

Book Review

The Data Protection Directive and Medical Research across Europe
Edited by Deryck Beyleveld, David Townend, Ségolène Rouillé-Mirza and Jessica Wright, Ashgate 2004 ISBN 0 75462367X pp253

This book is focused on the Directive 95/46/EC on data protection and how it applies to the use of medical data in different member states. For this reason, it will appeal to experts in the field because of the detailed analysis but it could also give someone new to this field a sense of how this directive operates and its implications for the use of medical data. Some of the key issues that are covered are:- anonymisation and pseudonymization, the exemptions for medical research, the over-riding of data subject's rights in the public interest, and the nature of genetic information. This edited book represents the first phase of the PRIVIREAL research project funded by the European Commission in 2001. The purpose of the PRIVIREAL project is to document what all the partner countries in the European Union have done or plan to do to implement the Directive 95/46/EC, and 'to evaluate the interaction between the implementation of the Directive and research ethics review in protecting Directive rights of research subjects.'

The structure of the book reflects the way that the research has been conducted, as it is broken into two parts. The first section is a series of background keynote papers that focus on specific issues that were presented at one of the meetings of the participants in the project. These papers address some of the key premises that the Directive rests on such as privacy, the public interest and the individual's right to be informed about processing and provide a basis for understanding the second part of the book. These papers demonstrate that the Directive 95/46/EC on data protection which is intended to have a wide application does not adequately address the issues and complexities that are posed by medical research. However as Lehtonen makes clear, the Directive must be read in conjunction with other legal instruments that relate specifically to medical research and be interpreted within the framework of human rights (Townend Chapter 7). As the authors demonstrate the first major concern is that the Directive provides no definition of medical research (Beyleveld Chapter 2) and essentially leaves it up to member states to provide safeguards in this undefined area which is usually determined by what is considered in the public interest (Nys Chapter 5). This has led to differences in the safeguards that are offered in different jurisdictions. Townsend's chapter goes on to discuss how this question is framed and how a utilitarian approach is often applied by the courts that tends to lead to a situation where individual rights are usurped by what is perceived as in the public interest which is essentially a political decision. This leads to a situation where the only option for individuals is to withdraw from medical research which 'could have catastrophic effects not only for the individual, but for the whole of society'.

Another major concern about the Directive raised by the authors is the lack of clarity about a number of key concepts that are intrinsic to the Directive as a whole. As Romeo Casabone points out in Chapter 3, the Directive does not define anonymisation or state what the process consists of, nor does it provide any means of regulating the process of anonymisation. In his discussion of anonymisation and pseudonymization he argues that these issues need to be addressed. He makes an

important point that the Directive regards anonymisation as a 'relative concept' and that it depends upon who has access, and the amount of time and effort it would take to make the personal data identifiable. Therefore data can still be considered anonymous if the person who receives it cannot identify it but the sender is still able to. Mette Hartlev in chapter 3 analyses the conceptual underpinnings of privacy and if such concepts are found in the the Directive. This task is not an easy one, as Mette Hartlev points out, when the concept of privacy is 'nebulous' and 'there is no single unitary perception of how privacy should be defined'. He points out that there is a tension between the integrity-orientated aspects of privacy (which protect the private sphere and the individual's integrity) and the autonomy-orientated aspects (the individual's ability to control and determine the use of information) of the Directive. He regards that both of these are essential to provide 'a comprehensive protection of the individuals' rights and freedoms'.

The second part of the book is devoted to a comparative analysis of the implementation of the Directive in the member states, Norway and the NAS countries. In 2002 a questionnaire was sent to all the organisations participating in PRIVEAL asking specific questions about the how the Directive had been implemented in that jurisdiction. These questions are listed in Chapter 9. This has provided a rich and detailed set of data to establish the ways in which the Directive has been implemented in different countries. This methodology illustrates how the Directive fails or where further clarification is needed. Once again it is obvious that there are glaring deficiencies in the coverage of the law in relation to medical data. Ségolène Rouillé-Mirza and Jessica Wright put forward a comprehensive list of issues on pages 230 and 185 that they consider need further investigation on based on this evidence. The ones that I think are particularly interesting and would personally like some answers to, are:-

- Is anonymisation a form of processing?
- What is in the public interest and who decides this?
- What does explicit consent mean?
- How would one define genetic information and protect it?
- Are biological samples personal data?

The editors have written two other books as part of this series on the PRIVIREAL project. These books cover the last two phases of the project and document the remit and practices of ethics committees and provide a comparative assessment of how the law protects the medical data of individuals across the European Union. These books are also published by Ashgate and are titled 'Implementation of the Data Protection Directive in Relation to Medical Research in Europe' and 'Research Ethics Committees, Data Protection and Medical Research in European Countries'. Watch out for them if you would like read further on this topic.

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