# Medical data protection in Europe: New rules vs. actual trends

*Joseph A. Cannataci & Jeanne Pia Mifsud Bonnici,*
*Law & Information Technology Research Unit, University of Malta*

## Abstract

1995 is set to be a key year for the rules governing medical data in Europe: the Council of Europe is in the process of approving the final draft of a new Recommendation on the Protection of Medical Data while the member states of the European Union have adopted a directive on data protection.

The paper will present:

i. some of the interim results of the University of Malta's LEXIMP 9 Project reporting on the extent to which the Council of Europe's 1981 Recommendation on Data Protection in the Medical sector was actually implemented in the 34 member states of the Council of Europe. This project includes a comparative analysis of specific rules, relevant case-law and other relevant regulations;
ii. an overview of the new Council of Europe Recommendation on Medical Data, specifically addressing confidentiality, access to data and information integrity;
iii. the relevance of the EU Directive;

## 1. Trends in Rule-Making

### *1.1 New Rules: Trendy Rule-making*

The advance in medical technologies would appear to bring with it a proportional increase in the legal rules governing various areas of the practice of medicine. Europe seems to be moving towards a bumper crop of new rules in the medical field. The Council of Europe has at least two different sets of rules in various stages of finalisation:

i. The draft Recommendation on the Protection of Medical Data (Rec96 [1])prepared by the Project Group on Data Protection (CJ-PD also known as the Committee of Experts on Data Protection);

ii. The draft Bioethics Convention (Draft Convention for the protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine: Bioethics Convention) prepared by the Steering Committee on Bioethics (CDBI previously CAHBI or ad hoc Committee of Experts on Bioethics)

while the European Union has, on the 24th July 1995, adopted a new draft directive on Data Protection, which has been the best part of five years in the making. The 15 member-states of the EU should bring their legislation in line with the Directive by no later than 24th July 1998.

Indeed, these new sets of rules all share a pedigree common to much consensus rule-making in Europe: each has been through several years of legal wrangling in a process which will have different consequences dependent on the nature of the legal instrument involved.

The Council of Europe initiatives have to be seen in the context of two previous landmarks in European law; the European Convention on Human Rights and Fundamental Freedoms (1950) and the European Data Protection Convention (Convention 108 [2])1981. These two Conventions mark the formal international agreement establishing (or, perhaps, merely recognizing) a fundamental right to private and family life [3]and consequently the implied right to protection of personal data as part of the attempt to preserve the informational privacy which forms an integral part of such a right "to private and family life".

### *1.2 Old Rules: Actual trends in Rule Adoption*

16 countries have ratified the Data Protection Convention, 13 of these being members of the EU together with Iceland, Norway and Slovene. Italy and Greece are the only EU member states not to have ratified this Convention, but now face the mandatory implementation of comparable data protection standards in accordance with the EU directive [4]. 5 other countries have signed the Convention with the declared intention of ratifying it in the near future.

**Rec96** was developed between 1990 and 1995 and will supersede a previous Recommendation on the Protection of Automated Medical Data Banks **R(81)1** which dates from January 1981.

It is important at this stage to clearly distinguish between the legal nature of a Treaty such as the Conventions on Human Rights and Data Protection and a non-binding instrument such as a Recommendation. Whereas treaties are binding upon signatory states on ratification, a Recommendation is issued by the Council of Europe's Committee of Ministers to the Governments of Member States as a policy document drafted with a view to harmonization of the various European legal systems. Although technically non-binding upon the 37 member states of the Council of Europe, these Recommendations exert considerable influence on developments within the states and are taken into account by the legislators, Governments and Data Protection enforcement agencies when formulating or implementing relevant data protection rules.

The drafting of the Recommendation on the Protection of Medical Data was also influenced by the drafting of the Bioethics Convention. The latter attempts to extend legal protection and enforceability to a number of principles: i) respect for the dignity of the person (including a ban on all forms of discrimination); ii) inviolability (protection of individual integrity); iii) security of both human genetic material and its information; iv) inalienability (including prohibition of all commercial agreements concerning the human body and its organs); v) assurance of the testing and quality of services (through an assertion of public responsibility regarding the application of the biomedical sciences [5] While the Bioethics Convention is undoubtedly of considerable interest to geneticists and related disciplines, from the point of view of medical informatics, the greatest interest lies in the specifics of Rec96. The European Union Directive is more important for the renewed emphasis that it brings to the notion of data protection rather than for any great sense of jurisprudential innovation. To a considerable extent, the EU Directive replicates the principles of the Council of Europe's Data Protection Convention, although it does extend the application of these principles to many forms of manual as well as automated personal data.

Both the Council of Europe Convention on Data Protection and the EU Directive are generic legal instruments covering the whole area of personal data, and both documents refer to medical data as sensitive data meriting special safeguards[7] Beyond the establishment of this basic character of special status for medical data, neither of these two instruments provides specific guidelines for the application of data protection principles to the medical sector. The details of the sectoral approach are left up to the pertinent Recommendations, previously Recommendation R(81) 1 and now the new Recommendation (Rec96).[8]

Before proceeding to examine the import of the new Recommendation on the Protection of Medical Data, it is useful to attempt to take stock of the situation obtaining in Europe in 1995, immediately prior to the adoption of this new Recommendation. In this way, it is possible to attempt to gauge the progress of the protection of medical data in Europe since the adoption of the 1981 Recommendation on Automated Medical Data Banks.

Project LEXIMP 9 within the University of Malta's Law & Information Technology Research Unit set out to find an answer to the question: What has the passage of 15 years since the opening for signature of the Council of Europe's Data Protection Convention and its adoption of its first recommendation on medical data meant in real terms for the protection of data typically collected in the health care environment? After all, the authors had, on a number of different occasions within different European countries, occasionally met the odd official responsible for implementing data protection in the medical sector only to be told that "Yes, we are aware of the existence of the Recommendation. It's in my bottom right hand drawer...but I've never really read it [8]!"Faced with this response on the one hand and the reality of a situation where the Council of Europe as an organization, and a good number of the member states, were expending much effort in formulating an entirely new recommendation, it appeared interesting to investigate to what extent the first Recommendation had been implemented

within Europe.
Thus, in August 1994, a questionnaire was distributed to the pertinent authorities within the (then) 32 member states of the Council of Europe. Of these, a response was received from 22 countries, a synopsis of which is represented in Figure 1 attached.
It would appear from the response that the issue of medical data has been tackled either by specific sections within a generic national law on Data Protection and/or specific regulations drawn up with the specific purpose of addressing many of the concerns which were originally raised in Convention 108 and/or Recommendation R(81)1.
The following countries have specific sections mentioning medical data in their generic Data Protection Acts: Luxembourg; Denmark; Switzerland; Hungary; Italy (Bill); Portugal; Netherlands; Iceland; Czech Republic, Germany.
The following countries enacted specific regulations aimed at sectoral coverage of medical data:

i. U.K.
ii. Luxembourg
iii. Denmark
iv. Switzerland
v. Hungary
vi. Italy
vii. Netherlands
viii. Iceland
ix. Finland
x. Austria
xi. Germany

The immediate aim of the LEXIMP9 project was not a detailed jurisprudential analysis of the implementation of various legal principles in different European states, (although in the end it netted sufficient material to carry out a section-by-section analysis at a level of detail which would pack several volumes of comparative analysis).
The immediate LEXIMP9 objective [9] coinciding with the requirement for this present study, is to obtain an overview, a snapshot of the pan-European position in medical data protection based on a comparative analysis of the progress achieved in national legislation since 1981. Given this aim, rather than going through the national laws on a nation-by-nation, section-by-section basis, the approach used will start off by constructing an achievement matrix on the framework of the 1981 Recommendation. In this way, it is possible, at a glance, to assess the extent to which the first Medical Data Protection Recommendation was implemented across Europe. The matrix was constructed by examining the extent to which (if any) the measures recommended in the principles of Recommendation R (81)1 were incorporated into the legal provisions of the 22 countries who responded to the LEXIMP 9 questionnaire. This matrix is reproduced in Figure 2.
After nearly fifteen years from the launch of Recommendation R(81)1 on automated

| Member State | General D.P. rules | Specific Section related to MD | Specific Acts MD | Bodies resp. for protection of MD | Existing internal guidelines | Traditional Med. Confidentiality | | Enforcement of P.M.D. | Court cases |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Penal | General | | |
| Austria | Data Protection Act | | Genetic Engineering Act 1994 s. 71, 105, 106<br>- Hospitals Act s.9b &10<br>- Doctors Act 1984 s.26 | DP Commission<br>- Federal Min. For Health<br>- Govt. of Provinces | Ass. of Austrian Social Security Agencies | | s.26 Doctors Act | | |
| CZECH Republic | 1992 Data Protection Act 29.04.92 | s.16 | | Min. of Health<br>- Min. of Interior<br>- District Authorities<br>- Health insurance companies<br>- Czech Medical Chamber | | | Health 1960 Act | | |
| Denmark | Danish Private Registers Act 1978<br>- Public Authorities Registers Act 1979 | s.2 (3)<br>s.3 ( 2-4)<br>s.4 (1) (3)<br>s.9 (2)<br>s.16 (1-5)<br>s.18a (1-4)<br>s.21 (1-5) | Right of Access 1.01.94 | Regional/County authorities<br>-D.P.A. | possibly | Act 152 | | Min. of Health State Univ. Hospitals in Copenhagen Statens Seruminstitut | |
| Finland | Personal Data File Act 1988 | | States & Rights of a Patient Act | Office of DP Ombudsman<br>- DP Board | Regulations by Min. of Social Affairs<br>- National Research & dev. Centre for Welfare and Health | | | | |
| France | Data Protection, data files & Individual Liberties Act 06.01.78 | | | | | Act 378 | | | |
| Germany | Federal Data Protection Act | s.24,28,35,39,40 | Code of Social Law s.67-85a s.96, 100, 100a s.35 (1) s.276, 284-305 | Panel Doctors' Associations federal DP Commissoner<br>- DP Commissioners at Land<br>- Min. of Health at federal & Land levels<br>- internal DP Commissioners | | s.203 penal code | | | |

*Table representing results of questionaire (1)*

| Member State | General D.P. rules | Specific Section related to MD | Specific Acts MD | Bodies resp. for protection of MD | Existing internal guidelines | Traditional Med. Confidentiality | | Enforcement of D.P.M.D. | Court cases |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Penal | General | | |
| Greece | | | | | | Art. 371 | Art.23 of L.1565/39 Art. 15 of Decree 171/55 | | |
| Hungary | Act LXIII of 1992 Protection of Personal Data & Disclosure of public Interest | Specific section requiring that for the disclosure of medical data - consent is required | Act II of 1972 on Health | Eventually DP Ombudsman | Hungarian Medical Research Council | | | National Institute of Rheumatology & Physio-therapy | |
| Iceland | Act Concerning the Registration & handling of Personal Data 1989 | Act 4c | Physicians Act 19.05.88 | DP Commissionar - Directorate General of Health - Min. of Health - Ethical Committees (Losgo) | | | | National hospital - Reykjavik Icelandic health ass. Icelandic Cancer Society | |
| Italy | Bill 11-1-95 | s.5 par. 1-3 s.8 par. 5&7 s.14 par. 3 s.16 s.17 par. 1a s.18 par. 1 s.33 par. 2 s.34 par. 1g | Law 135/1990 Law 833/1978 | N/A | N/A | Act 662-Profess. Secrecy | | N/A | |
| Luxembourg | Data Protection Act 1979 | s.28-1 (included on 11/01/92 | Regulation 2/10/91 | Consultative Commission - Min. of Justice - Min. of Health -Ass. des Medecins et Medecins dentistes -Ass. of hospitals | N/A | Chapter 8 | | | |
| Netherlands | Data Protection Act 23-12-88 | Art. 11 par. 3 | Civil Code (as amended) Art. 454 to 459 (17/11/94) | Registrariekamer | | | | Netherlands Council for Health Royal Netherlands Academy of Arts and Sciences | No breach of medical confidentiality linked to Data Protection Act |

*Table representing results of questionaire (2)*

| Member State | General D.P. rules | Specific Section related to MD | Specific Acts MD | Bodies resp. for protection of MD | Existing internal guidelines | Traditional Med. Confidentiality | | Enforcement of P.M.D. | Court cases |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Penal | General | | |
| Poland | | | Act 30.08.91 - arabissements de la sante Act 28.10.50 - medical profession : secrecy Art 14 Act 17.12.92 - hosting of medical Data | N/A | N/A | | Art 14 (a 28.10.50 | | Inclusion of medical condition in medical certificate coun ordered exclusion |
| Portugal | Protection of Personal Data Act 29-04-91 L 10/91 | Art. 11 Art. 17 | N/A | 1 National Commission for the Protection of Automated Personal Data (CNPDPI) 2. Medical Association 3 National Council of Ethics for the Sciences of Life | Medical Association Code of Practice / Statute Decree-Law No. 224/94 - non-donas of organs & human tissues | Art.184 - Prof. Secrecy | | | AA v ZZ Supreme Coun (3.IV.91) medical certification justifying non-appearance before justice services should not specify illness: since would cause psychological uneasiness |
| Romania | | | | | | | | | |
| Sweden | Data Protection Act 13-05-73 | 5.2a 5.4 5.6 5.7a | Secrecy Act 1980 Lagen (1994:953) on aliggarden for personal inom halso-och sjukvarden (s.8) Patientjournalla gen | 1. Data Inspection Board 2. National Social Welfare Board | | | | | Public prosecutor v B City Court of Gothenbourg April 1985. B, a doctor was accused of not having followed a regulation of erasing a file issued by the Data Inspectorate Board |
| United Kingdom | Data Protection Act 1984 | s.2(3) D.P. (Subject Access Modification) (Health Order 1987) | 1. Access to Health Records Act 1990 2. Access to Medical reports act 1988 3. Subject Access Modification (Health) Order 1987 4 The Human Fertilisation & Embryology act 1990 | D.P. register - Hospitals - health authorities -indiv. G.P.s -NHS Regional DP co-ordinator - General medical, Dental & Nursing Councils & equivalent bodies | NHS DP Handbook - Dep. of Health draft guidance on confid. use & disclosure of personal health info. - NHS guidelines on info. Systems security & handling confid. Patient Info. in contracting - General Medical Council's guidance to doctors | | | on all sites | X v Y Hunter v Mann R v Mid Glamorgan FHSA & South Glamorgan HA ex parte Martin |

*Table representing results of questionaire (3)*

| Member State | General D.P. rules | Specific Section related to MD | Specific Acts MD | Bodies resp. for protection of MD | Existing internal guidelines | Traditional Med. Confidentiality | | Enforcement of P.M.D. | Court cases |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Penal | General | | |
| United Kingdom | | | 5.The human Fertilisation & Embryology (Disclosure of Information) Act 1992 6. The Access to Health Records (Control of Access) Regulations 1993 7. The Venereal Siceases regulations | on prof. confidentiality | | | | | |

*Table representing results of questionaire (4)*

medical data banks, a careful examination of Figures 1 and 2 would support the following conclusions:

i. Many (9) countries have a section or two referring to medical data in their generic data protection law. Most of these are in a sensitive data context and appear to be related to the concerns expressed in article 6 of Convention 108.
ii. One should not be misled by a list of eleven countries who have enacted legislation aimed specifically at medical data. Of these, 7 countries have only a couple of sections relating to medical data and these are not necessarily capable of being mapped onto the safeguards originally proposed in R(81)1.
iii. Only 3 countries, Luxembourg, Denmark and Finland, and, to a lesser extent, the U.K. appear to have made the legislative effort to incorporate a majority of R(81)1's rules into its own laws.
iv. Only 7 court cases (relating to medical data) in 5 countries have been reported;

This state of affairs may be explained as being the result of one or a combination of the following:

a. R(81)1 spelt out rules for a technology that was rapidly becoming obsolete;
b. R(81)1 should have included rules about other aspects of data protection in the medical sector;
c. R(81)1 was not sufficiently publicized;
d. Protection of medical data is not very high on the scale of legislative priorities;
e. there are in practice few problems with data protection in the medical sector and the problems are more perceived than real;

| R (81) 1 | R (95) ? | Austria | Belgium | Bulgaria | Czech Republic | Denmark | Finland | France | Germany | Greece | Hungary | Iceland | Italy | Luxembourg | Malte | Netherlands | Poland | Portugal | Romania | Sweden | Switzerland | Turkey | United Kingdom |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1.1 | | | | | | | | | | | | | | | | | | | | | | | |
| 1.2 | | | | | | | | | | | | | | | | | | | | | | | |
| 1.2 | 3.1 | | | | | | 2.2.1 | | | | | | | | | | | | | | | | |
| 1.3 | | | | | | | | | | | | | | | | | | | | | | | |
| 1.4 | | | | | | | | | | | | | | | | | | | | | | | |
| 1.5 | | | | | | | | | | | | | | | | | | | | | | | |
| 2.1 | | | | | | | | | | | | | | R2 | | | | | | | | | |
| 2.2 | | | | | | | | | | | | | | | | | | | | | | | |
| a | | | | | | | | | | | | | | | | | | | | | | | |
| b | | | | | | | | | | | | | | | | | | | | | | | |
| c | | | | | | | | | | | | | | | | | | | | | | | |
| 3.1 | | | | | | R2 | | | | | | | | R5(1) | | | | | | | | | |
| a | | | | | | | 2.1 | | | | | | | | | | | | | | | | |
| b | | | | | | | | | | | | | | R5(1a) | | | | | | | | | |
| c | | | | | | R1(2) | 2.1 | | | | | | | R7 | | | | | | | | | |
| | | | | | | 4(3) | | | | | | | | | | | | | | | | | |
| d | | | | | | R2(iv) | | | | | | | | | | | | | | | | | |
| e | | | | | | | 2.2.1 | | | | | | | 28-1(1) | | | | | | | | | |
| | | | | | | | | | | | | | | R1 | | | | | | | | | |
| | | | | | | | | | | | | | | R8 | | | | | | | | | |
| f | | | | | | | 2.2.1 | | | | | | | | | | | | | | | | |
| g | | | | | | R2(ii) | | | | | | | | | | | | | | | | | |
| h | | | | | | | | | | | | | | R5(1)c | | | | | | | | | |
| i | | | | | | | 2.2.4 | | | | | | | | | | | | | | | | |
| j | | | | | | | 2.2.5 | | | | | | | R4(a) | | | | | | | | | |
| | | | | | | | | | | | | | | R5(1) | | | | | | | | | |
| k | | | | | | | | | | | | | | R6 | | | | | | | | | |
| l | | | | | | R3 | | | | | | | | R4(b) | | | | | | | | | |
| | | | | | | | | | | | | | | R5(1d) | | | | | | | | | |
| m | | | | | | R6 | | | | | | | | R3 | | | | | | | | | |
| 4.1 | | | | | | | | | | | | | | | | | | | | | | | |
| a | 4.1 | | | | | | | | | | | | | R11(a) | | | | | | | | | |
| b | | | | | | R4 | 2.1 | | | | | | | R11(b) | | | | | | | | | |
| c | | | | | | R4(4) | | | | | | | | R11(c) | | | | | | | | | |
| | | | | | | 4(3) | | | | | | | | | | | | | | | | | |
| | | | | | | 7 | | | | | | | | | | | | | | | | | |
| d | | | | | | | | | | | | | | R11(d) | | | | | | | | | |
| 4.2 | 9.2e | | | | | | | | | | | | | R12(1) | | | | | | | | | |
| a | 9.2e | | | | | | | | | | | | | R12(1a) | | | | | | | | | |
| b | 9.2e | | | | | | | | | | | | | R12(1d) | | | | | | | | | |
| c | 9.2e | | | | | | 2.5 | | | | | | | R12(1b) | | | | | | | | | |
| d | 9.2e | | | | | | 2.5 | | | | | | | R12(1c) | | | | | | | | | |
| 4.2 | | | | | | | | | | | | | | R12(2) | | | | | | | | | |
| 4.2 | | | | | | | | | | | | | | | | | | | | | | | |
| 4.3 | 5.1b | | | | | | 2.6 | | | | | | | | | | | | | | | | |
| 5.1 | 7.2b | | | | | R10(2) | | | | | | | | | | | | | | | | | |
| | | | | | | 24 | | | | | | | | | | | | | | | | | |
| 5.2 | | | | | | | | | | | | | | | | | | | | | | | |
| 5.3 | | | | | | | | | | | | | | | | | | | | | | | |
| a | | | | | | | | | | | | | | | | | | | | | | | |
| b | | | | | | | | | | | | | | | | | | | | | | | |
| c | | | | | | | | | | | | | | | | | | | | | | | |
| 5.4 | 7.1 | | | | | R32 | 2.7 | | 35(7)1 | | | | A16-1 | R16(1) | | 11(3) | | | | | | | D3 |
| | | | | | | 33(1) | | | | | | | | | | 457 | | | | | | | |
| 5.5 | | | | | | | | | | | | | | R3 | | | | | | | | | |

*Figure 2: Implementation of R(8101 (old recommandation) on automated medical data banks (1)*

| R (81) 1 | R (95) ? | Austria | Belgium | Bulgaria | Czech Republic | Denmark | Finland | France | Germany | Greece | Hungary | Iceland | Italy | Luxembourg | Malta | Netherlands | Poland | Portugal | Romania | Sweden | Switzerland | Turkey | United Kingdom |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 6.1 | 5.1a | | | | | | | | | | | | | R10(1) | | | | | | | | | |
| 6.1 | | | | | | R30(2) | | | | | | P16-1 | | 28-1(3) | | 456 | | | | | 8(3) | | C3 |
| | | | | | | 35 | | | | | | | | | | | | | | | | | G33(2h) |
| | | | | | | | | | | | | | | | | | | | | | | | G33(6a/h) |
| 6.1 | | | | | | | | | | | | | | | | | | | | | | | |
| a | | | | | | | | | | | | | | | | | | | | | | | |
| b | 8.2b | | | | | | | | | | | | | | | | | | | | | | B4(2) |
| | | | | | | | | | | | | | | | | | | | | | | | D7(1) |
| 6.2 | 8.3 | | | | | R30(1) | | | 35(2)(2) | | | | | | | | | | | | | | C6 |
| | | | | | | | | | | | | | | | | | | | | | | | D5 |
| 6.2 | | | | | | | | | | | | | | | | | | | | | | | |
| 7.1 | 10.1 | | | | | R(8)2 | | | | | | | | | | 454/455 | | | | | | | |
| | | | | | | 8(3) | | | | | | | | | | 556(4) | | | | | | | |
| 7.2 | 10.2 | | | | | | | | | | | | | | | | | | | | | | |
| 8 | 3.2(2nd para) | | | | | | 2.1 | | | | | P15-1 | | | | | | | | | | | |
| | | | | | | | 2.2 | | | | | P15-6 | | | | | | | | | | | |
| | | | | | | | 2.4 | | | | | | | | | | | | | | | | |
| | | | | | | | 2.4.1 | | | | | | | | | | | | | | | | |
| 9 | | | | | | | | | | | | | | | | | | | | | | | |

*Figure 2: Implementation of R(8101 (old recommandation) on automated medical data banks (2)*

### *1.3 Actual Trends: New Rules not yet adopted...but outstrip old*

The LEXIMP9 research is not sufficiently far advanced enough to establish the precise cause for the results obtained so far. What is certainly interesting is that, when pursuing the theory of obsolete/inadequate regulation, another matrix was drawn up, that reproduced in Figure 3, investigating the conformity of existing laws with the forthcoming Recommendation on protection of Medical Data **(i.e. Rec96).** This showed that more countries had provisions in their laws in line with the new recommendation (before it is formally adopted!) than there are countries with provisions in line with R(81)1, fifteen years after its adoption! Times have obviously been moving faster than the provisions of R(81)1.

This also seems to have been the gut feeling of the Council of Europe's Committee of Experts on Data Protection which, without the benefit of the 1995 results of the LEXIMP9 project, in 1990 deemed R(81)1 as being in need of overhaul and proceeded to set up a working party encharged with the task of writing the new Recommendation, to which it is now opportune to turn our attention, clearly emphasizing that, since it was adopted by the Committee of Ministers subject to the opinion of the CDSP, certain parts [10] of the Recommendation may possibly be amended before final adoption.

| R (95) ? | Austria | Belgium | Bulgaria | Czech Republic | Denmark | Finland | France | Germany | Greece | Hungary | Iceland | Italy | Luxembourg | Malta | Netherlands | Poland | Portugal | Romania | Sweden | Switzerland | Turkey | United Kingdom |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1(P) | | | | | | | | | | | | | | | | | | | | | | |
| 1(M) | | | | | | | | | | | | | 28-1(2) | | | | | | | | | |
| 1(G) | | | | | | | | | | | | | | | | | | | | | | |
| 2.1 | | | | | | | | | | | | | R1 | | | | | | | | | |
| 2.2 | | | | | | 2.2.2 | | | | | | | | | | | | | | | | |
| 3.1 | | | | | | 2.2.1 | | | | | | | | | | | | | | | | |
| 3.2 | | | | | R2 | | | | | | | | | | | | | | | | | |
| | | | | | R9 | | | | | | | | | | | | | | | | | |
| 3.2 | | | | | | 2.1.0 | | | | | | | | | | | | | | | | |
| | | | | | | 2.2.0 | | | | | | | | | | | | | | | | |
| 3.2 | | | | | | | | | | | P15-1 | | | | | | | | | | | |
| | | | | | | | | | | | P15-7 | | | | | | | | | | | |
| 4.1 | | | | | R2 | | | | | | | | R11 | | | | | | | | | |
| | | | | | R4(1) | | | | | | | | | | | | | | | | | |
| | | | | | R5(1) | | | | | | | | | | | | | | | | | |
| | | | | | R8 | | | | | | | | | | | | | | | | | |
| 4.2 | | | | | | | | | | | | | | | | | | | | | | |
| 4.3 | | | | 16 | | | | | | | | | | | | | | | | | | |
| a | | | | | | | | | | | | | | | | | | | | | | |
| bi | | | | | | 2.1.0 | | | | | | | | | | | | | | | | |
| bii | | | | | | 2.1.0 | | | | | | | | | | | | | | | | |
| biii | | | | | | | | | | | | | | | | | | | | | | |
| c | | | | | | | | | | | | | | | | | | | | | | |
| d | | | | | | | | | | | | A5-1 | | | | | | | | | | |
| 4.4 | | | | | | | | | | | | | | | | | | | | | | F33(8) |
| 4.5 | | | | | | | | | | | | | | | | | | | | | | |
| 4.6 | | | | | | | | | | | | | | | | | | | | | | |
| 4.7 | | | | | | | | | | | | | | | | | | | | | | |
| 4.7 | | | | | | | | | | | | | | | | | | | | | | |
| 4.8 | | | | | | | | | | | | | | | | | | | | | | |
| 4.8 | | | | | | | | | | | | | | | | | | | | | | |
| 5.1 | | | | | | 2.6.0 | | | | | | | R10(1) | | | | | | | | | |
| a | | | | | | | | | | | | | | | | | | | | | | |
| b | | | | | | | | | | | | | R10(1) | | | | | | | | | |
| c | | | | | | | | | | | | | | | | | | | | | | |
| d | | | | | | | | | | | | | | | | | | | | | | |
| e | | | | | | | | | | | | | | | | | | | | | | |
| f | | | | | | | | | | | | | | | | | | | | | | |
| 5.2 | | | | | | | | | | | | | R10(1)(2) | | | | | | | | | |
| 5.3 | | | | | | | | | | | | | R10(1) | | | | | | | | | |
| 5.4 | | | | | | | | | | | | | | | | | | | | | | |
| 5.5 | | | | | | | | | | | | | | | | | | | | | | |
| 5.5 | | | | | | | | | | | | | | | | | | | | | | |
| 5.6 | | | | | | | | | | | | | | | | | | | | | | |
| a | | | | | | | | | | | | | | | | | | | | | | |
| ai | | | | | | | | | | | | | | | | | | | | | | |
| aii | | | | | | | | | | | | | | | | | | | | | | |
| b | | | | | | | | | | | | | R10(2) | | | | | | | | | |
| 6.1 | | | | | P16(3) | | | | | | | | | | | | | | | | | |
| 6.2 | | | | | | | | | | | | | | | | | | | | | | |
| 6.3 | | | | | | | | | | | | | | | | | | | | | | |
| 6.4 | | | | | | | | | | | | | | | | | | | | | | |
| 6.4 | | | | | | | | | | | | | | | | | | | | | | |

*Figure 3: Conformity of existing laws with New Recommandation on protection of medical data (1)*

| R (95) 7 | Austria | Belgium | Bulgaria | Czech Republic | Denmark | Finland | France | Germany | Greece | Hungary | Iceland | Italy | Luxembourg | Malta | Netherlands | Poland | Portugal | Romania | Sweden | Switzerland | Turkey | United Kingdom |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 7.1 | | | | | | | | | | | | | | | | | | | | | | |
| 7.2 | | | | | | | | | | | | | | | | | | | | | | |
| a | | | | | P16(2)2 | | | 35(7)1 | | | | | | | 457 | | | | | | | |
| | | | | | P21(2)2 | | | | | | | | | | | | | | | | | |
| | | | | | R33(1) | | | | | | | | | | | | | | | | | |
| | | | | | R35 | | | | | | | | | | | | | | | | | |
| | | | | | R39 | | | | | | | | | | | | | | | | | |
| b | | | | | P16(2)3 | | | | | | P-15 | A17-i | | | 11 | | | | | | | |
| | | | | | P21(2)2 | | | | | | | B5(1) | | | | | | | | | | |
| | | | | | S4(1) | | | | | | | | | | | | | | | | | |
| | | | | | R37 | | | | | | | | | | | | | | | | | |
| | | | | | R38 | | | | | | | | | | | | | | | | | |
| c | | | | | P16(2)1 | | | | | | | | R16(1) | | 457 | | | | | | | |
| | | | | | P21(2)1 | | | | | | | | | | | | | | | | | D4 |
| | | | | | S4(1) | | | | | | | | | | | | | | | | | |
| 7.3 | | | | | | | | | | | | | R16(2) | | | | | | | | | |
| a | | | | | | | | | | | | | | | | | | | | | | |
| b | | | | | | | | | | | | | | | | | | | | | | |
| 7.4 | | | | | | | | | | | | | | | | | | | | | | |
| 8.1 | 71(1),1 | | | | R30 | | | | | | P16-1 | | 28-1(3) | | 456 | | | | | 8(3) | | C3 |
| | 71(1),4b,c | | | | | | | | | | | | R10(1) | | | | | | | | | G33(2h) |
| | | | | | | | | | | | | | | | | | | | | | | G33(6a-g) |
| 8.2 | | | | | | | | | | | P16-2 | | | | | | | | | | | C5 |
| a | | | | | | | | | | | | | | | | | | | | | | |
| b | | | | | | | | | | | | | | | | | | | | | | C4(1) |
| | | | | | | | | | | | | | | | | | | | | | | C5(1) |
| | | | | | | | | | | | | | | | | | | | | | | B4(2) |
| | | | | | | | | | | | | | | | | | | | | | | D7(1) |
| c | | | | | | | | | | | | | | | | | | | | | | D7(2) |
| d | | | | | | | | | | | | | | | | | | | | | | |
| 8.3 | | | | | | | | 35(2)(2) | | | | | | | | | | | | | | C6 |
| | | | | | | | | | | | | | | | | | | | | | | D5 |
| 8.4 | | | | | | | | | | | | | | | | | | | | | | |
| a | | | | | | | | | | | | | | | | | | | | | | |
| b | 71(1)2 | | | | | | | | | | | | | | | | | | | | | |
| c | | | | | | | | | | | | | | | | | | | | | | |
| ci | | | | | | | | | | | | | | | | | | | | | | |
| cii | | | | | | | | | | | | | | | | | | | | | | |
| 8.4 | | | | | | | | | | | | | | | | | | | | | | |

*Figure 3: Conformity of existing laws with New Recommandation on protection of medical data (2)*

| R (95) ? | Austria | Belgium | Bulgaria | Czech Republic | Denmark | Finland | France | Germany | Greece | Hungary | Iceland | Italy | Luxembourg | Malta | Netherlands | Poland | Portugal | Romania | Sweden | Switzerland | Turkey | United Kingdom |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 9.1 | 71(1)5 | | | | R18 | | | | | | | | R7 | | | | | | | | | |
| | | | | | R19 | | | | | | | | R8 | | | | | | | | | |
| | | | | | R20 | | | | | | | | | | | | | | | | | |
| 9.1 | | | | | | | | | | | | | | | | | | | | | | |
| 9.1 | | | | | | | | | | | | | | | | | | | | | | |
| 9.2 | | | | | R24-26 | | | | | | | | | | | | | | | | | |
| | | | | | R27-29 | | | | | | | | | | | | | | | | | |
| a | | | | | | | | | | | | | | | | | | | | | | |
| b | | | | | | | | | | | | | | | | | | | | | | |
| c | | | | | | | | | | | | | | | | | | | | | | |
| d | | | | | | | | | | | | | | | | | | | | | | |
| e | | | | | | | | | | | | | R12(1) | | | | | | | | | |
| e | | | | | | | | | | | | | R12(1a) | | | | | | | | | |
| e | | | | | | | | | | | | | R12(1d) | | | | | | | | | |
| e | | | | | | 2.5.0 | | | | | | | R12(1c) | | | | | | | | | |
| e | | | | | | 2.5.0 | | | | | | | R12(1b) | | | | | | | | | |
| e | | | | | | | | | | | | | | | | | | | | | | |
| f | | | | | | | | | | | | | | | | | | | | | | |
| g | | | | | | | | | | | | | | | | | | | | | | |
| h | | | | | | | | | | | | | | | | | | | | | | |
| i | | | | | | | | | | | | | | | | | | | | | | |
| 9.3 | | | | | | | | | | | | | | | | | | | | | | |
| 9.4 | | | | | | | | | | | | | | | | | | | | | | |
| 10.1 | | | | | | 4 | | | | | | | | | 454 | | | | | | | |
| | | | | | | 5 | | | | | | | | | 455 | | | | | | | |
| | | | | | | 7 | | | | | | | | | 56(4) | | | | | | | |
| 10.2 | | | | | | | | | | | | | | | | | | | | | | |
| 10.3 | | | | | | | | | | | | | | | | | | | | | | |
| 11.1 | | | | | | | | | | | | | | | | | | | | | | |
| 11.2 | | | | | | | | | | | | | | | | | | | | | | |
| 11.3 | | | | | | | | | | | | | | | | | | | | | | |
| 11.4 | | | | | | | | | | | | | | | | | | | | | | |
| a | | | | | | | | | | | | | | | | | | | | | | |
| b | | | | | | | | | | | | | | | | | | | | | | |
| 11.5 | | | | | | | | | | | | | | | | | | | | | | |
| a | | | | | | | | | | | | | | | | | | | | | | |
| b | | | | | | | | | | | | | | | | | | | | | | |
| 12.1 | | | | | | | A40-3 | | | | | | R13 | | 458(1) | | | | | | | |
| | | | | | | | | | | | | | R14 | | | | | | | | | |
| 12.2 | | | | | | | A40-4 | | | | | | | | | | | | | | | |
| a | | | | | | | A40-5 | 40 | | | | | R14 | | | | | | | | | |
| b | | | | | | | | | | | | | | | | | | | | | | |
| ci | | | | | | | | 40 | | | | | | | 458(2) | | | | | OALSP | | |
| cii | | | | | | | | | | | | | | | 458(2) | | | | | | | |
| ciii | | | | | | | | | | | | | | | 458(2) | | | | | | | |
| d | | | | | | | | | | | | | | | 458(2) | | | | | | | |
| 12.3 | | | | | | | | | | | | | | | | | | | | | | |
| 12.4 | | | | | | | | | | | | | | | | | | | | | | |
| 12.5 | | | | | | | | | | | | | | | | | | | | | | |

*Figure 3: Conformity of existing laws with New Recommandation on protection of medical data (3)*

## 2. New Rules: Overview

### *2.1 Scope and purposes*

The underlying scope and purpose of the new medical data recommendation (Rec96) varies greatly from R (81) 1 or any subsequent sectoral recommendations.

In the preliminary discussions leading to Rec96, the concept of "medical records" in R (81) 1 was considered to be overly restrictive in the context of electronic data processing. It was realized that the new recommendation had to go beyond the discreet relationship between the doctor and his patient, so as to cover any person likely to keep medical data [11]

"Aware of the increasing use of automatic processing of medical data by information systems, not only for medical care, medical research, hospital management and public health [12] but also outside the health care sector [13] a wider ranging protection was required.

Furthermore, the drafters of Rec96 were aware of the fact that Article 6 of Convention 108 required that "appropriate safeguards" provided for by law are required for the processing for whatever purpose of medical data.

There were however two approaches to this situation within the drafters: one approach favored a wide all encompassing provision and the other approach suggested that each purpose of medical data processing falling within the scope of the recommendation be listed.

At a later stage certain experts wished to restrict the scope of the Recommendation since, they contended, it would be impossible to apply the same provisions to medical data which, although all sensitive, do not have the same consequences for the respect of the rights and freedoms of the data subjects when they are processed. On the other hand, other experts insisted on a high level of protection, to ensure that medical data would be protected regardless of the method of processing or the person in charge. Two alternatives were therefore proposed and the final decision of the Committee of Ministers was in favor of an approach wherein Rec96 applies to all medical data, both within and outside the health sector. (The issue has been re-opened recently by the CDSP and a final decision is to be taken over the next few months).

Given this new raison d'être, a suitable definition of medical data had to be formulated.

### *2.2 Medical Data*

Indeed one of the major innovative features of the new medical data recommendation is the meaning being attributed to the term "medical data".

The importance of the new definition lies on two counts:

(i) it gives a definition which was lacking in previous legal documents
(ii) it is a definition verging on "breakthrough" status since it also incorporates a usable (though not definitive) definition of 'genetic data'

Recommendation R (81) 1 did not provide a definition of medical or health data. However, the Explanatory Memorandum of R(81)1 at point 21 explains that "the term "medical data" includes information concerning the past, present and future, physical or mental health of an individual, as well as related social or administrative information [14].There were at least two novel difficulties in finalizing this definition: whether one could define genetic data and whether this definition (if present) could, strictly speaking, be included within the notion of medical data.

Although, at one stage, it was noted that no definition of "genetic data" seemed to have been generally accepted. in Recommendation No. R(92)3 on genetic testing and screening for health care purposes, the following footnote appeared: "Genetic testing and screening can be carried out at different levels, such as on chromosomes, on genes (DNA), proteins, organs or a given individual, which can be complemented aspects of the family history." It was agreed to follow the same procedure a footnote was appended to the definition of "medical data", which, without conflicting with the footnote in Recommendation R(92)3, was less detailed.

It was later felt that the reference to the definition of "genetic data" should not be left to a mere footnote but that a suitable definition should be included in the main text of the Recommendation. Many meetings later, the following definition took shape: "The expression "medical data" refers to all personal data concerning the health of an individual. It refers also to data which have a manifest and close link with health as well as to genetic data [15].

*2.3.1 collection and/or processing: position of data handler*

Due to the sensitive nature of medical data only specific categories of people should be allowed to collect and process data. One of the arguments long advanced by doctors is that they do not need data protection because as doctors they are subject to the rules of medical confidentiality or medical secrecy as it is called in some countries (le secret medical).

The point is that medical data is today handled by many other people apart from nurses and doctors and these may include clerks, data input operators, social security advisers, insurance agents, etc. all of whom may have legitimate interests to process medical data and none of whom are subject to the same rules of medical confidentiality as doctors. It was therefore seen that this new recommendation on medical data would be introducing an additional safeguard by mandating comparable rules of confidentiality on everybody handling health-care data irrespective as to whether he is a health care professional or not. As currently drafted, the second paragraph of principle 3.2 of Rec96 underlines that in principle medical data should be collected and processed only by, or on behalf of, healthcare professionals subjected to rules of confidentiality [16].

*2.3.2 Purpose specification*
The sensitive nature of medical data, together with the requirement of appropriate safeguards, make it even more important that the purposes are defined. The way in which the legitimate purpose is specified may vary in accordance with national legislation.

*2.3.3 Purposes within permitted limits*
Principle 4.3 of Rec96 lays down when medical data may be collected:

a. if required under a legal obligation
b. if provided for by law for the purposes of
   i. the protection or the promotion of public health, or [17]
   ii. the safeguarding of vital interests of the data subject or a third person, or [18]
   iii. subject to principle 4.7, the prevention of a real danger or the suppression of a specific criminal offense [19]

In the case of "genetic data" the drafters of the recommendation consider it as an even more sensitive area of medical data and required that "for the purpose of a judicial procedure or a criminal investigation" processing should only be allowed only if specific appropriate safeguards are enacted in a specific law. Furthermore genetic data "should only be used to establish whether there is a genetic link in the framework of adducing evidence, to prevent a real danger or to suppress a specific criminal offense. In no case should they be used to determine other characteristics which may be linked genetically [20]
c. if authorized by law for preventive medical purposes or for diagnostic or therapeutic purposes with regard to the data subject or a relative in the genetic line [21].
d. if the data subject or his legal representative has given his consent. (Apart from any legal obligation or provision, medical data may also be collected and processed if the data subject - or his legal representative - has given his consent. The drafters of the Recommendation were aware that, from the point of view of protection of medical data, consent of the data subject gives fewer guarantees than legal obligations or legal provisions which - in virtue of Article 6 of the Convention - should be accompanied by appropriate safeguards.)
The issue of consent is dealt with in Chapter 6 of Rec96. There are several instances in the course of Rec96 where the data subject may or is expected to give his consent.

*2.3.4. Special attention:*

*2.3.4.1 "genetic data"*
Due to the specific sensitive nature of genetic data, further to all the conditions for collection and processing applicable to medical data, a number of additional conditions have to be respected in the collection and processing of genetic data.
Indeed "Genetic data collected and processed for scientific research, preventive treatment,

diagnosis or treatment of the data subject, should only be used for these purposes or to allow the data subject to take a free and informed decision on these matters. [22]

The problems that arise here are linked to whether a data subject should be put in a position to submit his genetic data to obtain some benefit or whether irrespective of his submission of data the benefit would still be offered to him. The Explanatory Memorandum points out [23] that "the drafters of the Recommendation emphasized that a candidate for employment, an insurance contract or other services or activities should not be forced to undergo a genetic analysis, by making the employment or the insurance dependent on such analysis, unless such dependence is explicitly provided for by law and the analysis is necessary for the protection of the data subject or a third party (e.g. work with dangerous substances)."

Principle 4.8 attempts to limit the collection and processing of genetic data for such other purposes by requiring that "in principle, [collection and processing should] only be permitted for health reasons and in particular to avoid any serious prejudice to the health of the data subject or third parties."

Furthermore, when such collection and processing is required in "order to predict [the occurrence or potential occurrence of an] illness" there must be proof "of an overriding interest or of a collective interest [24] and subject to appropriate safeguards defined by domestic law."

It is important to remember at this stage that principle 6.3 of Rec96 requires that "the results of any genetic analysis should be formulated within the limits of the objectives of the medical consultation, diagnosis or treatment for which consent was obtained."

*2.3.4.2 unborn child*

Another innovation introduced by Rec96 is that found in principles 4.4 and 4.5 which provide for data referring to unborn children:

Principle 4.4 "Medical data concerning unborn children should be considered as personal data. In respect of its medical data, an unborn child is considered to enjoy a protection comparable to the protection of a minor."

Principle 4.5 "Unless otherwise provided for by domestic law, the holder of parental responsibilities may act as the person legally entitled to act for the unborn child as a data subject [25].

Thus the person/s expected to act for the unborn child would depend in reality on the position established in the country of implementation. For example, if the mother is considered to be responsible for the unborn child then it is the mother who would be responsible. On the other hand, in the case of certain Civil law countries where a tutor or curator is appointed (e.g. "curatore del ventre"), then the tutor or curator would be the person responsible.

### *2.4 Collection and Processing*

*2.4.1 Collection from data subject unless conditions in principle 4.2 are satisfied*
"Medical data shall in principle be obtained from the data subject." [26]. There may, however, be circumstances where the data cannot be obtained from the data subject and other sources need to be consulted. Other sources may be used only if the provisions in chapters 4 (collection and processing), 6 (consent) and 7 (communication) and "if this is necessary to achieve the purpose of the processing or if the data subject is not in a position to provide the data."

*2.4.2. information for data subject*
The collector of the data should inform the data subject at the moment of collection of a number of elements listed in principle 5.1.[27] is obvious that such information is indispensable when the data subject is required to give his **informed consent.** [28]
If such data is being collected from the data subject then he should be informed individually. This requirement [29] is one of the most contested by collectors of data. Collectors of data claim that this requirement to inform individually is too time consuming. On the other hand, the data subject's right to be informed of the purposes, use and existence of his data has always been regarded as requiring such a requirement. There are instances where such requirement to inform has been interpreted widely. A mere notice of information written on some part of a collection sheet or on a public notice has been considered to suffice.
Where the data is being collected from other sources then the data subject is to be informed as soon as possible "unless this is manifestly unreasonable or impracticable, or unless the data subject has already received the information." [30]
The drafters of the recommendation recognized the fact that there are certain medical situations where the data subject should not or cannot be informed. In the spirit of Article 9 of Convention 108 which allows a number of restrictions and exceptions to the data protection principles established in the Convention, the drafters of the recommendation have allowed a number of derogation's to the duty of information.

*2.4.3 Communication*
Communication of data to other sources not contemplated in the purpose of collection is, in principle, not permitted in the field of data protection. This is even more so in the case of medical data [31]However there are certain situations where such communication can be permitted. Indeed principle 7.2 [32] holds that "medical data may be communicated if they are relevant and if" they satisfy a number of conditions namely: (i) specific provisions in domestic law; (ii) fall within the purpose for which data was collected; (iii) is required for the "public good"; (iv) the data subject has given his consent.

*2.4.4 Rights of the data subject are respected*

The "individual participation principle" is one of the most important data protection principles. An individual should have the right to know about the existence of a file containing data on himself, have access to it and furthermore can ask for the rectification or erasure of data pertaining to him. This principle poses a number of problems in the case of medical data. It has been argued that a normal data subject would be incapable of understanding medical data. Indeed, the recommendation requires that such information where given should be made "accessible in understandable form." Another issue arises where, when rendering accessible one's data, other third party's medical data can be revealed. This is especially the case for genetic data, where one's genetic code necessarily reflects that of other consanguine or uterine kin. In such cases [33] the drafters of the recommendation have permitted derogations from the right of access and rectification of individual data.

The recommendation goes a step further then the normal situations of rights of access and rectification. The drafters have identified the situation where, especially after genetic testing, where unexpected findings can result, that is, findings which were not necessarily those for which the test was made, for example, in the course of testing for the presence of a particular disease (genetic screening) one finds that in reality his parents are not the ones he has been accustomed to recognize as such. Should a data subject still have the right to access and ask for rectification of such unexpected findings? Principle 8.4 holds that "the person subjected to genetic analysis should be informed of unexpected findings [only] if the following conditions are met:

a. domestic law does not prohibit the giving of such information;
b. the person himself has asked for this information;
c. the information is not likely to cause serious harm
   i. to his/her health, or
   ii. to his/her consanguine or uterine kin, to a member of his/her social family, or to a person who has a direct link with his/her genetic line, unless domestic law provides other appropriate safeguards.

Subject to sub-paragraph a., the person should also be informed if this information is of direct importance to him/her for treatment or prevention [34].

*2.4.5 Conservation*

As pointed out in the Explanatory Memorandum [35], as a general rule, medical data must not be stored longer than is strictly necessary," for this could prove to be a threat to the data subject's privacy if information relating to any individual is allowed to accumulate as the years go by. "However, the interests of public health, scientific research, the treating physician, the controller of the file or historical or statistical reasons may require the long term conservation of medical data, even after the death of the persons concerned." When such conservation is necessary appropriate archival security should be ensured.

*2.4.6 Special Provisions*

*2.4.6.1 Transborder data flows*

With the increased mobility of people within Europe for employment, business, or other reasons the necessity of personal data being exchanged between different nations has increased. Furthermore due to the importance of medical data, especially since an individual's life may depend on the rapid and uncomplicated communication of his medical data and on the other hand the great risk the individual can be exposed to if his medical data is not taken care of, the drafters of Rec96 attempted to set out appropriate guidelines [36]within which data can or should not be transferred [37].

*2.4.6.2 Medical Research*

Some of the most effective lobbying on the drafters of the new Recommendation was made by members of the medical research community. The latter succeeded in keeping their options open when anonymisation of medical data "would make a medical research project impossible". In such cases, research could be effected if the data subject has given his consent or if the purpose of a defined medical project has been duly authorized, subject to non-objection by the data subject. or the research is provided for by law and constitutes a necessary measure to protect or promote public health.

Importantly, healthcare professionals, entitled to carry out their own medical research, should be able to use medical data which they hold as long as the data subject has been informed of this possibility and has not objected.

***2.5 Conclusions***

It is impossible to do justice to a complex set of new rules in such a short space as afforded by this paper, which can only attempt to take the reader through the bare outlines of the new recommendation on the protection of medical data. The new rules described above are being proposed to regulate a situation where the reality has shifted from large centralized and easily controlled systems to distributed processing with growingly large numbers of PCs which may or may not be connected to other systems on LANs, WANs, or via various other means. It is all very well to lay out well-intentioned rules on, say, transborder data flows, requiring minimum levels of data protection standards, but are all of these rules practical, and therefore enforceable? Can one really police the telephone lines to ensure that no transborder flow of medical data is flowing to countries which do not meet European standards of Data Protection? Where does one draw the line between effective, reasonable levels of data protection and pious hopes? The LEXIMP9 project has revealed that only a tiny minority of European states have attempted to translate the old 1981 Medical Data Bank Recommendation into law, let alone enforce the various provisions. Will Rec96 meet the same fate and remain, to all intents and purposes, a dead letter? A lot of time and effort has been put into the new set of rules but the onus lies on the Governments within the member states. Even those states bound by either the EU Directive or Convention 108 are not compelled to adopt Rec96 but may choose to rely

on their generic legislation to the extent that they may claim this meets their international obligations. In the final analysis, however influential, a Recommendation does not have the same compelling force as an EU Directive: Member states can nearly afford to ignore it. Will they?

## References

[1] Rec96" is not the official designation for the Recommendation but is being used here for handy reference. This Recommendation is still awaiting adoption and its official designation would be a equential number allocated at the time of formal adoption by the Committee of Ministers of the Council of Europe.

[2] The formal title of European Treaty Series No.108 is the Convention for the Protection of Individuals with regard to the automatic processing of personal data

[3] Article 8 of the European Convention on Human Rights is also kin to Article 17 of the International Covenant on Civil and Political Rights;

[4] Once integrated into the form of a Directive, these rules become binding upon the member states of the European Union.

[5] For a more detailed synopsis of the implications of the Bioethics Convention see KNOPPERS Bartha Maria, "Confidentiality in Genetic Testing: Legal and ethical issues in an International Context", Medicine and Law, Vol.12, pp.507-519, South Africa 1993,

[6] Art.6, Convention 108, Art.8 EU Directive

[7] This recommendation has had a chequered history: developed over 5 years at the end of a process which included 5 meetings of a six-nation Working Party, 5 meetings of a five-nation CJ-PD Bureau, 4 meetings of a 34 country plenary CJ-PD, submission to the European Steering Committee for Legal Affairs (CDCJ), review by the European Steering Committee on Bioethics and the European Health Committee (CDSP), prior to final submission to the Committee of Ministers. At the time of writing, (April 1995, revised September 1995) the Recommendation was the subject of comments by the CDSP prior to final adoption. The CDSP's opinion was examined by the CJ-PD Bureau during its September meeting and is now expected to be re-examined by the CJ-PD Plenary in November 1995. The process for final adoption is expected to be concluded by late 1996.

[8] While possibly a trifle disheartening from a Euro-regulator's point of view, this attitude is not altogether surprising and should not be too discouraging. On the one hand, the national official's primary concern is the implementation and enforcement of the national law. It is the legislator's responsibility, and specifically the Government to whom the Recommendation is addressed, to amend the national law in order to align it with European regulations.

[9] The LEXIMP 9 Project has a number of objectives short and long-term: these include overviews of current legislation to be matched against R(81)1 and the new Recommendation (Rec96) and, long-term, an on-going assessment of level and rate of take-on of Recommended provisions.

[10] At September 1995, the parts subject to substantial (as opposed to cosmetic/ clarification) amendment appear to be restricted to Principle 2.1 (Scope) wherein the CDSP is proposing that the Recommendation's application to medical data outside the health care sector is at the State's option rather than being mandatory.

[11] point 33 Explanatory Memorandum Doc. Ref. Addendum II to CDCJ(94)85

[12] these were the limits of the scope of R (81)

[13] Preamble to the draft recommendation Doc. Ref. CDCJ (94) 85

[14] There was no definition as the recommendation was intended to provide protection for "medical records" and not "medical data" at large.

[15] The text of Rec96 now also includes the following definition: "genetic data" refers to all data, of whatever type, concerning the heritable characteristics of an individual or on the pattern of inheritance of such characteristics within a related group of individuals. It also refers to all data on the carriage of any genetic information (genes) in an individual or genetic line relating to any aspect of health or disease, whether present as identifiable characteristics or not. The genetic line is the line constituted by genetic similarities between two or more individuals created by procreation."

[16] "In principle medical data should be collected and processed only by health-care professionals or by individuals or bodies working on behalf of health-care professionals. Individuals or bodies working on behalf of health-care professionals who collect and process medical data should be subject to the same rules of confidentiality incumbent on health-care professionals, or to comparable rules of confidentiality ". Doc. Ref. CDCJ (94) 85

[17] One could mention here the various national legislations requiring medical practitioners to disclose information about individuals who are under his/her medical care and discovered to be infected with some contagious or infectious disease.

[18] This is especially useful in the situation where the data subject is not in a position to give his consent nevertheless medical data may have to be collected to safeguard his "vital" interests.

[19] Here the wording of this provision is closer to that found in Recommendation no.R(87) 15 regulating the use of personal data in the police sector. Principle 2.1 of that Recommendation excludes an open-ended, indiscriminate collection of data by the police.

[20] principle 4.7 Doc. Ref. CDCJ (94) 85

[21] The Explanatory Memorandum points out that "authorised by law" here can be both "explicitly or tacitly" [point 77 Doc. Ref. CDCJ (94) 85]

[22] Principle 4.6 CDCJ (94) 85

[23] Point 95-96

[24] Explanatory Memorandum at point 96 Doc. Ref. CDCJ (94) 85

[25] Doc. Ref. unchanged since CJ-PD (93) 37

[26] Principle 4.2 Doc. Ref. CDCJ (94) 85

[27] Principle 5.1:
The data subject shall be informed of the following elements:
a. the existence of a file containing his medical data and the type of data collected or to be collected;
b. the purpose or purposes for which they are or will be processed;
c. where applicable, the individuals or bodies from whom they are or will be collected;
d. the persons or bodies to whom and the purposes for which they may be communicated;
e. the possibility, if any, for the data subject to refuse his consent, to withdraw it and the consequences of such withdrawal;
f. the conditions under which the rights of access and of rectification may be exercised

[28] Explanatory Memorandum point 98 Doc. Ref. CDCJ (94) 85.

[29] Principle 5.3
[30] Principle 5.2
[31] Principle 7.1
Medical data should, in principle, not be communicated, unless on the conditions set out in this Principle 7 and Principle 12 [dealing with medical data collected and used in medical research].
[32] Doc. Ref. CDCJ (95) 84
[33] Only in a number of limited cases: principle 8.2
[34] Doc. Ref . CDCJ(94)85
[35] Point 172 and 173 Doc. Ref. CDCJ (94)85
[36] cf. chapter 11 of recommendation Doc.Ref. CDCJ(94)85
[37] It is interesting to remember that R (81) 1 had no provision for transborder data flows notwithstanding the fact that its parent legislative act: Convention 108 dedicates considerable attention to transborder data flows. principle 4.7 Doc. Ref. CDCJ (94) 85

## Correspondence address

J.A. Cannataci, Law and Information Technology Research Unit, Center for Communication Technology, University of Malta, New Humanities Building, room 209-210, Tal-Qroqq Campus, Msida, MSD 06 Malta