Medical responsibility for nosocomial infections: legal review

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Summary

Background: **nosocomial infections represent not only a problem for public health – according to data provided by the World Health Organization (WHO) 4.1 million patients in Europe suffer from hospital infections every year – but they also have important legal implications. The Authors analyse this subject in the light of recent judgments that have introduced new elements of objective public liability at a civil level with debasement of the causal link assessment and reversal of the burden of proof on physicians. Consequently, there has been a tightening of judgments that, being increasingly aimed at protecting health, are often in favour of patients. Therefore we are witnessing the progressive weakening of the legal protection of physicians.**
Objectives: **with this work the Authors, starting from the problems that emerged in recent judgments, point out the judiciary attitude of being increasingly on the side of the patient that is identified as the "weak subject". They identify possible solutions inspired by the experience of management of medical errors in some European countries, such as the "no fault" system of the Scandinavian countries or the "social insurance" system in force in France. This system provides for the introduction of forms of social insurance mandatory for public structures, allowing physicians not to take any direct and personal responsibility in case of an error with the user-patient; indeed, in this case it is the latter who has the burden of proving the faute (error).**
Material and Methods: **this research is based on recent judgments of the Civil Cassation Court and the current increase in litigation that the National Health System is facing, due also to media influence. The Authors illustrate how European countries, through social security systems and mediation, try to control the problem and protect the physician.**
Results and Conclusions: **finally, the Authors point out that the current increase in litigation along with a progressively more favourable attitude towards the patient, has fostered attitudes of defensive medicine by the physician who has felt more and more defenceless. It is to be hoped that a final regulatory framework that establishes forms of protection for physicians will be achieved, in order to give the best treatment to patients. This should, at the same time, avoid the adoption of defensive behaviour by the physician to reduce the risk of cases involving professional responsibility. Therefore, the Authors suggest the possibility of using new legal means inspired by the European experience.**

KEY WORDS: nosocomial infections, medical responsibility, legal review.

Background

Much has been written in recent years about the legal nature of the relationship that develops between the patient and the physician, and also between the patient and other health care facilities; moreover, identification of the nature of this relationship is essential in order to establish responsibilities in case of harm coming to the patient.
With regard to the first report, it is noted that unlike in the criminal responsibility of the physician, in the civil sector we are now frequently witnessing, especially on the part of the Supreme Court, judgments increasingly favourable to the patient given his position of "weak subject" between the two parties of the medical report (1).
The actual orientation of the Supreme Court in matters of responsibility within healthcare facilities, whether public or private, and in matters of the freelance health professional, is that public sector employees fall under the same form of contract. This type of approach has important consequences concerning the procedural limitation rules (ten years, against five for non-contractual liability) and above all, the burden of proof.
Regarding this last aspect, the Supreme Court now considers that the patient should only demonstrate the existence of a contractual relationship between himself

and the doctor, as well as the onset of a disease or aggravation of one already in place, as a result of a medical treatment. The doctor, according to Art. 1218 of the Civil Code (2) must demonstrate diligence in their performance, the unpredictability of the event that has led to the damage and the special difficulties of the task. Therefore, this category of responsibility offers the advantage of the burden of proof: it will be the hospital/professional's duty to provide evidence that the infringement has been determined by the "impossibility of performance resulting from causes not attributable to them".

The nosocomial infections problem and its impact on public health

In this context there is the problem in relation to hospital infections, known also as nosocomial infections (NI), meaning infections occurring during hospitalization in a nosocomial institution, and their attribution to professional liability.
We define "hospital infections" as those infections acquired during hospitalization, and not clinically manifest or incubating at the time of admission.
By convention, infections that make themselves evident within forty-eight hours of hospital admission are considered to have been contracted in the community (Community Acquired Infection), while those that occur later are considered to have been contracted in a hospital (Hospital Acquired Infection), unless there is clear information on the incubation in place at the time of admission (3).
Hospitalization of a patient in view of surgery is also considered as medical treatment. Therefore infections contracted during their stay in hospital, if long and unjustified, can be a source of liability for the physician who ordered the admission of the patient, and also for the healthcare facility where the incident occurred.
Nosocomial infections are a major challenge in public health systems; they constitute a rather heterogeneous group of conditions including microbiological, physiological and epidemiological emergencies that have a high impact on health care costs and are indicators of the quality of service provided to the patients. These infections are caused by opportunistic organisms in the environment, which usually do not lead to infections. They may occur in immunocompromised patients during hospitalization or, in some cases, even after the patient is discharged, and may exhibit different degrees of severity up to lethal outcomes. These same infections may also be contracted by health professionals who work with patients, so appropriate measures must be taken not only to treat hospitalized people but also to prevent the spread of nosocomial infections among the staff that provide care and treatment.
According to data of the World Health Organization (WHO), 4.1 million patients in Europe contract infections within hospitals every year. It's estimated that the European Centre for Disease Prevention and Control (ECDC) collects up to 4.5 million cases, yet it must be considered that patients may also be affected by more than one infection during the same hospitalization. As a result, 16 million additional days of hospitalization occur with up to 37000 deaths, at an estimated cost of 7 billion euro per year (4).
This phenomenal rise is increasingly a worry particularly in Italy, where nosocomial infections are within a range between 450.000 and 700.000 each year, killing 1% of cases. These occurrences make hospital stays several days longer and also it results in a burden on the National Health Service, with annual costs exceeding 1 billion euro. The alarm refers in particular to the "*super-bacteria*" ("superbugs") that are resistant to antibiotics, responsible for nearly one in five hospital infections, 16%; and especially the MRSA (methicillin-resistant Staphylococcus aureus), which is responsible for 8% of hospital infections. It is estimated that in Europe, this germ is the cause of 50% of cases of infections of the blood, skin, soft tissue and lungs. Given these clinical premises, the frequency of MRSA infections varies from less than 1% in northern Europe to more than 50% in the south, with peaks of 60% in ICUs (5).
Despite the social and economical impact of the NI, surveillance systems and control protocols installed in order to reduce the effects of these infections are still quite unbalanced between countries, as well as within the countries themselves, although in recent years numerous programmes have been developed and implemented. The studies that are being carried out demonstrate that it is possible to prevent 30% of the NI, resulting in lower costs and improved health service. NI are significantly impacting on health care costs and in prolonging hospital stays for the patients, ending up greatly affecting the ability of hospitals to ensure admission to other patients in need of healthcare.
The micro organic sources that may give rise to NI are numerous: the structures themselves, ventilation systems, water flows, tissue processing and laboratory samples, contact with animals, staff and environmental hygiene, surgical practices and invasive treatments (such as catheters and valves); the antibiotic treatment can also provoke resistance in the bacteria. Normally, development sites of infections include the lungs, sites of insertion of catheters, urinary tract, wounds (including surgical wounds and bed sores).
Among the risk factors for NI we may identify: endotracheal tubes, artificial respiration and immobility, urinary catheters and veins, and high use of antibiotics, which can cause bacterial resistance and growth of fungal organisms.
Moreover, other factors contribute to constitute the risk: high density of patients in the ward and in the intensive care units, all the routine operations carried out in the preoperative preparation (such as shaving), duration of the intervention; intrinsic factors (such as age, obesity, diabetes, severity of illness, the general state of immunity).
The most frequent nosocomial infections occur on surgical sites (Surgical Sites Infections), bacteremies, pneumonias, urinary tract infections (UTIs) and infections associated with intravascular central catheters (CIC) (6).

Not all healthcare facility associated infections are preventable: therefore it is advisable to monitor selectively those that may cause problems in terms of quality of care. Many infections, especially the ones associated with specific procedures, can be reduced if the procedures are not necessary, or by the choice of alternative and safer procedures, or by ensuring aseptic conditions in patient care (7).
In an attempt to solve this issue, specific solutions have been developed by the American CC (Control Centers) but also by European organisations such as HELICS and EARSS. In the United States and Northern Europe a control and surveillance system has been developed, while in our country this system is not yet operating. Italian studies, however, have found that the epidemiological characteristics of NI already identified are similar to those described by the American system, the National Nosocomial Infections Surveillance System (NNIS), which therefore constitutes a valid source of references.

The evolution of case law in the matter of nosocomial infections in the Italian scenario

Examining the Italian legislative developments, in the 1980s the Ministry of Health issued two Ministerial Circulars (no.52/1985 "Fight against hospital infections" and no.8/1988 "Fight against hospital infections: surveillance") in which the basic requirements of control programmes were defined. A committee was formed to control the spread of infections in each hospital, with the availability of a nurse dedicated mainly to surveillance and control activities (DPR 13 Sept. "Determinazione degli standard del personale ospedaliero" – 24 September 1988 G.U. no. 225).
Later on, with the M.D. of 27 July 1995, NI rates were introduced as indicators of the quality level in healthcare: therefore, the National Health Plan (NHP) had the objective of reducing the incidence of NI by 25 % at least during the period between 1998 and 2000, and at a later stage, from 2003 to 2005, the importance of surveillance of hospital infections with particular attention to those of iatrogenic origin.
The objectives of the NHP from 2006 to 2008, however, were aimed at the surveillance and control of infectious diseases and infectious complications related to health care.
To this end, epidemiological survey instruments have been made at the regional level, while at the national level new surveillance networks have been implemented, as well as the promotion of effective care practices to reduce the risk of nosocomial infection (8).
As for the jurisprudential consequences led by these issues over infections, there has been an exponential growth in litigation.
Indeed, such increases, about real or imagined harm towards the patients caused by actual or alleged faults of the professionals, has acquired a prominent role in Italy and in Europe. This is characterized by inexperience, carelessness, negligence, or failure to comply with laws, regulations, orders and disciplines.
In the Italian scenario, the determination of liability by various professionals should refer to the general principles contained in the civil and criminal codes and the interpretation given by judgments, by case law.
At the outset, we must remember that there are two structural elements that define the type of responsibility of health care professionals in the matter of nosocomial infections:

1. the essential fault in case of negligence (material element);
2. the necessary existence of a causative link between the unlawful conduct and the occurred harmful event (material element) (9).

Regarding the first point, we have professional negligence in the event that the person has operated according to the laws of the profession, meaning that a particular treatment has been carried out according to a set of rules and technical requirements, that science (evidence based practice) and professional experience have been applied in the interest of the patient.
With regard to the second point, to state a responsibility in the matter of professional fault, demonstrating that the unpredictability of an event isn't sufficient, the verification of the existence of a relationship, or causal link, between the behaviour of the health professional and the injury suffered by the life or physical integrity of the person is also necessary.
Now, regarding the problem of establishing the causal link, there has been over the years a general tendency in civil proceedings to circumvent a finding of actual causation, with consequent tightening of judgments and weakening of the legal protection of the healthcare professional.
In many judgments, the causal link has been based on mere presumption, such as the so-called "easiness" of the intervention, or the abstract detrimental capacity related to the professional conduct of the physician.
Many judgments (10) confirm the general approach, based on an extensive use in the evaluation criteria presumption of a causal link between the conduct and implementation of medical infectious phenomena, the gradual increase of sophisticated evidentiary burden imposed on doctors and medical facilities and the tendency to extension of those responsible.
For example, in the Court of Turin a known case in 1999 (11) considered the responsibility of a nursing home. While the accusation had not stated in detail what the measures of asepsis omitted were, the type of bacteria appeared capable of establishing the infection appeared during the medication due to insufficient measures of asepsis. Also in this case it was not required to identify the precise cause of his injury, because "it would be unreasonable to ask the CTU to indicate which practice had not been carried out correctly, since the CTU, time passed by the fact may not possibly control the instruments used during the procedure and if the conditions in which it had taken place were excellent ...".
The widespread use of presumptive criteria to establish the causality in the specific field of hospital infections is usually justified by the difficulties of reconstructing the presence of the germs that caused the infections that

are of uncertain origin, and the anonymous nature of many healthcare procedures involved in the process to prevent infections. This makes it *de facto* impossible to investigate the presence of a specific conduct or omission, at the origin of the infectious disease.
Emblematic in this regard is a judgment of 2010, in which the Supreme Court (12) condemned the hospital for serious injuries dealt to a baby. The parents of a baby girl had brought a claim for damages in view of the serious neurological injury suffered by the baby, due to a cerebral haemorrhage that arose after birth. The Supreme Court, while not having recognized the existence of a causal link between the actions of the medical staff and the occurrence of cerebral haemorrhage, stated that the responsibility of the injuries suffered by the child were to be ascribed exclusively to the hospital, given that the bleeding was caused by Klebsiella sepsis, a nosocomial infection agent. The proof of a nosocomial infection was considered sufficient as liability cause.
Therefore in case law, once the aetiology between admission and infection has been ascertained, almost automatically a judgment on negligence follows (13). In this regard, the evaluation of the conduct of the physician tends to be merely potential, since the guilt is no longer an essential requirement for the purposes of accountability.
Among the specific elements taken into account in the case law, in order to confirm existence of a causal link, the chronological sequence between the time of manifestation of the infection and the period of hospitalization is considered sufficient.
In this respect it should be noted, among others, the judgment of the Supreme Court, 29 September 2005, no. 19145 that reformed the previous judgment of the Court of Appeal. This ruled out the existence of a causal relationship and had determined that the importance of the time interval between surgery and the onset of the infection had not been sufficiently verified in order to establish if it was compatible or not with a causative role of the intervention, and noted that the determination of the latter could have affected the decision differently.
Two other Court decisions are related to this same point. Court of Alba on 19 January 2005: "... while highlighting the failure to identify the exact cause of the infection and to specify if the genesis was due to the intervention, considering the fact that the infection had not become clear before surgery, favourable conditions were not present, and had risen in close temporal connection with the operation and, therefore, could be traced to contamination of the operating theatre or the tools..." and that of the Court of Campobasso of 15 June 2005: "... despite the rarity of the complication ascertained (1% of cases) and the possible origin of a haematogenous cause, we consider a causal link between infection and operation on the basis of the apparent chronological link ...".
Therefore, these judgments show the evolution of case law in civil proceedings with an increase in responsibilities for healthcare professionals. The now increasingly common tendency to use the presumptive criterion in the assessment of causal relationship, has come to a widespread use of the notorious principle "*Post hoc ergo propter hoc*".
In fact, according to the latest guidance from the Court the chronological criteria by itself would be sufficient to assess the causal relationship between the medical conduct and the injury.

The social insurance as a solution to the problem: Italy-Europe in international comparison

In the European context, the solution to the progressive increase of litigation in healthcare is attempted in various ways. For example, in the Scandinavian countries the practice of "no fault" for the management of medical error; in France, Germany and the United Kingdom, the use of the system of mediation to reduce litigation in court.
In France, in particular, forms of social insurance for public facilities have been introduced as mandatory, as patients are considered to be using a public service. They can sue the structure, but not the health professionals, not assuming the existence of any direct and personal responsibility, therefore the patient-user will have the burden of proving the *faute* (error).
With the law on automatic compensation of 4 March 2002 the principle of liability without *faute* was also introduced, with exceptions among nosocomial infections: in these cases the victim of an adverse health event is exempt by the burden of proof. The law referred introduced a form of compensation through national solidarity in the absence of *faute*: it is the case of medical risk regardless of faults and/or errors (14).
In Italy, however, the problem remains unsolved; there is no real form of social insurance designed to protect the interests of the patient, nor the healthcare professional. Furthermore, in recent years there has also been an increase in claims for damages on the part of individual citizens against healthcare professionals, due to the severity of the judgments, also facilitated by the highlighting of the issue by the media.
These facts have led to increasing isolation of the healthcare professional who is without any form of protection, and has fostered attitudes of defensive medicine.

Conclusions

The responsibility of the physician in the field of nosocomial infections reflects precisely the current jurisprudence in civil liability, introducing elements of overcoming the old distinction between legal obligation of means and obligation of result, with a consequent reversal of the "burden of proof" and debasement of the establishment of the causal relationship.
This last occurrence is particularly critical in our case since, as demonstrated by the case law, the finding of causation plays a marginal role as the policy that was common in the "more likely than not" criteria is now closer to the concept of "strict liability".
This trend is particularly worrying because it promotes the spread of high compensation, without a concrete and

effective assessment of the condition of culpable conduct on the part of the healthcare professional and the structure. Excessive protection of the person considered to be weaker, or the patient, has prompted the judiciary to introduce systems of "overcompensation" on the one hand, and favouring the spread of defensive medicine and also the crisis in the insurance market on the other.

The doctor is increasingly alone and disoriented by the lack of reference points and the medical act has become more fragile than in the past.

On the other hand, the approach to medical liability is increasingly addressed with "*animus adiuvandi*" (sometimes expressly stated) to the claimant (the injured party), to a "good disposition" which ends with increased damages demands.

It is also mandatory to consider that adverse events that occur in healthcare can not always be attributed to a category of error, since in medicine unforeseen and unpredictable courses of the events, as well as the natural course of the disease, are fairly common.

However, this state favours attitudes leading to defensive medicine, not aimed to ensure the "good health" of the patient but rather to protect the work of the doctor. Just to avoid the possibility of a medical-legal litigation, many physicians adopt or avoid certain diagnostic and/or therapeutic measures and decisions. Respectively we can consider a defensive medicine "positive" (assurance behaviour) or "negative" (avoidance behaviour).

This phenomenon causes serious economic repercussions; it has been estimated as more than 10% of health care costs (15).

Now in some EU countries, such as France, the problem has come to a solution through the system of "no fault" for the management of medical error, in which it is the structure that assumes direct responsibility for the error, whose assessment lies with the patient.

In the Italian scenario, however, forms of social insurance have not been introduced as mandatory for public facilities, to reduce the burden of responsibility for the healthcare professionals.

It would be desirable in Italy, to adopt new legislative instruments inspired by the European experience: not only the definition of new and strict principles regarding the setting up of the technical advisers but also deflationary means of litigation. Unfortunately, mediation/conciliation in our country has proved unsuccessful and it is still too early to assess the effects of the recent health care reform (14, 16).

In addition, new cultural tools to read and interpret the complexity of world health would be necessary: to obtain the recognition of the undeniable peculiarities of the medical profession, naturally along with new forms of legal and insurance protection. The complex universe of nosocomial infections is a tangible demonstration of such issues.

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