La Task-force medico legale della SICCH ricevuta dal Commissario Europeo alla Salute Tonio Borg

Mercoledì 28 maggio u.s. una rappresentanza della task-force medico legale della SICCH (composta dal presidente Menicanti, dai colleghi Pagliaro e Parolari e dagli avvocati Isolabella e Meterangelo) è stata ricevuta a Bruxelles, presso la sede della Commissione Europea a palazzo Berlaymont, dal Commissario Europeo alla Salute Tonio Borg e dal suo staff. Nel corso dell'incontro il presidente Menicanti ha esposto non solo il crescente senso di difficoltà dei medici (e soprattutto dei chirurghi) italiani nei confronti dei sempre più numerosi procedimenti penali e civili che vengono intrapresi nei confronti dei medici.

Ha inoltre sottolineato come, nonostante la legislazione Europea preveda la libera circolazione dei pazienti tra gli stati membri, vi siano tuttora notevoli discrepanze legislative sia sul piano penale che civile ed assicurativo (vedi slides allegate), e come l'Italia sia il paese con il più elevato numero di denunce per omicidio colposo a carico dei medici; inoltre ha evidenziato come la Convenzione per la protezione dei diritti dell'uomo e la dignità dell'essere umano riguardo alle applicazioni della biologia e della medicina, nota come convenzione di Oviedo, sia totalmente disattesa dallo stato italiano proprio nella parte che riguarda i risarcimenti per danni (articolo 24) (vedi pdf allegato che riporta le slides di preparazione al meeting).

Il commissario Borg ha accolto con grande interesse le argomentazioni prodotte dalla task force, ha sottolineato di essere favorevole in linea di principio alla creazione, nell'ordinamento legislativo, di specificità precipue per la colpa medica che dovrà essere differenziata dal concetto di colpa in generale. Ha infine garantito il proprio impegno a farsi latore, nei confronti del governo italiano e del relativo dicastero alla salute, delle problematiche discusse nel corso della riunione nel corso degli incontri che avverranno nelle prossime settimane in corrispondenza dell'inizio del semestre di presidenza Italiano dell'Unione Europea, iniziando proprio dal primo incontro che avrà luogo col ministro della salute Lorenzin il 2 luglio p.v..



Foreword



4.4.2011

EN

Official Journal of the European Union

L 88/45

DIRECTIVES

DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 March 2011

on the application of patients' rights in cross-border healthcare

(3) The health systems in the Union are a central component of the Union's high levels of social protection, and contribute to social cohesion and social justice as well as to sustainable development. They are also part of the wider framework of services of general interest.







CHAPTER II

RESPONSIBILITIES OF MEMBER STATES WITH REGARD TO CROSS-BORDER HEALTH CARE

Article 4

Responsibilities of the Member State of treatment

- 1. Taking into account the principles of universality, access to good quality care, equity and solidarity, cross-border healthcare shall be provided in accordance with:
- (a) the legislation of the Member State of treatment;
- (b) standards and guidelines on quality and safety laid down by the Member State of treatment; and
- (c) Union legislation on safety standards.







2. The Member State of treatment shall ensure that:

(c) there are transparent complaints procedures and mechanisms in place for patients, in order for them to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive;

(d) systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory;







However, there are currently several discrepancies in legislation and normative issues within EU countries.

And this may imply, given the european patients rights to cross the borders to receive healthcare, difformities in patients treatments as weel increased costs in case of lawsuits.



Italy



Penal laws (aspects/issues)

- There are no specific figures of crimes charged to health workers, who are equalized to common criminals (charged for homicide).
- When there is a notification to the judge/magistrate of a possible wrongful death possibly due to malprqactice, the prosecution from a penal standpoint starts automatically. The physician, if guilty, can be sentenced to prison
- The Balduzzi Law was recently approved to reform in part the system, but this did not affect possible penal charges.

Civil laws (aspects/issues)

- Common hospital and physician liability (the hospital can also request partial contribution of the physician to reimbursements or even charge the whole reimbursement to physician).
- The burden of proof is for physician and hospitals, and not for the patient.
- Contractual liability (but contra, Cass. Civ. n.8940/14).

- There isn't a No-fault compensation system.
- There's personal insurance obligation for the doctors
- The insurance should provide 10 years retroactive coverage.

Did Italy applied Oviedo convention?



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

Oviedo, 4.IV.1997

The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. As a consequence, as from that date, any reference to the European Community shall be read as the European Union.

Chapter VIII – Infringements of the provisions of the Convention

Article 23 - ...omissis....

Article 24 – Compensation for undue damage

The person who has suffered <u>undue damage</u> resulting from an intervention is entitled to <u>fair compensation</u> according to the conditions and procedures prescribed by law.

Article 25 - ...omissis....\



Article 24 – Compensation for undue damage

The person who has suffered <u>undue damage</u> resulting from an intervention is entitled to <u>fair compensation</u> according to the conditions and procedures prescribed by law.

Patients can sue the physician anytime within 10 years from possible damage

The ask compensation for whatever damage they got, not only for due damage

There is no limit to compensation (e.g. patients usually ask several millions euro)

Patients do not suffer from any drawbacks when they sue physicians



France



Penal laws (aspects/issues)

- Complaint lawsuit only for severe cases.
- Criminal liability for medical malpractice is subject to the different casual connection between the physician's culpable conduct and the suffered injury. In case of direct casualty, a coefficient of simple neglicence is enough. In case of indirect casualty, a particularly serious misconduct is necessary.

Civil laws (aspects/issues)

- Hospital-physician joint and several liability, with burden of proof against them, but only in cases of willful misconduct or gross negligence
- The Loi Kourchner (2002) is a specific medical liability law.

- No-fault system, but only in case of alea therapeutique and nosocomial infections.
- There is a compensation fund (Oniam) for cases of precarious treatment.
- Mandatory insurance for all hospitals.



Germany



Penal laws (aspects/issues)

- Medical malpractice can be qualified as negligent manslaughter (section 222 CC) and negligent bodily injury as well (section 223 and 229 CC).
- Prosecution only upon complaint of the patient.
- Very few cases reach the judge.
- Burden of proof has to be provided by the injured patient

Civil laws (aspects/issues)

 Hospital-physician joint and several liability, with burden of proof against them but only in cases of willful misconduct or gross negligence.

- Arbitration commission, established by professional associations of doctors.
- Ethical obligation of insurance for each physician.



United Kingdom



Penal laws (aspects/issues)

 There are no specific figures of crimes charged to health workers, who can anyway be charged only in case of recklessness, or gross negligence, that requires "criminal indifference to the safety of others, the biggest ignorance, carelessness or worse". Under the limit of the above mentioned (very high) seriousness, any criminal liability is excluded.

Civil laws (aspects/issues)

• Burden of proof against the patient: negligence or predictability and avoidance of damage must be demonstrated.

- There isn't a No-fault compensation system.
- Arbitration commissions.



Spain



Penal laws (aspects/issues)

 The common criminal offences of homicide and unintentional injuries (similar to what is ruled by the Italian law system) are applied to the physician. In case of gross negligence – which however has no clear definition but is identified with negligence, violation of the essential requirements of medicine and with heavy violation of duty of care – sanctions can lead even to the perpetual disqualification from medical practice.

Civil laws (aspects/issues)

• For public structures, the responsibility of the physician is dependent on them; private physicians have an obligation to ensure themselves.

Reimbursement and insurancies

• There isn't a No-fault compensation system



Portugal



Penal laws (aspects/issues)

• The Criminal Code provides specific figures of crimes for physicians, but explicitly discriminates the medical act if justified by consent or by the therapeutic benefit.

Civil laws (aspects/issues)

• The Civil Code doesn't have any particular regime for medical malpractice, but jurisprudence tends to impose on doctors the presumption of guilty.

Reimbursement and insurancies

• There are some institutions legitimate to control the activity of health professionals and even with power to sanction with administrative measures



Austria



Penal laws (aspects/issues)

 The physician's criminal liability – homicide or negligent bodily injuries – can be activated only by a complaint made by the offended part. Complaints are seldom made by victims or by their relatives and in any case the Public Prosecutor is used to dismiss the case if the charge is not supported by provable and demonstrable proofs.

Civil laws (aspects/issues)

- Probands and non-contractual liability onus borne by the patient.
- Responsibility only for the medical institution, wich has the right of recourse against its staff.

Reimbursement and insurancies

• Doctors are answerable not only to courts of law, but also to their local disciplinary commissions.



Scandinavian countries



Penal laws (aspects/issues)

• The penal code doesn't provides specific figures of crimes for physicians.

Civil laws (aspects/issues)

- Recourse against public structures and physicians, in the event of willful misconduct or gross negligence.
- Mandatory insurance for all the hospitals.

- No-fault compensation system.
- Compensation is based on each victim's specific injury, but non-economic damages (i.e.: pain and suffering), based on age and injury, are capped.



Czech Republic, Slovakia and Bulgaria



Penal laws (aspects/issues)

• The penal code doesn't provides specific figures of crimes for physicians.

Civil laws (aspects/issues)

- Hospitals are responsible for damages caused by physicians misconduct.
- Fault-based juridical system.

Reimbursement and insurancies

 There are alternative dispute resolutions, such as arbitration.



Conclusions



- There are several important differences in the legislation concerning medical malpractice across European Countries
- In the majority of European Countries, a specific legislation concerning the issue of medical liability does not exist.
- The physician's misconduct/mistake is regulated on the basis of the general principles of the civil, penal and in some cases administrative responsibilities.
- Most of the European juridical systems belong to the system of damage compensation, based on the Fault model.



Conclusions



- We suggest that European Commission
 - starts a survey of all the European Countries about cuurent legislative approaches concerning medical malpractice
 - starts a committee to uniform the legislation across European countries in this setting