Editorial

An Outlook on the Future of Medical Research in Europe and Data Protection: Grim or Prosperous?

1 Introduction

The European Association of Health Law (EAHL) held its 2013 conference under the topic “European Health Law and Patient Safety”. Within the conference it has been made clear that a broader scope on patient safety as well as medical research also needs to consider patient privacy: informed consent, fundamental patient rights, the legal relevance of guidelines or data protection in general are only a few factors which constitute key elements in the area of patient safety in particular and health law in general. Medical information in that area is always also reliant on the availability of patient data. Taking into account the technical advancements in health-IT in relation to patient safety and medical research, there have been quite remarkable developments which influence all of these areas not only by themselves, but also their interplay: the proceedings of European policy makers to implement a General Data Protection Regulation (GDPR) for the European single market.

2 The Proposed GDPR, Medical Research and Consent

There are many reasons to put a special focus on the proposed GDPR. It shall replace Directive 95/46/EC, the framework for data protection in Europe. The European legislator aims for a comprehensive reform: even though many rules persist, the GDPR forms a completely new framework; a framework which would be directly applicable — with no more (or rather only very few, but more on that below) country specific regulations. It would have an impact on
multinational companies, non-governmental organizations, academics, and foreign governments and moreover extraterritorial effects on data controllers located outside of the European Union. To put it in a nutshell: The GDPR would heavily influence each and every one of us, working with (medical) data.

Hence — keeping patient safety and therewith also patient autonomy in mind — it would also influence the patient. An important finding for medical research may be drawn from the evolvement of the concept of consent within the two different draft versions (i.e., the draft from the European Commission and the latter LIBE draft). The concept of informed consent gained an important role in the legislative process. The fact that there is a functioning draft ready for the trilogue said to start in the summer months of 2014 could be called a miracle. From a first draft in January 2012 (EC draft) to around 3100 amendment proposals in the European Parliament alone, Jan Phillipp Albrecht, rapporteur in the leading LIBE committee (Civil Liberties, Justice and Home Affairs), somehow managed to consolidate a compromise text which passed the LIBE votes in October 2013 (LIBE draft) and was adopted by the Parliament in a first voting round with 653 votes (621 yes, 10 no, 22 abstentions). Moreover, the view on consent for medical research changed within this process, shifting from a rather liberal concept to a strict, compulsory need for a patients’ informed consent.

It could be argued that there is a potentially restricting effect of the GDPR, in its present LIBE draft, on lawful bases for research projects using patient data. The current status within the Directive does not even provide any specific provisions on the use of patient data for medical research but rather a general concept demanding explicit consent with a further exceptional basis in Member State’s law to allow processing (subject to “suitable safeguards”) of sensitive personal data “for reasons of substantial public interest”, which included — at least according to a Directive recital — research in general. This changed within the first EC draft: Art. 81 2) stated that “[p]rocessing of personal data concerning health which is necessary for historical, statistical or scientific research purposes (…) is subject to the conditions and safeguards referred to in Article 83”. Article 83(i) then suggested that research data should where possible be anonymised or securely pseudonymised — but they could then for example be used for research within a closed community without consent.

The LIBE draft now again seems to oppose that concept. The new Article 81(2) states that:

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\text{[p]rocessing of personal data concerning health which is necessary for historical, statistical or scientific research purposes shall be permitted}
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