

LEGAL REQUIREMENTS ON SECONDARY USE OF MEDICAL DATA IN THE EU AND USA – A CASE STUDY

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Background: The use of secondary data in health care research has become a very important issue over the past few years. Data from the treatment context are being used for evaluation of medical data for external quality assurance, as well as to answer medical questions in the form of registers and research databases. Additionally, the establishment of electronic clinical systems like data warehouses provides new opportunities for the secondary use of clinical data. Because health data is among the most sensitive information about an individual, the data must be safeguarded from disclosure. Depending on type of data to be used and the purpose of research, legal requirements on secondary use of clinical data vary between countries. The US regulations Health Insurance Portability and Accountability Act (HIPAA), Health Information Technology for Economic and Clinical Health Act (HITECH) and the EU's Directive 95/46/EC form the legal basis for medical research in the United States and the EU and are subject to be compared in this project.

Methods: It is of interest to investigate the legal requirements as outlined in US and European laws and regulations with the objective to identify potential similarities and differences. In order to explore the commonalities and differences, a model will be developed that contains all aspects that need to be considered prior to providing data for secondary uses. The criteria used in this comparison will include data privacy how the US and EU regard the secondary use of clinical data, which ethical issues are pertinent, and how identifiable and de-identified data can be shared.

Results: Some preliminary results include that the US and EU have significantly different legal structures for data protection and protect personal data differently. While the US approaches privacy by sector (i.e. financial and health care separately), the EU takes a more comprehensive general approach to privacy. Each European member state has its own data protection regulations that must meet the Directives requirements. This is accomplished by implementing Directive 95/46 in their legal structure. In the United States, data protection is fragmented into different regulations and acts. While the EU requires unambiguous consent from the data subject prior to the collection, processing and use of data, HIPAA, the US healthcare privacy law, allows organizations to share data for research purposes without individual authorization. Both US and European data protection laws require that organizations de-identify data prior to disseminating it. This implicates that both the United States and the EU assume that anonymization protects privacy, which is subject to controversy.

Discussion: The current cursory review has shown a few differences; however, a much deeper analysis will be conducted. Indications show a much more comprehensive exploration should be conducted since the laws and regulations on data protection in the EU and United States are immense. Based on the current literature review, little past research has compared these complex regulations to this extent before. A comprehensive review offers the potential to improve and facilitate joint research projects on health care issues between the EU and the United States.
