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**PISA, 5<sup>TH</sup> AND 6<sup>TH</sup> JUNE 2009:**  
*MEDICAL LIABILITY AND MEDICAL ACCIDENTS  
COMPENSATION - FROM THE BLAME GAME TO  
INDIVIDUAL RIGHTS PROTECTION IN THE PROVISION  
OF MEDICAL SERVICES*

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**Abstract**

The LIDER-Lab of the Scuola Superiore Sant'Anna hosted, from 5th to 6th June 2009, the International Workshop "Medical liability and medical accidents compensation. From the blame game to individual rights protection in the provision of medical services", a subject highly debated in the current European context. This paper gives a summary of the papers presented at the Workshop and of the two days of interdisciplinary discussion among international experts.

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The LIDER-Lab of the Scuola Superiore Sant'Anna hosted, from 5th to 6th June 2009, the International Workshop "Medical liability and medical accidents compensation. From the blame game to individual rights protection in the provision of medical services", a subject highly debated in the current European context. Indeed the cross border, and indeed ocean, aspect of this topic was well represented by the array of papers submitted for the event from far and wide.

The Director of the Scuola Superiore Sant'Anna, Prof.ssa Maria Chiara Carrozza, opened the workshop by welcoming the public and emphasising the importance of the event and of the central theme. Prof. Giovanni Comandè (LIDER-Lab, Scuola Superiore Sant'Anna, Pisa) introduced the Workshop, observing that the order of the presentations during the two days was specifically designed in order to develop our understanding of the issues "from the top to the bottom" – positioning the audience at the top of the Leaning Tower of Pisa so that when looking down one can appreciate the larger context by observing the connection and inter-relation of specific points.

The first day of presentations was entitled "Mechanisms for the protection of patients and the compensation for harm: circulating models, integrating them".

Patrizia Di Benedetto, representative of ISVAP, the National Agency supervising the insurance market in Italy, introduced the first paper. She focused on the Italian sector of insurance coverage against civil liability for losses or damages caused by medical malpractice or, more generally, for damages afflicted in a healthcare institution.

In Italy nowadays, the Agency is registering a peculiar phenomenon: while the insurance market in this field is shrinking, the demand for medical coverage by healthcare providers is increasing. The reasons for the increase in demand for insurance products for medical damages can be summarised in the following: the cultural changes in society; the case-law which has broadened the scope of liability and the range of people liable to compensate; and the increasing importance of the right to health.

In the opinion of the discussant, the apt solution in closing the gap between the healthcare sector, and its need to be insured, and the general drift of the insurance market away from healthcare insurance in order to avoid healthcare damages, is not the introduction of a compulsory coverage and/or of an obligation for the undertakings to provide insurance products. On the contrary, the solution should be found with the collaboration of all the market participants, in order to bring into effect a broad set of measures aimed at mitigating the difficulties of the insurance market. The paper stressed that it is important to focus on both "risk management" and "risk assessment".

Finally, everybody agreed that there are two important actions that must be taken immediately: 1) the creation of an efficient database capable of registering all the cases of medical malpractice at national level; 2) the adoption of regulatory tables of disability points, to guarantee uniform criterions for compensation.

Indeed it was observed that a suitable basis for this could be the Permanent International Observatory on Personal Injury Damages which the ISVAP and the Scuola Superiore Sant'Anna have established ([www.lider-lab.org](http://www.lider-lab.org)).

All the participants shared the perception that patient safety is an emerging patient right. Herman Nys (University of Leuven, Belgium) pointed out that one of the means to promote patient safety is the reporting of adverse events by health personnel, a premise also evident in Recommendation 2006 (7) of the Council of Europe. This document was juxtaposed, by the discussant, with the Danish Patient Safety Act and the Belgian Bill (2009) amending the Hospitals Act to introduce a reporting system. Nys opened the evening debate with questions related to the reporting of adverse events: should it be mandatory or voluntary? Related to litigation or "blame free"? If "blame free" how to balance it with the rights of patients to be informed and to be compensated? By

exemplifying the Danish Act, differences between the Recommendation and actual Danish practice became apparent. Particularly, the discussant demonstrated that mandatory reporting, as practiced in Denmark, is well received by society, contrary to the indication of the Council of Europe (that reporting should preferably be voluntary). Cultural aspects also influence the implementation of compensatory systems. Nys's concluding remarks stressed that Danes are a law-abiding society accepting the need for social order, a strong social security network, and a broad tolerance for diversity. As a result of this, he affirmed that their innovative approach to patient safety, by constructing separate pillars, i.e. patient compensation, professional discipline and the reporting of adverse events, is in fact fundamental to the 'buy-in' of health professionals in Denmark.

The discussion crossed European frontiers and arrived at New Zealand's no-fault system. Ken Oliphant (Institute for European Tort Law, Vienna) presented the three stages in which accident compensation was developed there, showing the different ideologies and ambiguous definitions concerning concepts such as "medical misadventure", "personal injury by accident", "medical error" and "medical mishap" (and, here, how to define elements of "rarity" and "severity" in medical treatment), and the difficulties these terms introduced in the Courts. The stages expose the improvement of the no-fault system in New Zealand, introduced by the Accident Compensation Corporation (ACC) on April 1974. Oliphant pointed to the idea of community responsibility inside New Zealand society, with an emphasis on causal responsibility for medical injuries, rather than obligations of social solidarity as such. He affirmed that a system-based approach now prevails, based on collective action rather than individual responsibility. The New Zealand's no-fault system was also one of the examples of the last presentation of the day, showing the interconnection between the subjects presented in the workshop.

According to Ewa Baginska (Nicolaus Copernicus University, Torun, Poland), the differentiation between patients' rights considered as personality rules (values) or as subjective rights aimed at the protection of personality interests (values) has always been a bone of contention in Polish legal doctrine. She exposed that the legal status of the patient is subjected to public law rules, a concept still strongly supported by doctrine, in particular in the former socialist countries. The discussant emphasised the link between patients' rights and personality rights, giving examples of how their violation and consequent compensation requests were decided by Polish Courts. She also discussed the differences among European countries with respect to compensation for non-pecuniary loss in non-personal injury cases, arguing that a person harmed by a violation of their rights as a patient, even though no material damage ensued, should have an explicit claim for pecuniary compensation.

The compensation of medical mishaps in French legislation was presented by Sophie Hocquet-Berg (Université Paul Verlaine de Metz, France), who explained how the new principle of national solidarity passed from a complementary procedure to an alternative procedure within the compensation system. She illustrated that the 2002-303 Act introduced two joint procedures for the identification of harms: the first one based on civil liability, the second one on a new principle of national solidarity. The current problem, according to the speaker, revolves around a sort of deviation from the initial proposal of this system. She observed that in the name of national solidarity, society as a collective group is now liable for part of the insurance premium, a development not met with much enthusiasm by Hocquet-Berg herself, who instead believes that insurance policy premiums should not be paid by society, since these premiums are linked to the practice of a private profession. In this sense, society should never stand for the person who caused the harm and replace his or her insurer, be it totally or partially. That is, when an accountable person is let off without any sanction, national solidarity should not be a cover-up for such immunity. Hocquet-Berg exposed that the National Indemnification Agency was bestowed

117 millions of euro in 2009, and that the share of this public money which is devoted to the victims that cannot claim compensation in civil liability is spent with a genuine sense of collective assistance. However, she concludes, “the portion of these funds which society uses to pay the damages that should be disbursed by the accountable or their insurers does not match our own vision of solidarity”.

The French panel was followed by another aspect of medical accident discussion: the patient’s understanding of their medical condition. Brenda Dayle (Dublin City University, Ireland) highlighted a different goal of claimants in medical accident cases, illustrating that grievances are pursued not only in terms of financial compensation, but also in terms of norms relating to integrity, apology, or improvement in future patient care. According to the discussant, seeking an explanation is one of the main objectives of claimants. Dayle analysed the no-fault systems in New Zealand and Sweden, questioning if these systems could be implemented in the UK. She came to the conclusion that both systems – with some particularities differing among them – could not address properly these alternative objectives. For her, the adoption of a no-fault system in the UK would not be more effective than the current tort system, particularly with regard to the claimant’s objectives because the introduction of this scheme would interfere with the claimant’s right to take legal action. It would usurp the right to a fair trial and, according to Dayle, this is contrary to the provisions of the Human Rights Act 1998 and established human rights jurisprudence in the UK.

Beside the culture remarks related to the introduction and acceptance of no-fault systems in the countries analysed, the discussants also raised issues relating to the difficulties concerning information during medical process, especially between the physician and the patient. The contribution of the audience who attended the workshop (jurists, economists and medical doctors) enriched the discussion, allowing the juxtaposition of the position of physicians outlining the difficulties they face in providing prompt information, and that of others present who argued that dialogue between professionals and patients forms the base of a relationship founded on trust and solidifies the informational medical process. The aspect of timing in giving this information was strongly discussed.

The theme of the second day of discussion (chaired by Luigi Arru, President OMCeO Provincia di Nuoro) was: “Patients rights in cross border delivery of medical services – The role of access and use of personal data concerning health” and was developed through the discussion of four papers.

The first paper was presented by a panel of economists including: Giuseppe Turchetti (Scuola Superiore Sant’Anna), Elie Geisler and Nilmini Wickramasinghe (both from the Center for the Management of Medical Technology, Stuart School of Business, Illinois Institute of Technology, Chicago, USA). The authors outlined interesting research conducted on the American experience, concentrating on the interstate delivery of healthcare and the growing efforts of the Obama administration in establishing a nationwide technological system of Computerised Medical Records (CMR). This innovation involves the transfer of paper-based medical notes, data and other clinical information relating to a patient’s medical experience to electronic format.

The implementation and adoption of the CMR in the U.S.A. has been very slow, placing the nation far behind Australia, Canada, Finland, Israel and the United Kingdom. Given this situation, the study identified six categories of barriers to the adoption and implementation of the CMR evident in all the developed countries where the new system is being implemented, but that are particularly present in the United States. The first category is represented by political barriers, including the different priorities and policies of healthcare providers, municipalities, state governments and the federal government. The American political system is very complex and this situation represents a significant

problem in the elaboration of unified standards. In particular, each individual state has competence in regulating the health care system and the health care insurance industry, allowing each state the privilege of applying its own political interest and standards of care inside its boundaries. The economic barriers represent the second category. This revolves around the substantial expenses involved in installing CMR systems, training the clinical and administrative staff and integrating the system with other information technologies. The CMR system is in fact, a complex innovative technological system that requires massive investments and a comprehensive program of adoption, interaction and constant updating. This aspect leads to the third set of barriers, concerning the technical problems related to the complexity of the CMR system and the difficulties of integrating it with the other existing, more obsolete, information systems. A related technical issue is the security of the data, fundamental in order to protect patients' rights. The fourth issue is the complicated web of local, state and federal regulatory agencies that control the healthcare services. The care providers have to comply with all the different levels of regulations, thus they are reluctant to introduce another system, such as CMR. The last set of barriers concerns issues of privacy and confidentiality of medical records. The introduction of the CMR system implies that intimate details of a patient's medical history and personal life are coded into the electronic information-base so that they will be available to a large network of providers, regulators, insurers and regulatory agencies. In particular, the paper focused on this last set of barriers, attempting to answer the key following questions: who owns the information? Who controls the management of the data? Who is responsible for an eventual breach of privacy and confidentiality? The panel identified five categories of threats to patients' privacy and confidentiality that clinicians and administrators perceive in the CMR system. The first concerns the complexity of health information that will be stored on the system and the possibility of loss or corruption of this data. The intricacy of the CMR system, the lack of uniform standards and measures to protect the content lead to the second issue, which can be summarised as problems in the organisation, control and management of the data. The third threat concerns the ubiquitous use of CMR and the difficult interpretation of state and federal regulations, since both states and federal government have jurisdiction over privacy and confidentiality of medical records when they are exchanged across the state borders. The fourth problem is the misinterpretation and incorrect match of medical information. However, the most important set of problems that must be solved concern the legal responsibility of CMR users in relation to errors in managing the data and unauthorized use, as well as liability for violating the different local and federal rules, and the ethical issues related to the breach of patients' confidentiality. The analysis of the American system led the experts to sketch different crucial points and to explore interesting solutions that might give better insight to the European Union in developing a similar system.

The second paper presented by Jasminka Katić Bubaš (Ministry of Health and Social Welfare, Republic of Croatia) contributed further to the debate on the EU legal system, outlining the Croatian legislation concerning patients' rights and medical liability. In 2004, Croatia enacted the first law regulating patients' rights: the *Act on the Status and Rights of Patients*. This Act has established nine fundamental rights of patients: to join the decision making process and to be informed; to accept or refuse a medical procedure; to voluntarily discharge oneself from a medical institution; to privacy; to confidentiality; to be protected while participating in clinical testing; to keep personal contacts; to access medical documents; to compensation. The *Act of the Status and Rights of Patients* focuses on two different levels of the system of patients' rights protection: the regional level, with a *Commission for the Protection of the Rights of Patient* active in each county and the *Commission for the Protection and Promotion of the Rights of Patients* of the competent Ministry. As the speaker stressed, the Croatian patients' rights protection system is based on the right to be

informed. The patient, in fact, is entitled to have feedback at any given moment of the monitoring procedure on the care provider.

In consideration of patients' migration across Europe, Bubaš underlined that Croatia recognises the same rights even to non-citizen patients, in accordance with the principles of equality, egalitarianism and health care availability, coded in the *Act on the Health Care of Foreigners*. Croatia has also stipulated contracts on social insurance with a large number of countries, besides the agreement on the use of the European Health Insurance Card that was signed with some EU countries. The Croatian Constitution considers these agreements as *lex specialis*.

The paper also focused on the relationship between patients' rights protection and medical responsibility. The Croatian legal system acknowledges different types of medical responsibility: the Disciplinary responsibility; the Offence responsibility; the Criminal responsibility; and the Civil and Legal responsibility. It is worthwhile to point out that the amended *Civil Procedure Act* (2008) introduced the provision of an obligatory request for mediation, so that a person who wants to file a suit against a health institution is required to file a claim for mediation to the Public Prosecutor's Office.

Finally, the speaker pointed out how Croatia is presently facing the difficult task of conforming to the growing web of EU regulations on the application of patients' rights in cross-border healthcare and medical responsibility, trying to improve its system of patients' protection. Significant efforts are invested in the education of healthcare providers on the procedure for the protection of patients' rights. Besides this, the Croatian institutions are taking further steps in order to improve a system of mediation and arbitration between the public institutions (since the majority of the healthcare institutions in Croatia are state-owned) and the patient.

The European experience in the field was deepened by the third discussant, Alessandro Ianniello-Saliceti (European Commission, Bruxelles), who delineated medical responsibilities according to the EU legal system and to the fundamental rights of European citizens, especially that to health. Regarding the exercise of the medical profession in Europe, the Treaties include two basic principles: 1) the principles of free movement and free exercise of professions; 2) the principle of mutual recognition of qualifications and diplomas.

The EU is an institution that recognises the free movement and free exercise of both medical services and medical professions; at the same time, the EU Institutions consider as an important task the protection of the fundamental rights of citizens during processes implementing European politics. Focusing on the relationship between these two different policies, the discussant successfully highlighted the need to reaffirm the supremacy of the fundamental rights of patients, despite the importance of the interests and freedom of the medical professions. The EU Treaty recognises two categories of fundamental rights. The first one is based on the rights that are commonly recognised by the national Constitutions of the Member States. The second group comprises the rights included in the European Convention on Human Rights. As Saliceti stressed, the following rights should be primarily considered: to life, to prevent any illness, to privacy, and to human dignity.

Moreover, in the European context, each Member State is responsible for guaranteeing the protection of life and health within hospital structures. This implies the duty to execute a judicial like system, supervising medical responsibility. In fact, in line with the Subsidiary Principle, the EU can only intervene to complete the national legal systems in order to ensure an effective protection of patients' rights.

This is the basic principle enshrined in the Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, issued by the European Commission in July 2008. The Proposal aims at ensuring a "high level of protection of health" and underlines that "it is the authority of the

Member State, on whose territory the healthcare is provided, to be responsible for ensuring compliance with the common operating principle”, in order “to ensure the confidence of patients in cross-border healthcare”. Besides, an effective compensation system is an essential element of any framework whose goal is to ensure “safe, high-quality and efficient healthcare”.

The final paper, presented by Prof. Vern R. Walker (Hofstra University School of Law, Hempstead, New York, USA), focused on the compensation system for medical accidents in the context of cross-border healthcare. A healthcare system should achieve an efficient outcome through a compensation mechanism that avoids under-compensation and over-compensation. Such an efficient compensation system would also contribute to ensuring “safe” and “high-quality” health care, by providing an optimal level of deterrence. The thesis underlined the need to create an accurate, consistent, evidence-based, factfinding method of assessing medical accidents, sensitive to the extent, the cause and the nature of healthcare-related injuries in cross-border medical systems in order to obtain outcome efficiency and optimal deterrence. Prof. Walker demonstrated how such a factfinding model could be created, without necessarily having to create a centralised institution. The discussant outlined the *National Vaccine Injury Compensation Program* (VICP) of the United States as a robust example of one attempt to build an efficient compensation framework based on transparent and concrete factfinding; from this he delineated examples of general principles, institutional structures and specific rules of evidence assessment, as necessary insights in the debate of establishing a similar structure for other areas of medical accidents. As the Professor explained, “factfinding” is a process that involves three phases: receiving evidence and creating an evidentiary record; assessing the probative value of evidence in the record; using the evidence to make findings of fact that determine the applicability of legal rules. In the case of VICP, petitions claiming compensation are filed in the U.S. Court of Federal Claims, where the Secretary of the U.S. Department of Health and Human Services is named as the respondent. If the Secretary contests the petition, the case is decided by a Special Master, who operates within the Court of Federal Claims. The special master has the duty to perform the three tasks of the factfinding process (that is based on the evidence produced by the parties) and he should award compensation only if he can make all the findings in the record “as a whole”. The special master’s decision must include “findings of fact and conclusions of law”. As the speaker stressed, it is important to underline that the evidentiary record is made according to rules of law, so the basis of the decision will be transparent; therefore the potentially affected party will be able to ascertain if the factfinding process was legitimate or not. The Court of Federal Claims has jurisdiction to review the Special Master’s decision and has the special power to sustain this decision or to set it aside. In this second case, the Court can either issue its own findings of facts and conclusions of law or send the petition to the master. In order to set the first decision aside, the standard of law is the following: “the court must find the findings of fact or conclusion of law to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law”. According to the U.S. Supreme Court<sup>1</sup>, the factfinder’s decision would be “arbitrary and capricious” if: 1) the factfinding is based on irrelevant evidence or on evidence not in the record, 2) the factfinding doesn’t take into account relevant evidence, 3) the reasoning connecting the evidence fails to provide a rational explanation. The VICP’s system of judicial review is two-layered and the judgment of the Federal Court of Claims can be appealed to the U.S. Court of Appeals for the federal Circuit.

Prof. Walker explained that during the level of adjudication in the first instance, it is sometimes useful to create different factfinding processes for distinct issues. This is

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<sup>1</sup> Caso: *Zatuchini v. Secretary of health and Human services*, 69 Fed.Cl. 612, 620 (Ct.Fed.Cl. 2006).



especially true when several petitions present a single issue of fact in common (see the case of “general causation”). But it is also efficient where different complicated issues are present in a single case. Another technique in deciding an issue common to different cases is to confer the task to an administrative agency that can exercise its rulemaking powers to create an evidentiary record and take a decision that is binding for all particular cases.

In conclusion, the International Workshop brought together experts from different experiences around the world, with the aim to discuss the delicate problem of the relationship between the exercise of medicine by medical professionals and the protection of patients’ rights, without concentrating exclusively on the tort liability system. The experts attempted to focus on the multiple aspects of a legal field that is in evolution and they delineated the importance of the contribution of all the involved institutions as well as all the legal tools.