Healthgrid from a legal point of view

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9. Healthgrid from a Legal Point of View

The introduction of grid technology in the health care sector may appear to be only of technical significance and, in any event, without any legal relevance. It appears only to concern a uew computing technology participating in the provision of healthcare services and in scieutific research, mostly by providing huge computing and memory resources, possibly internet based. The first projects deal with medical imaging, medical tele-assistance, medical or pharmaceutical research, human genomic studies, and the creation of databases for therapeutic, scientific, statistical or epidemiologieal purposes.

However these projects are ruled by radically different legal contexts. Indeed, distinct legal rules govern the practice of medicine, scientific and pharmaceutieal research, epidemiologieal studies, even if all these diseiplines contribute to medical progress.

Hence there is no unique answer to the determination of the legal framework in which healthgrid technology may be implemented and used. In reality, the answers are multiple and depend on the context of each project as well as on the considered legal viewpoints. Healthgrid technology must conform to the legal context specific to each project aiming at its implementation.

Nevertheless describing the different legal contexts in which healthgrid technology might be implemented is not sufficient. The adequacy of the legal context coupled to the characteristics of this particular technology should also be evaluated. In other words, one should question whether certain rules should not (have to) be adapted with respect to healthgrid technology.

9.1. HEALTHGRID TECHNOLOGY'S STATUS

Technologies must frequently comply with precise technical norms with a view to their legal utilization. The same assertion is also valid for the health care sector. It is therefore important to define the content of the technieal norms relevant to each project.

In this matter, some technical norms have been harmonized at an international or European level. With respect to this, it is useful to note that the European Committee for Standardization has issued a very interesting study entitled "*European Standardization of Health Informatics – Results of the mandated work by CEN/TC 252*" (CEN TC 251/N01-024 – 2001-06-17).

The European Union has also adopted several rules concerning medieal devices:

- Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active inplantable medical devices.
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

It is hence required in each project to:

- determine the technical norms applicable to healthgrid technology in the project under consideration, depending on the national legal orders likely to rule it;
- verify the adequacy of these technical norms.

The Council of Europe states that the improvement of hnman life quality and the respect of human rights should prevail when dealing with new technologies. It namely recommends in this regard that the precise evaluation of any technology should as much as possible rely on the following criteria (cf. Recommendation (90) 8 of 29 March 1990 on the inpact of new technologies on health services, particularly primary health care):

- Validity of outputs,
- Validity of data capture,
- Ability to fit within the framework of primary health care,
- Social acceptability,
- Ethical acceptability,
- Professional acceptability,
- Reliability,
- Capacity for continuous assessment,
- Safety for providers, consumers and the environment,
- Cost effectiveness compared to older technologies,
- Availability of full information on the technology and experience in implementing it,
- Protection of confidentiality,
- Ability to be integrated smoothly into existing systems,
- Availability of adequate resonrces.

This evaluation should consist of appropriate studies giving conclusive results, and shonld be carried ont prior to the general introduction of any new technology.

9.2. STATUS OF THE PROCESSED PERSONAL DATA

Most of healthgrid technology-related projects imply personal data processing for therapeutic purposes or scientific research (e.g. medical imaging, tele-assistance, medical or scientific research, human genomic studies, creation of healthgrid databases).

However personal data processing is subject to numerous regulations. Indeed, these data are particularly sensitive and consequently require high protection. Furthermore, because of the therapeutic or scientific stakes, personal data processing must be reliable, or it may lead to medical errors or erroneous scientific results.

On the international level many norms govern personal data processing (including the processing of personal data related to health).

Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms is particularly to the point in this respect.

In the case M.S. v. Sweden of 27 August 1997 (74/1996/693/885) (§ 41), the European Court of Human Rights vigorously stated that "(...) *the protection of personal data, particularly medical data, is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the Convention. Respecting the confidentiality of health data is a vital principle in the legal systems of all the Contracting Parties to the Convention. It is crucial not only to respect the sense of privacy of a patient but also to preserve his or her confidence in the medical profession and in the health services in general. The domestic law must afford appropriate safeguards to prevent any such communication or disclosure of personal health data as may be inconsistent with the guarantees in Article 8 of the Convention. (Case Z. c Finlande of 25 February 1997, 1997-I, p. 347, § 95).*"

Article 7 of the Charter of Fundamental Rights of the European Union similarly confirms the right to privacy while Article 8 establishes the right to the protection of personal data.

The Council of Europe has issued important norms relative to personal data processing. Its Convention for the protection of individnals with regard to automatic processing of personal data (28 January 1981) (Treaty n° 108) represents a significant source for all member states.

The Council of Europe has also adopted specific recommendations concerning personal data processing involved in projects implementing healthgrid technology:

- Recommendation (83) 10 of the Committee of Ministers on the protection of personal data used for scientific research and statistics, adopted on 23 September 1983.
- Recommendation (90) 8 of 29 March 1990 on the impact of new technologies on health services, particularly primary health care.
- Recommendation (97) 5 of the Committee of Ministers to Member States on the protection of medical data, adopted on 13 February 1997.
- Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine (Treaty n° 164) (4 April 1997).
- Recommendation (97) 18 concerning the protection of personal data collected and processed for statistical purposes, adopted on 30 September 1997.
- Recommendation n° R (99) 5 of the Committee of Members to Member States for the protection of privacy on the Internet – Guidelines for the protection of individnals with regard to the collection and processing of personal data on information highways, adopted on 23 February 1999.
- Recommendation 2/2001 on certain minimum requirements for collecting personal data on-line in the European Union, adopted on 17 May 2001.

The Council of Europe recommends that specific models designed to ensure confidentiality of patient information should be developed in relation to the application of information technology to health care systems (cf. R (90) 8 of 29 March 1990, *op cit*, point 8 of the Guidelines).

In the extent of its attributions, the European Union has adopted special norms relative to personal data processing, namely:

- Resolution of the Council and of the Representatives of the Governments of the Member States, meeting within the Council, of 29 May 1986, concerning the adoption of a European emergency health card.
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communieations sector (Directive on privacy and electronic communications).

The European Group on Ethics has adopted an important opinion concerning the processing of personal data related to health (cf. Opinion of the European Group on Ethics in Science and New Technologies to the European Commission, Ethical issues of healthcare in the information society, n° 13, 30 July 1999).

The World Medical Association has issued several documents of interest to some healthgrid projects:

- Declaration on the patient's rights (World Medical Association Declaration on the Rights of the Patient, adopted by the 34th World Medical Assembly Lisbon, Portugal, September/October 1981 and amended by the 47th General Assembly Bali, Indonesia, September 1995);
- Guidelines concerning the practice of Telemedicine (World Medical Association Statement on Accountability, Responsibilities and Ethical Guidelines in the Practice of Telemedicine, adopted by the 51st World Medical Assembly Tel Aviv, Israel, October 1999);
- Declaration on Ethical considerations regarding Health Data Bases (adopted by the WMA General Assembly, Washington 2002);
- Declaration on Ethical Principles for Medical Research involving Human Subjects (adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975 35th WMA General Assembly, Venice, Italy, October 1983 41st WMA General Assembly, Hong Kong, September 1989 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996 and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000 Note of Clarification on Paragraph 29 added by the WMA Geueral Assembly, Washingtou 2002).

National norms on personal data processing must comply with this international framework, although a certain margin is generally allowed to member states in their implementation. This may cause some disparity in national norms in this matter, adding to the existence of natioual norms for which no international rules exist and upon which member states are free to decide.

In any case it is of prime interest to qualify correctly any operations carried out on personal data when using healthgrid technology and to define the role of each person involved (health care practitioners, service providers, patient, etc.).

From a technieal viewpoint, PETs (see chapter 8) offer very strong support to the security and the confidentiality of the processed personal data. They aim to reduce the processing of personal data and to suggest appropriate measures to secure data processing.

9.3. HEALTHGRID SERVICES' STATUS

Some projects aim at providing services to health care professionals or to scientists. These services must be qualified according to the norms applicable to 'information society' services.

An information society service is any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.

- ***"At a distance"*** means that the service is provided without the parties being simultaneous present. Services provided in the physical presence of the provider and the recipient, even if they involve the use of electronic devices are not provided "at a distance".
- ***"By electronic means"*** means that the service is sent initially and received at its destination by means of electronic equipment for the processiug (including

digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means. Services that are not provided via electronic processing/inventory systems are not services provided "by electronic means" (e.g. telephone/fax consultation of a doctor).

- ***"At the individual request of a recipient of services"*** means that the service is provided through the transmissiou of data on individnal request.

Information society scrvices also include services consisting of the transmission of information via a communication network, in providing access to a communication network, or in hosting information provided by a recipient of the service.

Activities which by their very nature cannot be carried out at a distance and by electronic means, such as medical advice requiring the physical examination of a patient are not information society services.

The taking up and pursuit of the activity of an information society service provider may not be made subject to prior authorization or any other requirement having equivalent effect (art. 4.1 of D 2000/31/EC of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market – Directive on Electronic Commerce). The service provider must therefore comply with a number of special rules when offering information society services.

This provision of services may result from a contractual relationship. The latter must be analysed on an individual basis in each project. In case of an international situation, when providing information society services, one should preliminarily examiue what are the competent jurisdictions before defining the law applicable to the contractual obligations of the parties.

Several international instruments can be mentioned in this regard:

- Convention on the law applicable to contractual obligations opened for signature in Rome on 19 June 1980 (80/934/EEC).
- Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures.
- Directive 2000/35/EC of the European Parliament and of the Council of 29 June 2000 on combating late payment in commercial transactions.

9.4. END-USER'S STATUS

The use of healthgrid technology by health care professionals raises special questions. Ou one hand, is the end-user legally authorized to use the healthgrid technology? Is the ıse of healthgrid technology permitted in medical practice or in seientific researeh? The answer lies in the rules governing the professional activities of the end-user.

Concerning some projects, it is useful to remember that the European Union has ıdopted the Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions ıf member states relating to the implementation of good clinical practice in the conduct ıf clinical trials on medicinal products for human use.

On the other hand, in case of medical tele-expertise, medical tele-consultancy, or nedical tele-assistance, involving healthcare practitioners from different member states, he question is to know if the health care practitioner in charge of the patient is legally ıuthorized to seek the assistance of a foreign healthcare practitioner, and, if positive, ınder which conditions.

Simultaneously this foreign healthcare practitioner should also find out whether he is legally authorized to provide assistance to a healthcare practitioner located in another country.

Beyond the determination of the persons liable in case of medical accident or fault, one must define the status of the health care practitioner participating to the provision of health care in another member state, and the status of the healtheare practitioner having asked his assistance. This problem is far beyond the simple question of medical qualification equivalency.

In the same way, the cooperation between health care practitioners inside a same member state or from different member states raises the very delicate question of the legal framework of this cooperation.

9.5. PATIENT'S STATUS

Implicitly or explicitly all the healthgrid projects aim to participate in the search for medical progress as well as in its preventive and curative aspects. Hence the patient is very much at the heart of the implementation of healthgrid technology.

The Council of Europe is clear on the patient's interest in his active participation in his own treatment (cf. Recommendation R (80) 4). The legal qualification of the parties involved in the processing of the patient's personal data, including the place of the patient, is likely to highlight some tensions underlying the medical relationship.

9.6. LIABILITY ISSUES

The question of the determination of the persons liable in case of medical accident or fault relative to the use of healthgrid technology when providing health care to a patient is crucial but delicate. In case of an international situation, the question is far more complex. With respect to this, one shonld take into account several factors which are not necessarily likely to be under complete control.

The first element of uncertainty results from the determination of the possible jurisdictions likely to recognize the case. With respect to this, the European Union has recently adopted the Council Regnlation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters. The determination of the jurisdiction will permit to determine the law applicable to the case.

The European Union has adopted some norms relative to the matter of liability:

- European Convention on Products Liability in regard to Personal Injury and Death (Council of Europe, Treaty n° 91, adopted on 27 January 1977);
- European Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products.

It has to be remembered that the European Union has also adopted special rules concerning the resolution of disputes:

- Council Decision 2001/470/EC of 28 May 2001 establishing a European Judicial Network in civil and commereial matters. Its objectives are to improve effective judicial cooperation between member states and effective access to justice for persons engaging in cross-border litigation;

- Council Regulation (EC) No 1206/2001 of 28 May 2001 on cooperation between the courts of the member states in the taking of evidence in civil or commercial matters.

Mention should also be made of alternative dispute resolution and on-line dispute resolution.

9.7. IPR AND COMPETITION ISSUES

The creation and the use of healthgrid technologies may raise important Intellectual Property Rights (IPR) questions. Indeed, healthgrid technologies are sometimes created like patchworks. This poses the question of the IPR relative to the constitutive elements of the 'patchwork' under consideration.

The European Union has adopted several Directives concerning IPR issues:

- Council Directive 91/250/EEC of 14 May 1991 on the legal protection of computer programs;
- Council Directive 92/100/EEC of 19 November 1992 on rental right and lending right and on certain rights related to copyright in the field of intellectual property
- Council Directive 93/98/EEC of 29 October 1993 harmonizing the term of protection of copyright and certain related rights;
- Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases;
- Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the informatiou society;

Usually projects aimiug at implementing healthgrid technology bring together several partners into consortium. Their behaviour also has to comply with competition law (Monopolistic positions, abuse of dominant position, concerted practices).