection in the European Union" (COM(2010)609)[1].

The "European Public Health Expert Workshop on Privacy Protection" is a group of public health experts gathered for the first time at the European Public Health Conference 2010, Amsterdam, Netherlands (Friday 12th November 2010).

According to the Communication, the Commission is reviewing the general EU legal framework on data protection to be translated in new legislation in 2011.

The main policy objectives therein stated include:

- *to modernise the EU legal system for the protection of personal data, in particular to meet the challenges resulting from globalisation and the use of new technologies*
- *to strengthen individuals' rights, at the same time reducing administrative formalities to ensure a free flow of personal data within the EU and beyond*
- *to improve the clarity and coherence of the EU rules for personal data protection and achieve a consistent and effective implementation and application of the fundamental right to the protection of personal data in all areas of the Union's activities*

The EUPHEX fully agrees with the above goals and warmly welcomes the possibility of providing the EU with a reinforced regulation that would respond to the new challenges of privacy protection. As a group of experts deeply engaged in promoting the universal values of individual rights and the respect of international regulations at all levels, we support the adoption of a comprehensive EU legislative approach that would improve what has been already recognized "*as a driving force behind the development and promotion of international legal and technical standards for the protection of personal data*".

Our group involves experts dealing with the most sensitive aspects of personal data on an everyday basis – health conditions – for which we strive to adopt all precautions in the interest of the individual.

We need to highlight that public health monitoring and the governing of the quality and safety of health care services need to be harmonized across Europe. However, the Commission Communication does not seem to address this crucial issue.

We believe that without the inclusion of substantial points related to the usage of personal information for public health, the revision of the Directive would not realize such a comprehensive approach. To overcome the pitfalls of the current legislation, it is paramount that the individual right to privacy is balanced with other rights that would benefit society, including the right to health and its protection. Here we provide brief explanations on WHY public health interests shall be guaranteed in data protection legislation, WHAT should be explicitly allowed under the proposed revision, and HOW to improve the current proposal in the interest of public health.

2. WHY PUBLIC HEALTH NEEDS SHALL BE GUARANTEED IN DATA PROTECTION LEGISLATION

The use of accurate information has been increasingly recognized to be crucial for health systems governance and public health monitoring since the introduction of the Data Protection Directive.

The following principles are included in the **EU Health Strategy 2008-2013**[2]:

- *focussing on shared health values, putting patients in the centre and reducing inequalities*
- *recognising the links between health and economic prosperity*
- *integrating health into all policy areas*
- *strengthening the EU's voice in global health, through greater cooperation with international organisations*

A correct evaluation of the progress made in each of the above areas requires the adoption of health indicators. Various systems of health and health care indicators are available through EU projects that are relevant to the Health Strategy, producing influential policies e.g. the routine production of ECHI indicators[3]. These indicators can be only produced through a structural integration of data sources maintained by Member States.

Unfortunately, limited and heterogeneous access to micro data across Europe influences negatively the process of accurate and timely information delivery, generating health policy input that may not be comparable or easy to interpret.

A comprehensive framework for data protection must create the best conditions to ensure harmonized access to accurate information across Europe.

Until now, issues of data accuracy have not been met by the EU Data Protection Directive. The Work Group on Data Protection of the Network of Competent Authorities (NCA) established by DG-SANCO addressed this issue, delivering a commentary in the European Journal of Public Health[4] including results of an ad hoc survey[5]. The conclusion was that leaving to Member States the possibility to establish rules allowing the use of identifiable health data, has created a substantial divergence in the possibility of processing data for public health purposes across Europe.

The time has come to recognize that **public health monitoring and the governing of the quality and safety of health care services is vital** for the correct functioning of health systems, and that **the EU Data Protection Directive is a critical instrument to ensure the accomplishment of key activities in the public interest**.

Using individual health records allows the following:

- **optimizing efficiency**, through a detailed analysis of costs of health services provided to specific categories of individuals
- **enhancing data quality,** through linkage of different databases at the subject level, which will prevent that events are missed or double counted

- **monitoring appropriateness and quality of care,** through a structured comparison of processes and outcomes across different categories of users
- **targeting equity,** through the analysis of health records relative to 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 allow the secondary use of health data
- **enhancing the competitiveness of the European Union,** through an increased ability in using health data, ensuring that the same conditions apply across Europe and equal opportunities are effectively realized.

International organizations included as partners in the EU Health Strategy, such as the OECD and WHO, have also endorsed similar strategies to make health information available for public health. Following the global financial and economic crisis started in 2007, fifty-three Member States of the WHO European region approved three important Resolutions addressing their commitment in improving the capacity of monitoring the health-related consequences of the crisis and the performance of their health systems[6-8]. These goals require the regular production of comparable statistical figures to assess the correct functioning of health systems in terms of equitable health gain, financial protection, responsiveness, efficiency improvement, fair financing, universal access to health promotion, disease prevention and quality of health care. The OECD requests the same conditions to collect accurate and comparable information on all quality indicators, for which health records are required to monitor the various dimensions involved.

The Final Communiqué of the OECD Meeting of the Health Committee at Ministerial Level, Paris, 7/8 October 2010 (http://www.oecd.org/dataoecd/4/55/46163626.pdf) states the following about the need to address the need for data on quality and safety of health care: "We welcome the development of a set of indicators which help us to compare the quality of health acre across countries and we look forward to them being further improved in the future. However, this will require better health information systems, and more effective use of the data that are already collected. The Forum on Quality of Care held before our meeting shows that we must reconcile the legitimate concerns of our citizens to protect their privacy with the need to monitor health care episodes involving multiple care providers".

In summary:

- **no accurate statistical analysis for public health is possible without envisaging direct access to individual data at some stage/level. The most accurate results can only be obtained if data linkage across multiple data sources is explicitly allowed and duly organized under conditions that still guarantee sufficient privacy protection**
- **health information systems that do not explicitly allow the processing of individual health data for public health purposes cannot assure proper governance**
- **substantial variations in the possibility of using health data for public health purposes may generate unequal opportunities at all levels, including differences in the level of transparency towards citizens and unequal capacity in managing health information across Europe**

3. WHAT SHOULD BE EXPLICITLY ALLOWED UNDER THE PROPOSED REVISION

The use of identifiable health related data is vital for public health analysis. However, access to those data is not allowed in many European countries.

The case of disease registers is highly emblematic of the undesirable disparity of approaches that currently exist across Europe. In Scandinavia, secure data linkage across registers and administrative databases is possible, so that novel technologies can be used to directly access micro-data online, allowing both researchers and policy makers to identify better strategies for health improvement[9]. On the other side of the Baltic, in Estonia, the epidemiological investigation has been made virtually impossible[10]. In the Italian decentralized health system, the privacy authority discourages the maintenance of personal identifiers even to regional governments, so that each register requires a specific local legislation, creating further obstacles to the usage of identifiable health data.

Nonetheless, the privacy protective use of individual data at the local level is fundamental to allow unprecedented collaborative opportunities for public health in Europe, within the legitimate boundaries of the EU legislation, as successfully demonstrated by recent projects funded by the European Commission[11].

The revision of the Directive should foster solutions to overcome such unequal conditions across Europe. To overcome the current differences, Member States should be mandated to implement codes of conduct (approved/certified at EU level) and specify good practices. Such a homogeneous approach would favor the application of rigorous objective procedures, e.g. the establishment of Ethical Review Boards, that would foster the **application of secure procedures** e.g. designating unique data custodians and trusted third parties for data management.

The results that can be obtained are important for both the public as a whole and the single individual: while better prevention strategies can be elaborated for subgroups at risk, each subject will directly benefit from more targeted approaches that can be applied to protect his/her health as a result of finely tuned epidemiological investigations.

Considering all the above, the revised Directive should allow the processing of identifiable information for secondary purposes and for linking across multiple sources without patient consent, in the interest of public health, if appropriate safeguards are implemented, including:

- privacy by design
- privacy impact assessment
- privacy enhancing technologies (PETs)
- privacy performance evaluation[12]
- trusted third parties for data linkage
- using trustworthy methods of anonymisation

The legitimate processing of identifiable information should be regarded as a means to foster both the right to privacy and the right to health.

1. LEGITIMATE PROCESSING OF IDENTIFIABLE INFORMATION FOR PUBLIC HEALTH. The proposed revision shall include a normative provision that allows the legitimate processing of identifiable information for public health at the specific stage/level, specifying the conditions under which it can be safely carried out without patient consent.

The characteristics and specific procedures required to access health databases for public health analysis are rarely documented in a systematic way by Member States. **More transparent rules for access** should be provided to all citizens to understand and regulate the secondary use of health data.

2. TRANSPARENCY OF ACCESS TO HEALTH DATABASES. The proposed revision shall mandate Member States to transparently document the availability of public health databases and publicize the conditions required to get approval to access the databases from the competent authority.

The documentation related to the national availability of health databases shall be matched by a similar activity at the European level. The European Commission shall **provide citizens with a unified framework** through which the conduction of public health studies can be properly planned and easily evaluated.

3. HARMONIZE DOCUMENTATION FOR ACCESSING INDIVIDUAL DATA FOR PUBLIC HEALTH. The proposed revision shall envisage the creation of a common dictionary of public health databases, directly linked to the documentation provided by Member States.

Many EU projects have been specifically funded to generate and exchange national statistical data on a routine basis, without specifying a clear pathway for their sustainability. Indeed, in many cases **their continuation is heavily dependent on the possibility to exchange data at the international level**. Currently, the transfer of individual data for a generic scope (multiple secondary uses), without patient consent, is practically forbidden. In many cases it is possible to use finely tuned aggregate data (large population studies on chronic diseases). In other cases (rare events e.g. those included in safety indicators, or rare diseases) the correct conduction of public health studies requires the centralization of individual data towards an international server. Finally, in a limited number of applications (e.g. cost effectiveness analysis) specific databases may be formed ad hoc to perform a specific task within a well defined time frame. In this context, it is crucial that the free flow of health information is not hampered.

4. TRANSNATIONAL FLOW OF HEALTH INFORMATION FOR PUBLIC HEALTH. The proposed revision shall state the conditions for the legitimate flow of health data across Member States for public health.

Finally, there would be no effective revision without an accurate monitoring of the effect of the new Directive. We believe that this step was not completely carried out for the current EU Data Protection Directive, causing an unexpected negative impact on the conduction of public health activities. Such a problem may have translated into **lost opportunities for health improvement, in ways that have not been adequately controlled and may have created inequity across the continent.**

5. HOMOGENEOUS IMPLEMENTATION OF THE EU DATA PROTECTION DIRECTIVE FOR PUBLIC HEALTH. The proposed revision shall commit the European Commission to monitor the homogeneous implementation of the EU Data Protection Directive across Europe and its impact on public health.

4. SUGGESTIONS ON HOW TO IMPROVE THE CURRENT PROPOSAL FOR PUBLIC HEALTH

The EU Data Protection Directive includes two possible exemptions to the general prohibition of processing sensitive data, which are of potential interest for public health: Art. 8(3), for which data can be disclosed for preventive medicine, medical diagnosis, provision of care or treatment, or management of health care services; and Art.8(4), for which Member States may lay down additional exemptions for reasons of substantial public interest. Ex Recital 34, the notion of substantial public interest includes public health. There is sufficient evidence that the above paragraphs did not allow for a homogeneous implementation of the Directive in the interest of public health.

Seeking patients' consent is often not feasible for public health studies, as it would involve a disproportionate effort for researchers. At the same time, the processing of identifiable information without patient consent for public health purposes, be it secondary uses or data linkage, is not allowed in several Member States.

In this context, any application relying on the direct access to computerized data sources, particularly those related to the production of series of health indicators (including indicators on quality and safety in health care) promoted by the European Commission, would be practically not usable. Furthermore, an unbalanced composition of the group providing consent compared to those who refuse, would inevitably bias the results and undermine the validity of any study.

The processing of sensitive data in identifiable form for public health purposes should be the subject of specific normative provision that should foster, at the same time, the homogeneous application of suitable security measures across Europe, including protocols that apply the concept of "privacy by design". The specification of guidelines/good practices for the usage of individual data for public health should be also realized at the European level.

The following normative provision is required to specify the conditions under which the legitimate processing of identifiable information is possible for public health purposes:

1. LEGITIMATE PROCESSING OF IDENTIFIABLE INFORMATION FOR PUBLIC HEALTH.

"Processing of identifiable information* without patient consent is legitimate only when all the following conditions are satisfied: 1) performed for public health governance and research; 2) approved by a competent ethical committee; 3) implemented through the application of secure protocols that apply the concept of "privacy by design" (including privacy enhanced technologies, privacy impact assessment, the identification of unique data custodians, lists of accredited users and trusted third parties).

Definitions of legal concepts (e.g. public health interests, public health study/research, identifiable information, anonymization, deidentification, pseudo-anonymization, one way encryption) shall be specified in the preamble"

There is a need to overcome the current lack of common terms of reference for the transparent access to the secondary use of health data.

The following recommendation is required to mandate all Member States to document the availability and the specific conditions applied to each database amenable to data processing for public health:

2. MEMBER STATES SHALL ENSURE THE TRANSPARENT ACCESS TO HEALTH DATABASES FOR PUBLIC HEALTH.
"Member States shall maintain updated National Registries of Health Databases including all specifications related to the content, management and the precise conditions under which health databases can be made available for public health".

The national availability of health databases allows better planning and enhanced usage of health databases at the European level. The European Commission shall establish common terms of reference for the conduction of public health studies involving the use of national databases.

The following recommendation is required to commit the European Commission to document the availability and the specific conditions applied by Member States for using individual data for public health:

3. THE EUROPEAN COMMISSION SHALL ORGANIZE A CENTRAL REPOSITORY OF THE DOCUMENTATION NEEDED TO ACCESS INDIVIDUAL DATA FOR PUBLIC HEALTH.
"The European Commission shall maintain a European Registry of Public Health Databases to standardize and link all documentation provided by Member States for the usage of individual data for public health."

Provided that the quality of health data is high at the local level, not all public health applications will require access to individual data at the European level. In many cases, it is possible to rely on finely tuned aggregate data. To deliver best information for European public health policy, it is essential that the European Commission specifies rules for international data flows.

The following recommendation is suggested to assign the mandate to the European Commission to specify rules for the transnational exchange of health information for public health:

4. THE EUROPEAN COMMISSION SHALL SPECIFY RULES FOR THE TRANSNATIONAL EXCHANGE OF HEALTH INFORMATION FOR PUBLIC HEALTH.
"The European Commission shall specify rules for the legitimate exchange of health information across Member States for public health through the preparation of targeted European codes of conduct".

Practical instruments are required to allow accurate monitoring of the impact of the revised Data Protection Directive on Member States.

The following recommendation is suggested to assign the mandate to the European Commission to collect timely information across Europe:

5. THE EUROPEAN COMMISSION SHALL ROUTINELY MONITOR THE IMPLEMENTATION OF THE EU DATA PROTECTION DIRECTIVE.
"The European Commission shall monitor the homogeneous implementation of the Directive through the establishment of a 'EU observatory for the implementation of the Data Protection Directive for public health' and specific tasks to be included in the workprogrammes of FP7 (DG-RESEARCH) and Public Health (DG-SANCO)

5. SUMMARY RECOMMENDATIONS

The present document reports the position of the "European Public Health Expert Workshop on Privacy Protection" on the revision of the EU Data Protection Directive in the interest of public health. The position includes details on WHY the group of experts believe this should be done, WHAT should be allowed by the proposed revision, and HOW to improve the current proposal.

In summary, the group of experts recommends to revise the proposal for the revision of the EU Data Protection Directive put forward by the European Commission by including the following:

- **one normative provision**
  - definition of legitimate processing of identifiable information for public health
- **one recommendation to Member States**
  - to define common terms of reference to access individual health data for public health
- **three recommendations for the European Commission**
  - to harmonize national documentation regarding access to individual data for public health
  - to specify rules for the transnational exchange of health information for public health
  - to routinely monitor the homogeneous implementation of the EU data protection directive for the public health area

The European Public Health Expert Workshop on Privacy Protection looks forward to the uptake of the above recommendations in the interest of European Public Health.

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