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ΕΥΡΩΠΑΪΚΟΣ ΣΥΛΛΟΓΟΣ ΝΟΣΟΚΟΜΕΙΑΚΩΝ ΙΑΤΡΩΝ ΔΙΕΥΘΥΝΤΩΝ
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EUROPSKA UDRUGA BOLNIČKIH LIJEČNIKA
ЕВРОПЕЙСКА АСОЦИАЦИЯ НА СТАРШИТЕ БОЛНИЧНИ ЛЕКАРИ
ASOCIATIA EUROPEANA A MEDICILOR DIN SPITALE

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Italian Delegation Report

The Italian delegation will focus their report on the following issues:

1. The implications of law no. 150/2009 (so-called Brunetta Decree) for the Italian Health Service sector;
2. The central position of the issue of treatment safety: recent developments and perspectives;
3. Defensive medicine: open debate
4. Conciliation in the Health Service sector
5. The renewal of the Hospital Doctors' Contract

Below is a short presentation of the above topics.

1. The implications of law no. 150/2009 (so-called Brunetta Decree) for the Italian Health Service sector

On November 16th 2009 Legislative Decree no. 150/2009, proposed by the Minister for the Civil Service, and approved by the Italian Government, entered into force.
This law aims at optimising the productivity of public jobs, and improving the efficiency and the transparency of public administrations. One of the declared objectives is to tackle the problem of absenteeism.
As far as the health sector is concerned, the implementation of this law entails some problems, such as the medical certification, and the disciplinary procedures against doctors, whom FNOMCEO did not fail to represent in all institutional events.
As far as the issuing of sickness certificates for civil servants is concerned, doctors are allocated duties which are difficult to implement, as they are expressly required to issue such certificates based on clinical data that are "directly ascertained and objectively documented". However, it is in reality a well known fact that the issuing of the certificate by the doctor is substantially based on the information received by the patient, without any documented medical records available.
It is in effect very similar to a self-certification signed in front of a public officer (the doctor), who certifies it after assessing it, based on their own competence and experience, as well as on their knowledge of the patient.
As a consequence, the medical sector has felt the need to ask to the Italian Authorities to introduce a system of simple self-certification, with workers able to issue self-certificates to justify short absences from the workplace (up to three days).
Another critical point of the Brunetta law is the possibility of doctors being removed from the Professional Register, or their exclusion from the convention (hospital doctors or general practitioner), if found guilty of producing, in conjunction with the civil servant, an untruthful medical certificate.
On this occasion, it is only worth mentioning that the Medical Association is responsible, following the appointment from the State, for the keeping of the Register and the implementation of any disciplinary measures against their members.
Therefore, it seems a contradiction in terms to think of automatic removal without, a disciplinary procedure managed by the Medical Association itself.

2. The central position of the issue of treatment safety: recent developments and perspectives;

Following a path initiated already a few years ago, on specific request and instructions from the Ministry of Health, our country has shown a continuous advancement in the field of treatment safety. In particular:

- The following "ministry recommendations" have been defined and published (which represent the technical-professional recommendations with which Italian health organisations and personnel must comply)

Recommendation no. 11 - January 2010

- Death or serious harm following a malfunctioning of the transport system (within or outside the hospital premises)

Recommendation no. 10 - September 2009

- Recommendation for the prevention of osteonecrosis of the upper/lower jaw due to biphosphonates

Recommendation no. 9 - April 2009

- Recommendation for the prevention of adverse events following the malfunctioning of medical devices/medical electrical equipment

Recommendation no. 8 - November 2007

- Recommendation for the prevention of violence against health personnel

Recommendation no. 7 - March 2008

- Recommendation for the prevention of death, coma, or serious harm, due to pharmacotherapy errors

Recommendation no. 6 - March 2008

- Recommendation for the prevention of the death of the mother, as a result of labour and/and childbirth

Recommendation no. 5 - March 2008

- Recommendation for the prevention of transfusion reactions due to ABO incompatibility.

Recommendation no. 4 - March 2008

- Recommendation for the prevention of patient suicide inside the hospital premises

Recommendation no. 3 - March 2008

- Recommendation for the correct identification of the patient, the surgical site, and the procedure

Recommendation no. 2 - March 2008 - the stages to ensure correct identification of the patient, the surgical site, and the procedure

- Recommendation for the prevention of the retention of surgical gauze, instruments, or other materials inside the surgical site

Recommendation no. 1 - March 2008

- Correct use of concentrate solutions of Potassium Chloride - KCL - and other concentrated solutions containing potassium.

The Sistema Nazionale Linee Guida (SNLG - National System of Guidelines), is constantly updated and enriched with new content. It's made available to all operators and includes

national and regional guidelines, as well as other evidence based documents (link: http://www.snlg-iss.it/).

In October 2009 the Minister of Public Health produced and distributed the manual for the safety of operating theatres (and related checklist). This was issued on the basis of the OMS recommendations following the program "Safe Surgery, Saves Lives". At present many Italian hospitals are engaged in introducing this additional safety tool.
The Law Decree of December 11th 2009 established the "Sistema Informativo per il Monitoraggio degli Errori di Sanità (SIMES - Information System for the Monitoring of Errors in the Health Service). The aim if this information system is the collection (at national level) of information relating to sentinel health events, and the requests for compensation for damages in connection with health care activities.
A sentinel health event is a "particularly serious, adverse event, which could potentially be avoided, and which could cause death or serious harm to the patient, and results in the citizens loosing trust in the health service. The occurring of even one single case is enough to initiate a cognitive investigation, to ascertain the presence of any contributing factors that may be eliminated or reduced, and to enable the organisation to implement suitable corrective measures"
The Ministry of Public health has completed the definition with a list that in its final version includes 16 cases for which notification by the health care organisation is compulsory. Such notification must be followed by an in depth analysis of the event, the results of which must be notified, at a later stage, to the ministry offices.

Below is the list of the 16 sentinel health events

1. Surgical or invasive procedure performed on the wrong patient
2. Surgical procedure performed on the wrong part of the body (side, organ or part)
3. Execution of a wrong diagnostic/therapeutic treatment, different from the one actually prescribed to the patient, causing death or serious harm
4. Instrument, or other material, left inside the surgical site, requiring further operation, or further procedures
5. Transfusion reaction due to ABO incompatibility
6. Death, coma or serious harm, due to pharmacotherapy errors
7. Death of the mother, or serious illness related to labour and/or childbirth
8. Death or permanent disability of a healthy newborn baby weighing >2500 grams, not related to a congenital illness
9. Death or serious harm of the patient due to fall
10. Suicide or attempted suicide of the patient while inside the hospital premises
11. Violent act on the patient committed by anyone, while inside the health care establishment, causing harm to the patient
12. Violent act on a health care operator, causing serious harm
13. Death or serious harm following a malfunctioning of the patient transport system (inside and outside the hospital), both within the scope of the 118 emergency-urgency service system, and in relation to planned care, due to one of the following cases:
    - failure to reach or delay in reaching the event location by the emergency rescue vehicle;
    - inappropriate emergency rescue vehicle, on the basis of the type of emergency, or the environmental conditions;
    - interruption of transport or delay, due to mechanical fault;

- accident due to unsafe use of the transport vehicle, or to use by untrained medical or nursing personnel;
- unsuitable transport vehicle, due to the health care structure lacking in suitable emergency treatment devices and instruments, or due to the presence of health personnel not qualified or not suitable for treating the type of emergency;

14. Death or serious harm following incorrect allocation of the triage code by the 118 operating unit, or inside the emergency department;
15. Unexpected serious harm or death following a surgical procedure;
16. Any other adverse events caused by error, and resulting in death or serious harm of the patient.

3. Defensive medicine: open debate

According to ministry sources, for every half million Italian citizens being hospitalised, 3 million citizens visit their own family GP. After saying this, one must also point out that much too often, the information society communicates "information pathologies", emphasizing the so-called "health service inefficiency" cases. If the health operators become the terminal link of responsibility, without protection they end up being uncommitted and defensive. And these are the real causes of health service inefficiencies.
During the last few decades there has been a strengthening among citizens of the belief of the certainty of results. This will never be achieved in medicine, because (as it is well known) medicine is not an exact science.
These topics have given way to a heated debate between operators and institutions. An example are the contributions of the Centro Studi Federico Stella of the Università Cattolica of Milan, among which it is appropriate to mention a survey initiated following the proposal, and with the support, of the Società Italiane di Chirurgia (SIC - Italian Surgical Association), that became instrumental in expressing the unhappiness among Italian surgeons due to a regulatory and legal framework deemed unable to provide clarity on the boundaries of responsibility, and in particular criminal responsibility, within which the health profession is destined to operate.
The above mentioned survey also showed that 77.9% of the doctors interviewed through the questionnaires had adopted a defensive medicine approach at least once during their last month of activity (this appeared higher among young doctors).
Some of the most widespread defensive medicine behaviours are:

- including avoidable information in the clinical records (82.8%)
- the proposal of hospitalising patients that could be treated as outpatients (69.8%)
- prescription of a higher number of diagnostic exams than necessary (61.3%)
- unnecessary consultation with other specialists (58.6%)
- the prescription of unnecessary drugs (51.5%)

The lawmakers are currently studying some law proposals, combined together in a unified text, which are substantially aimed at stating the need and the responsibility for the health structure to have a suitable level of insurance, preventing the possibility of recourse against health personnel, unless in case of serious harm or fault.
Some are also proposing the creation, within the Ministry of Public Health, of an office responsible for ministry surveys in case of adverse events (for example by creating a commission consisting mainly of external inspectors, to be selected from credited lists, and trained by the Ministry itself).

4. Conciliation in the Health Service sector

Another important chapter in our Country is Law no. 69/2009, which gave way to the "legislative decree on the conciliation of civil and commercial disputes" approved on February 19th 2010. The objective of this law is to limit the recourse to civil judicial proceedings, in order to reduce the times and costs for the resolution of controversies.
Article 5 of this law indicates that anyone wishing "to engage in legal proceedings for a controversy connected with ..... compensation for damages deriving .... from a medical responsibility .... must initially take part in a mediation process ....
The mediation process is a condition for the acceptance of the request for judicial proceedings....."
Article 19 of the law prescribes that "The Councils of the Professional Associations can establish, for the matters of their competence, … special bodies ….", which means bodies in charge of helping the parties to reach an agreement.
For this reason, the Italian Federazione Nazionale degli Ordini dei Medici Chirurgici (FNOMCEO - National Federation of the Associations of Surgical Doctors) is working together with law experts to produce a set of regulations for the conciliation body, to be evenly implemented across the branches of the Associations. FNMOCEO is also working to create a training school for mediators on medical responsibility.

5. The renewal of the Hospital Doctors' Contract

Following a period of extremely demanding negotiations, during the first quarter of 2010 the representatives of the medical unions succeeded in undersigning an agreement for the 2008-2009 period.
This ended the procedure for the renewal of the contract, which had dragged on for a few years. But we cannot avoid pointing out that the contract signed just recently has, on an economical point of view, already expired.
However, on a regulatory point of view, some important points concern:

- the regulation of the disciplinary code
- the creation of a set of procedures dealing with the sanctions prescribed by the "Brunetta reform" (see item 1 of this report)
- the introduction of the reintegration to work, if the dismissal is proved to be unlawful (not required until now)
- the obligation for the organisations to include safety and clinical risk management among their priorities.