Abstract title : **Making optimal use of individual health records for public health monitoring and research in a privacy respecting manner: current developments and best practices**

Contact name : Dr M Marieke Verschuuren
Institute : RIVM
Address : PO Box 1
Post code : 3720 BA
Town : Bilthoven
Country : Netherlands
Telephone : + 0031-30-2748520
Fax : +
Email : Marieke.Verschuuren@rivm.nl

Abstract : Possibilities to use individual health records for Public Health(PH)/Health Services Research(HSR) differ between EU Member States (MS), as MS apply divergent approaches towards balancing the interests of the data subjects (data protection) and the interests of society (a good and efficient health system). Though it is fully justifiable that MS aim to protect the privacy of their citizens, current technical developments allow for optimal use of individual health records while at the same time ensuring very adequate safeguards for privacy protection. This workshop firstly aims to give a summary of the current legal data protection framework underlying current PH/HSR practice, highlighting important developments such genomics and biobanks. This background information will help participants appreciate the specifications of the best practices presented next. After the introduction on legal aspects, representatives from DG Research will highlight challenges and opportunities for EU funded projects that involve cross-national sharing of PH/HSR data. Next, several best practice examples will be presented in more detail. First, researchers from the EUBIROD Consortium will introduce a novel approach to realize “privacy by design” in the cross-border flow of information among diabetes registries using very different procedures for data collection and management. Next, the 'Nordic' federal model will be explained. This model is being developed to both protect privacy and facilitate access for authorized users by using modern technology. Finally, researchers from the Sax Institute in Sydney will present a model, which concerns probabilistic matching of individual records from different databases using Trusted Third Parties. This workshop focuses on a topic which is of relevance for all who work in PH/HSR. Individual health records, i.e. routinely collected health data, form a valuable source of information for PH/HSR, which in many MS cannot be (optimally) used. This workshop aims to contribute to improving this situation by showing examples of novel approaches that enable efficient and safe use of health data within the legal boundaries set by the EU.
Chairpersons : Niek Klazinga (University of Amsterdam, the Netherlands), Marieke Verschuuren (RIVM, the Netherlands)

Abstract 1 :
Title : The position of public health in the European legal data protection framework
Presenting author : Mr T. Tobias Schulte in den Bäumen
Authors : Schulte in den Bäumen T, Verschuuren M
Affiliation(s) : Institute for Public Health Genomics (IPHG), Maastricht University, the Netherlands Centre for Public Health Forecasting, National Institute of Public Health (RIVM), Bilthoven, the Netherlands
Abstract : The use of data from different sources is a necessary condition for evidence-based public health policies and actions. However, stakeholders experience difficulties when it comes to the exchange of data and their linkage on a European level. The Work Group on Data Protection of the Network of Competent Authorities (NCA) addressed this issue and detected substantial divergence across EU Member States in possibilities for the usage of person identifiable health data. Underlying this situation is the European legal data protection framework, in which it is left up to the MS to decide whether to allow for the use of person identifiable health data for public health purposes. The

Work Group analyzed the position of public health in the European Data Protection Directive, and wrote a Commentary in the European Journal of Public Health on the outcomes of this exercise, as well as a Position Paper on behalf of the NCA. These will be presented during the workshop. Special attention will be given to biobanks (including genetic information). These play an increasingly important role in public health research and monitoring. In the context of data protection, biobanks cause particular concerns as they are often not purpose specific. In the Data Protection Directive the need for a purpose-unspecific research infrastructure is not foreseen, and the legal basis of biobanks is therefore questionable. Another current extremely relevant development that will be addressed is Electronic Health Records (EHRs). As the Data Protection Directive dates from 1995, it is questionable whether it provides an adequate legal framework for new technologies such as EHRs.

Abstract 2 :
Title : Health services data in European Public Health Research: challenges and opportunities of ongoing projects
Presenting author : Mr K. Kevin McCarthy
Authors : McCarthy K
Affiliation(s) : DG Research, European Commission, Brussels, Belgium
Abstract : The third pillar of the FP7 health work programme ("Optimizing the delivery of health care to European citizens") calls for more effective comparative cross-national health systems research. Many data sources exist in this field (OECD, WHO, EUROSTAT) and must be efficiently used in combination with regional/national data. The ethical evaluation of FP7 projects duly takes into account legal guidelines. In this presentation the focus will be on ongoing projects funded by the FP7 programme of the third pillar and the related challenges and opportunities in the use of health data. The availability and comparability of healthcare related data require access for health services researchers across EU member states. Successful proposals that are considered relevant for ethical evaluation undergo ethical review before final approval. It is important that researchers are fully aware of challenges and opportunities that arise both in the preparation and during the conduction of EU projects.

Abstract 3 :
Title : Cross-border flow of health information: is "privacy by design" sufficient to obtain complete and accurate data for public health in Europe? The case of BIRO/EUBIROD diabetes registers.
Presenting author : Mrs C.T. Concetta Tania Di Iorio
Authors : Di Iorio CT, Carinci F
Affiliation(s) : On behalf of the EUBIROD consortium
Abstract : The BIRO (2005-2009) and EUBIROD (2008-2011) projects funded by DG-SANCO aimed at developing and implementing a shared evidence-based information system for diabetes in Europe. The BIRO system was conceived as an innovative method to build practical tools that would process diabetes data to deliver accurate standardized indicators at both local and European level. EUBIROD aimed at implementing the system in diabetes registries from 20 Member States. The successful construction of the BIRO system has been underpinned by the application of a novel methodology of Privacy Impact Assessment (PIA) that allowed identifying the best privacy enhancing infrastructure. "Privacy by design" was realized through a structured process that included revision of the relevant EU legislation, data flow analysis, application of a revised Delphi procedure and privacy analysis of the selected architecture. Subsequent development of open source software led to the production of EU reports based on standardized routines used at all levels. Further results obtained in EUBIROD show variability in the implementation of the Directive among participating registries, a potential obstacle for the collection of complete, accurate and homogeneous data on diabetes across Europe. The above topics will be presented in detail during the workshop. Points for discussion will include questions on how such variability could be further investigated to understand the critical areas of interpretation and provide possible solutions to optimize the impact of data protection legislation on public health and health services research.

Abstract 4 :
Title : An example of optimizing the usability of personal health data: the Nordic 'federal data model'
Presenting author : Mr M. Magnus Stenbeck
Authors : Stenbeck M
Affiliation(s) : Database Infrastructure Committee, Swedish Research Council, Stockholm, Sweden
Abstract : Background: During the past few years, both the requirements on data protection and the requirements on using data for public health and other social policy development have increased. The statistics offices in Sweden and Denmark have introduced new technologies for access to microdata online, in Sweden called MONA (Microdata Online Access), and are hesitant to provide data in other ways than by remote access through a virtual desktop for the user. The system is used for both researchers and policy makers. This however poses a problem for those who need to combine Statistics Sweden data with health data from other authorities or research data that are too sensitive or complicated to ship to Statistics Sweden.

Objective: To present a model for federated data sharing of authority, health care provider and researcher data using modern database technology and distributed systems for accessing data from several sources.

Material and methods: A demonstration project has been developed for federated access to microdata from Statistics Sweden, the National Board of Health and Welfare, and labs for cervis cancer screening. The project aims at showing how to use federated technique to evaluate the results screening. The project also evaluates the legal possibilities and obstacles for implementing this solution as a general model for datasharing of sensitive personal data.

Abstract 5 :
Title : Best practice example from Australia: privacy-preserving approach using semi-trusted-third-party models
Presenting author : Mr T. Tim Churches
Authors : Churches T
Affiliation(s) : Sax Institute, Sydney, Australia
Abstract : In Australia several varieties semi-trusted-third-party models are being applied to deterministically and/or probabilistically link identifiers (unique identifier numbers, names, addresses, dates-of-birth etc), which have been separated at source from their corresponding health/medical data items. Through such approaches linked but de-identified individual-level health data sets can be supplies to researchers. In this presentation these models will be explained in more detail, addressing the following aspects:
- the benefits and dysbenefits (extra costs, operational problems) of such a privacy-preserving approach
- the Australian regulatory frameworks which permit and facilitate such a privacy-preserving approach
- the – generally positive- attitude of privacy advocates and health care consumers to such a privacy-preserving approach to the research use of health data
- the use of perturbed and/or synthetic data subsets to overcome some important operational problems with such privacy-preserving (semi-trusted-third-party) approaches
- the use of secure data enclaves/remote access data analysis laboratory facilities to address some important residual privacy risks with such privacy-preserving (semi-trusted-third-party) approaches
- the use of web-based metadata access and application/approval workflow facilities and associated automated data manipulation/handling systems to streamline and improve the efficiency of obtaining research access to de-identified, linked, individual-level health and social data sets.

- the use of encryption technologies to help lower running costs of semi-trusted-third-party data linkage approaches as used in Australia.

Authorisation given for publication (if accepted) in the EJPH supplement