NOSOCOMIAL INFECTION

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ABSTRACT

Hospital or nosocomial infections or healthcare-related infections (ICAs) are defined as infections that arise during hospitalization, not incubating at the time of the patient's admission to hospital and which occur at least 48 hours after admission.

Infections arising after the patient's discharge but causally referable to hospitalization are also considered as such and have a large-scale impact also from an economic point of view. Nosocomial infections are a serious public health problem as they represent a major cause of mortality and morbidity, and their incidence is constantly increasing.

The article aims to examine the nature of compensation claims for alleged health malpractice in the context of hospital infections in Italy.

Keywords: Nosocomial Infections, Damage Assessment, Health Malpractice, Risk Management
Abbreviations: ICAs, Healthcare-Related Infections

INTRODUCTION

Hospital or nosocomial infections or healthcare-related infections (ICAs) are defined as infections that arise during hospitalization, not incubating at the time of the patient's admission to hospital and which occur at least 48 hours after admission.

Infections arising after the patient's discharge but causally referable to hospitalization are also considered as such (Moroni, 2012).

They are the most frequent complication of staying in a healthcare environment and can occur in any care setting (hospitals, day-hospital/day-surgery, long-term care, clinics, home care, territorial residential structures) (Ministry of Health, 2021).

Nosocomial infections are a serious public health problem as they represent a major cause of mortality and morbidity, and their incidence is constantly increasing.

About 5% -10% of hospitalized patients develop a nosocomial infection (2000000/year in the US) with about 90,000 deaths/year.

In Italy, 5%-8% of hospitalized patients contract an infection related to care.

The ever-increasing incidence is due to multiple factors: average age of hospitalized patients, critically ill patients, aggressive antibiotic and immunosuppressive therapies, increase in invasive techniques, increase in pathologies requiring long-term hospitalization, dimensional and structural inadequacy of hospitals and wards (Cucci & Casali, 2009).

Nosocomial infections have a large-scale impact also from an economic point of view.

The total estimated annual costs of ICAs prevention and treatment vary between € 3.5 billion in the United States and € 1.3 billion in England.

In Italy the total estimated costs are 2.5-5.0 billion euros/year with the cost of the single case ranging from 9,000 to 10,500 euros (Agozzino et al., 2008).

It is estimated that 30% of diagnosed nosocomial infections can be prevented, thus being able to consequently direct the economic resources saved in other areas of public health.

It is therefore essential to prevent, as far as possible, the onset of hospital infections.

Since 1971, the Council of Europe has issued numerous recommendations to individual Governments dealing with the topic of Hospitaller Infections; and in 1984, with Recommendation no. 5 1984/20, stated that the solution, or at least the containment of the phenomenon, requires the implementation of a "global strategy" that affects all hospital sectors to be implemented, with the collaboration of inpatients, outpatients, visitors, staff Healthcare and not, and of all those who are part of the institution.

Also in 1984, the WHO considered the fight against Hospital Infections a priority within the "Health for all in the year 2000" project (sub-project: "Infection-related diseases").

The Council of Europe, in its recommendation no. 5, in order to put the aforementioned strategy into practice, suggested setting up, within each hospital structure, a Committee for the fight against Hospital Infections, defining it as: "... the central body that chooses and elaborates the strategy, it imposes it on all people in the hospital, controls and evaluates its implementation ".

In Italy, the Circular of the Ministry of Health 52/1985 "Fight against hospital infections" established, for each Health Authority of the National Territory, a technical surveillance commission with the task of defining the strategy for the fight against Hospital Infections, verifying the effective application of surveillance and control programs and their effectiveness and to take care of the cultural and technical training of personnel.

The committee set up, assisted by the Health Director, must include experts in hygiene, infectious diseases, microbiology and representatives of the nursing staff.

The committee also has the task of designating a small operational group to be entrusted with specific tasks relating to the program and consisting of a hygienist from the Health Department, an expert in microbiology, an expert in infectious diseases, a head nurse, three professional nurses specially trained in the subject, a clinical pharmacologist or hospital pharmacist.

Due to the growing judicial dispute, even in this matter, it is certainly appropriate that the coroner be part of the technical commission for the fight against hospital infections.

In fact, due to specific training, he is the most suitable figure to direct the complex process of clinical risk management (Dell'Erba et al., 2003) which also includes the prevention of nosocomial infections.

In addition, the medical-legal practitioner is responsible for the ethical and deontological implications of the problem of healthcare-related infections, problems relating to informed consent and, more generally, to the patient's information about the risk of acquiring a nosocomial infection.

The development of prevention protocols has made it possible to contain the ICAs phenomenon, while leaving a non-preventable residual risk quota.

This risk is borne by the Health Authorities which, having a role of guarantee towards the citizen, are in an unfavorable position from a procedural point of view and are therefore called upon to compensate the damage even in situations in which the connection causal is extremely uncertain, as it is not always easy for the structure to provide proof of its fulfillment

In a hospital environment, some infections can get out of control despite an appreciable, tangible and valid commitment in addressing the problems relating to the sanitation of environments, personnel, equipment and any other possible source of contact and contagion, also through the work of suitable protocols.

Therefore, it must be acknowledged that infections not attributable to the hospital can occur, because they are predictable but not all and always preventable; this means that, once the nosocomial infection has arisen and the principles governing the burden of proof have been applied, in contractual matters the hospital structure must be required to prove that it has adopted all the useful and necessary measures for proper sanitation, aimed at avoiding contamination of patients by nosocomial bacteria.

This means that the hospital will have to prove that the harmful event (infection by nosocomial bacterium) was indeed possible and predictable, but not preventable, because it is included in that percentage of cases which, according to medical science, constitute events that can escape control. Safety measures put in place by the healthcare facility.

Therefore, it is a question of providing negative proof by demonstrating, in positive terms, that all those precautions have been put in place which, according to the knowledge of the moment, could have avoided, or reduced, as much as possible, the infectious risk.

These principles are the cornerstone of the rulings made, on the subject, by the Supreme Court of Cassation, a body at the top of the ordinary jurisdiction, which has established that, in the event of a nosocomial infection, the responsibility, if ascertained, falls on the Health Structure where the infection was acquired.

In fact, as part of the "hospitalization" contract that is created between the patient and the Structure, the structure must provide all the means necessary to prevent the development of an infection, guaranteeing a sufficient standard of sterility (Civil Cassation Sections United of 01/07/2002 n. 9556).

In the event that the infection develops, the Health Structure involved must demonstrate that it has applied all the prevention measures provided and that the infection has arisen for an external cause (Civil Cassation Section III of 07/06/2011 n. 12274).

Without the "release proof", the defendant Healthcare Facility must, after being sentenced, compensate for the damage (Vallega, 2014).

In light of these data and the frequent litigation in the medical-legal field, we examined eighteen civil judicial judgments issued in Italy between 2020 and 2021 and relating to civil cases initiated between 2014 and 2018 for damages from alleged health malpractice.

Aim and Scope

The article aims to examine the nature of compensation claims for alleged health malpractice in the context of hospital infections in Italy.

In light of the new Italian legislation on the subject of health responsibility (Law 24/2017) and the numerous sentences issued by the Supreme Court of Cassation regarding health responsibility in hospital infections, we asked ourselves what were the characteristics of the disputes that arose, such as were the alleged damages most often complained of, what were the possibly reprehensible behaviors of the health workers and, above all, what were the reasons for accepting or rejecting the request for compensation.

MATERIALS AND METHODS

We conducted a retrospective study.

For the search of the sentences, the Portal of Telematic Services (PST) of the Ministry of Justice was used, a tool that allows the search and display of the judgments of merit only to those registered in the REGINDE, without the need for a subscription.

We randomly selected eighteen judgments issued from 2020 to 2021 in Italy and concerning claims for healthcare-related infections promoted from 2014 to 2018.

The terms "hospital infection", "nosocomial infection" and "health responsibility" were used to select the sentences then analyzed.

The content of the judgments was then examined in detail also for the aspects concerning the outcome of the Judge's decision.

In addition to the competent Court and the date of delivery of the sentence, the sex and age of the plaintiff/appellant, the type of hospital infection, the pathogenic microorganism responsible for the " infection, the type of intervention/treatment suffered by the patient, the outcome of the dispute, the damage recognized in case of acceptance of the request for compensation (in terms of permanent biological damage, temporary partial and total disability and economic recovery of the overall damage non-patrimonial) and the motivation of the sentence.

These data are shown in table 1.

However, even for the Italian privacy legislation which is severe (in favor of the protection of the rights of individuals), some data relating to the plaintiff/plaintiff were not found.

In all the judgments the outcome and motivation of the same was clarified. This aspect is fundamental as it allows tracing some recurring characteristics.

Table 1
THE CONTENT OF THE JUDGMENTS AND JUDGE'S DECISION

COURT	GENDER-AGE OF THE APPLICANT	TYPES OF INFECTION	FURTHER SPECIFICATIONS	TYPE OF INTERVENTION/TREATMENT	OUTCOME JUDGMENT	DAMAGE RECOGNIZED	REASON FOR JUDGMENT
Court of Rome 2020	F - 76	Surgical infection (meningitis)	N.A.	Intervention of decompression of the soma of L-1	Rejection of the application	No	No recognition of the cause link
Court of Perugia 2020	F - 55	Osteomyelitis	S. Aureus mrsa	Orthopedic treatment of hallux valgus	Acceptance of the application	Biological damage 5% -	Lack of protocols to avoid nosocomial infections
						partial disability at 75% 1 month	
						partial disability at 50% 1 month partial disability at 25% 1 month non-asset damage - 6.839, 47 €	

Court of Catania 2020	F - 17	Prosthesis infection	Staphiloccus (not specified)	Corrective mastopexies	Acceptance of the application	Biological damage 15% -	Lack of protocols to avoid the nosocomial infections - inadequate therapy
						total disability :60 days	
						partial disability at 75%: 80 days	
						partial disability at 50%: 30 days 81.251,00 €	
Court of Palermo 2020	F - 73	Infection of prostheses	N.a.	Right knee arthrothesis	Acceptance of the application	Biological damage 30%	Lack of protocols to avoid the nosocomial infections
						total disability :107 days	
						partial disability at 75% 294 days	
						partial disability at 50% 475 days partial disability at 25% 108 days 324.936, 00 €	
Court of Latina 2020	F - N.A.	Synovitis	S. Epidermidis	Arthroscopy left knee	Acceptance of the application	Biological damage 9%	Lack of protocols to avoid the nosocomial infections
						total disability :90 days	
						partial disability at 75% 80 days	
						29,444.60 €	
Court of Milan 2020	F - N.A.	N.A.	P. Aeruginosa	N.A.	Acceptance of the application	Parental loss damage	Lack of protocols to avoid the nosocomial infections
Court of Brindisi 2020	M - N.A.	Pneumonia	K. Pneumoniaea	Surgical treatment for intestinal occlusion	Rejection of the application	None	No recognition of the cause link
Court of Milan 2020	M - 38	Prosthesis infection	E. Coli	Gluteoplastics	Acceptance of the application	Biological damage 12-13%	Lack of protocols to avoid the nosocomial infections
						Partial disability 165 days not specific over	
						35.700, 00 €	
Court of Pistoia 2020	F - 57	Osteomyelitis	P. Aeruginosa	Neurinoma removal of Morton	Acceptance of the application	Biological damage 4-5%	Lack of protocols to avoid the nosocomial infections
						total disability :1 month	
						partial disability at 75%: 1 month	
						partial disability at 50% 2 months	
						partial disability at 25%: 2 months 8.585, 80 €	

Court of Catania 2020	F - 37	Injury infection	N.A.	Foreign body removal	Acceptance of the application	Biological damage 50%	Lack of protocols to avoid the nosocomial infections - inadequate therapy
						total disability :50 days	
						partial disability at 75%: 200 days	
						170.571,37 €	
Court of Turin 2021	F - 82	Endophthalmitis	C. Freundii	Intervention for cataract	Acceptance of the application	Biological damage 28%	Lack of protocols to avoid the nosocomial infections
						total disability :14 days	
						partial disability at 75%: 16 days	
						partial disability at 50% 30 days	
						104.692, 00 €	
Court of Vicenza 2021	F - 57	Surgical infection - loss of visus post-infection	S. Marcescens	Surgical treatment for meningioma removal	Acceptance of the application	Biological damage application as differential damage: 45% (75% - 30%)	Lack of protocols to avoid the nosocomial infections
						total disability :30 days	
						335.76 €	
Court of Lecce 2021	M - N.A.	Post - surgical infection	A. Baumanii	Cholecystectomy	Acceptance of the application	Parental loss damage	Lack of protocols to avoid the nosocomial infections
Court of Milan 2021	F - N.A.	Prosthesis infection	S. Aureus	Prosthesis infection left knee	Acceptance of the application	Biological damage 55%	Lack of protocols to avoid the nosocomial infections
						total disability :753 days	
						partial disability at 75%: 306 days	
						137.550,00 €	
Court of Palermo 2021	F - 63	Infection of surgical wound	S. Aureus	Aureus internal osteosynthesis for fracture of the anatomic neck right humerus	Acceptance of the application	Biological damage: 18%	Inadequate therapy
						total disability :47 days	
						partial disability at 75%: 150 days	
						partial disability at 50%: 130 days	
						partial disability at 30%: 105 days	
						38.152, 00 €	
Court of Rieti 2021	F - 61	Prosthesis infection	S. Epidermidis	Reduction and osteosynthesis femur fracture	Rejection of the application	None	No recognition of the cause link
Court of Florence 2021	M - N.A.	PM infection	S. Aureus	PM implant	Acceptance of the application	Parental loss damage	Infection diagnostic delay

Court of Bologna 2021	F - N.A.	Post - surgical infection	Staphylococci various	Arthroprotesis right knee	Acceptance of the application	Biological damage application as differential damage: 5% (20% - 15%)	Lack of protocols to avoid the nosocomial infections
						total disability :34 days	
						partial disability at 50%: 30 days	
						partial disability at 25%: 240 days	
						31.172, 00 €	

STATISTICAL ANALYSIS

Statistical analysis was conducted using Microsoft Excel 2013 software (Microsoft Corporation, Redmond, WA, USA) and IBM SPSS Statistics version 25 for windows (IBM Corporation, Armonk, NY, USA). The categories examined were then represented in percentage terms.

RESULTS AND DISCUSSIONS

We examined in detail eighteen sentences issued by various Italian Courts from 2020 to 2021 and relating to cases of alleged health malpractice in the context of infections contracted in a hospital setting. Four causes were promoted by male individuals (22.2%), while fourteen by female individuals (77.8%) (Figure 1). In fifteen cases (83.3%) the reported infections were related, in our series, to surgical interventions, eight of which (53.3%) concerned orthopedic interventions. The judgments examined resulted in acceptance of the plaintiff/plaintiff's claim in fifteen cases (83.3%) and in the rejection of the claim in 3 cases (17.7%) (Figure 2). In eleven (73.3%) of the fifteen sentences that accepted the request for compensation, the reason given was the lack or non-compliance with protocols aimed at avoiding nosocomial infections. In two cases (13.3%) the motivation for acceptance was twofold (lack or failure to comply with protocols aimed at avoiding nosocomial infections and therapeutic inadequacy). In one case (6.7%) the application was accepted only for therapeutic inadequacy and, finally, in another case (6.7%) the health workers were recognized as responsible for a diagnostic delay of the nosocomial infection (Figure 3).

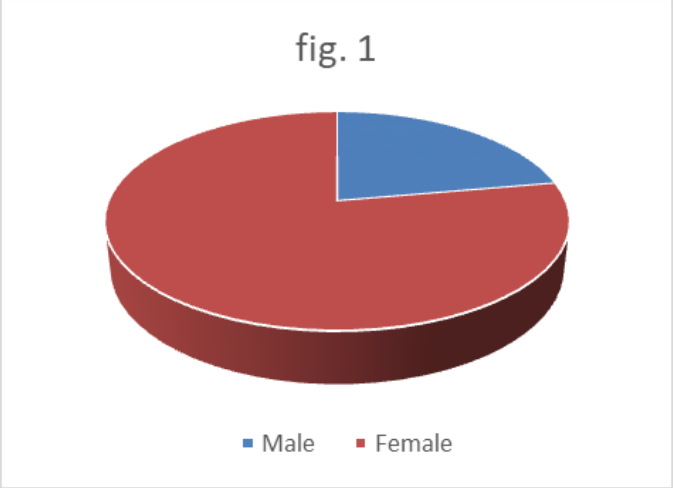

FIGURE 1
CASES OF ALLEGED HEALTH MALPRACTICE AMONG MALES & FEMALES

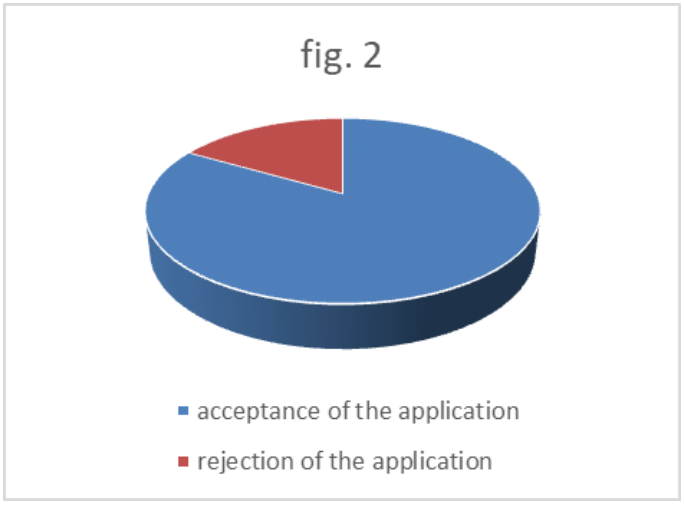

FIGURE 2
ACCEPTANCE & REJECTION OF THE APPLICATION

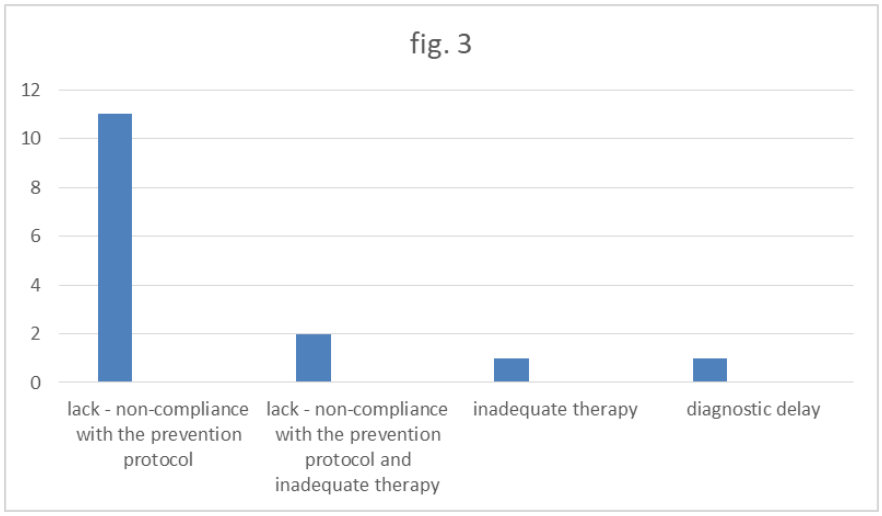

FIGURE 3
DIAGNOSTIC DELAY OF THE NOSOCOMIAL INFECTION

It is therefore clear that the main reason why the Health Authorities have been sentenced to pay compensation for the damage is the total lack or non-compliance with protocols aimed at the prevention of hospital infections.

In Italy, the legal principles governing the civil liability of health workers and the health facility are linked to the "hospitalization contract". In the event of non-compliance, the provisions of art. 1218 "liability of the debtor" and art. 1228 “responsibility for acts of auxiliaries” of the Civil Code.

There is also the duty to indicate the rules for the prevention of nosocomial infections, the duty to verify and supervise compliance with these protocols through periodic meetings, and to verify the adequacy of the surveillance process as indicated by the literature [8] and by the recommendations formulated by the National Guideline System (SNGL 17, "Antibiotic-perioperative prophylaxis in adults", Directorate-General for Planning of the Ministry of Health, September 2008) for example as indicated in the Operating Room Safety Manual - Recommendations and Checklist, published in October 2009 by the Quality Department of the Ministry of Labor, Health and Social Policies (Bonelli, 2012).

Regarding the peri-operative antibiotic-prophylaxis, it was specified that the antibiotics used for prophylaxis must be administered in the 30-60 minutes prior to the surgical incision, according to appropriate dosages and based on the spectrum of effective action against the most contaminating agents predictable.

Therefore, the need clearly emerges, in relation to the above obligations, to note what has been implemented in order to demonstrate, in a possible dispute, the execution of the practices aimed at controlling the infection.

Furthermore, at the company level, interventions aimed at the prevention of hospital infections must be carried out periodically, without neglecting microbiological investigations on health workers, and the management of the departments must provide, at least twice a year, the drafting of a monitoring report of pathogenic germs.

The Italian Supreme Court of Cassation (Cass. SU n. 577/2008) has in fact established that, in the event of a hospital infection, proof of having fulfilled the specific obligations (disinfection, sterilization ...) or, alternatively, of the absence of the causal link between the infection and the alleged non-fulfillment.

The legal premises just made allow us to understand the reason why, in our case law, in almost all cases the case law condemns health structures to compensation for damage from hospital infections (Donelli & Gabbrielli, 2018), since it is extremely complex for the latter to provide proof of fulfillment.

The comparison between our cases and the results of the Civil Processes for reasons of health responsibility allows us to detect a substantial difference between the acceptance of compensation requests for hospital infections (cases of our work) and acceptance of compensation requests for alleged health malpractice of other areas.

Data extracted from Consulcesi an Italian company operating in the field of legal health assistance and health professionals, in fact report that about 66% of civil proceedings in the field of health responsibility in Italy are rejected: in our case, however, only 17.7% of the cases examined result in a non-acceptance of the plaintiff/plaintiff's request.

This data, albeit based on limited numbers, confirms, as recognized by the medico-legal doctrine, the difficulty on the part of the health facility to demonstrate that it has put into practice all the means (or all the recommended means) aimed at preventing the onset of hospital infection.

A further numerical discrepancy must be highlighted between the preventability of hospital infections (estimated at 30% according to the scientific literature on the subject) and the percentage of acceptance of the compensation request of our case series (86.7%). In other words, if the scientific literature agrees that 30% of hospital infections are preventable and that 70% are not preventable (thus being a complication not attributable to responsibility), a similar percentage of acceptance of requests would be expected. Compensation (30% - a figure, however, in line with those reported by Consulcesi in relation to the acceptance/rejection of compensation claims for civil health liability cases).

CONCLUSION

The clear difference observed between the national data of acceptance of compensation claims for civil cases of health responsibility (34% according to the data of Consulcesi) and the data of acceptance of compensation claims for nosocomial infections of our case series (86.7%), to opinion of the authors, is due only in part to the inadequate execution of the ICAs prevention protocols. In fact, it seems plausible that the main reason for this high acceptance of compensation claims originates from incongruous or inadequate annotation/registration of the preventive procedures actually carried out.

It would therefore be appropriate, also in relation to the consequent social cost that the causes in this area cause, that all the precautions aimed at these surveillance procedures were actually implemented or adequately noted in order to allow, as the Italian legislation on the subject provides, to the health facility to produce the "release proof" of the correct fulfillment.

CONFLICT OF INTEREST

There isn't any conflict of interest.

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