

## Infections in hospital departments. What is Hospital Responsibility?

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### Abstract

Infections in hospitals still have a high incidence and many of them could be avoided through better welfare standards. To try to overcome them, a strategy based on prevention is needed, but cleaning, disinfection and sterilization procedures are also a key tool. It is important to provide for all healthcare professionals a constant update and the creation of protocols that take into account the technical, scientific and economic aspects, but also specific operational needs, so that the proposed solutions can be applied in daily routines.

The authors outline the mandatory duties to the doctors and hospital and underline the need to document in the clinical record the treatments performed. In case of infections occurred in hospital environment, the patient must demonstrate the guilty nature of the hospital's conduct, the existence of a harm and the causal connection. The hospital must demonstrate that asepsis measures were adopted according to the actual scientific knowledge and they must cover not only the treatment but also the diagnosis, all the activities prior to surgery and the postoperative phase.

The sentences examined show that hospitals can avoid being accused of negligence and imprudence only if they can prove that they have implemented all prophylaxis measures contained in the guidelines and protocols. They must demonstrate that the infection was caused by an unforeseeable event. While some initiatives to improve the quality of hospital care have already allowed a decrease in the incidence and cost of these infections, much remains to be done. *Clin Ter 2017; 168(4):e266-270. doi: 10.7417/CT.2017.2018*

**Key words:** antibiotic, clinical record, infection, liability, negligence

### Introduction

Since the nineties, health care is not only carried out in hospitals, but also in assisted living residences (ALR) for the elderly, at the patient's home and in private clinics.

Many surgical treatments, anticancer or immunosuppressive therapies, are provided with outpatient management (day-hospital). The consequence of this change is that many infections do not occur during hospitalization as the mean hospitalization time has decreased, but they happen in other

care facilities. Thus, today the term "hospital infection" has been replaced by "infection associated with health care".

These infections represent a complication of health care. We talk about infections not clinically manifested or incubated at the time of admission to hospital, as they usually occur during hospitalization, after at least 48 hours or within 30 days from dismissal. The sources of microorganisms that can give rise to hospital infections are numerous: the same structures or plant failures, as in the case of infections transmitted through water or air (1,2).

They are present in both industrialized and developing countries. Despite the wide range of available knowledge in terms of both risk factors and appropriate prevention methods, the frequency of health care-related infections is increasing (3). International studies attribute this failure to an inadequate organization of the structures. Transmission can be avoided with simple cautions: use of the coat, disinfection of skin wounds such as decubitus wounds, separation of clean from dirty linen, sterilization of hospital units, but, above all, hand washing (4,5).

International studies have shown that if healthcare professionals strictly observe hand hygiene, the rate of infection decreases from 10 to 50% (6). Hospital infections cannot be eliminated because about 70% are endogenous, that is, they appear when a microbial flora, already present in the patient's body, becomes virulent for the fall or collapse of immune defenses (the so-called autoinfections). Thirty percent of them can be prevented and managed because the responsible microorganism comes from outside. These infections occur when hygiene standards for environmental cleanliness, sterilization of equipment, and hospital units are not respected, or when antibiotics are not appropriately administered (7,8).

Nevertheless, even inadequate hospital facilities and lacks in air and water conditioning systems can cause infections, such as legionella infections. Recent studies have shown that the preventable quota is much wider. Some authors consider each single infection as an adverse event that is no longer tolerable and advise on implementing measures for the prevention of all infections, (the so-called "zero tolerance") (9). Prevention is achieved through the issuance

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of guidelines and behavioral codes that hospital operators must scrupulously apply, but also through training programs and ongoing assessment to see if the measures taken are effective. Experts in various disciplines must be present: microbiologists, epidemiologists, hygienists, infectologists, and occupational doctors. They must cooperate with the head doctor who is responsible for ensuring that the preventive protocol is scrupulously applied.

### The problem of antibiotic resistance

Scientific studies have shown that the phenomenon of antibiotic-resistance is closely associated with excessive and inappropriate use of antibiotics (10).

In many cases, hospital infections are caused by multi-resistant, or even anti-biotic, bacteria, which can thus survive the action of drugs. The main factor influencing the antibiotic resistance is the high consumption of antibiotics; in fact, their excessive and improper use accelerates the onset and spread of such bacteria. The 2014 European Center for Prevention and Control report stresses that in Italy antibiotic resistance is among the highest in Europe.

In the four-year period 2009-2013 there was a sharp increase in resistance to carbapenem for *Klebsiella pneumoniae* (from less than 1% in 2008 to 34% in 2013), while Gram-positive data are stable but high (14% Penicillin and 25% macrolides for *Streptococcus pneumoniae* and 36% methicillin for *Staphylococcus aureus*) (11,12). In general, drug-resistant bacteria have caused about 25.000 deaths in Europe every year, and the economic impact, health costs and productivity loss has been estimated at about 1.5 billion euros (13).

To worsen the problem of antibiotic-resistant drugs, the auto-prescription phenomenon is added. People often take antibiotics without doctor's prescription and use the "remnants" of previously purchased packages. The European Union has funded the Arna project that confirmed this problem: from 9.313 Italian patients interviewed, 9% took antibiotics without a prescription, and 87% of them used antibiotic remnants available at home (the so-called left over) (14).

To reduce the bad use of antibiotics, the Ministry of Health is considering the possibility of marketing antibiotic packs with calibrated doses to reduce their bad use (15) and therefore the antibiotic resistance phenomenon (16). On its side, the World Health Organization has launched two campaigns with the slogan "Antibiotics: handle with care" and "Antimicrobial resistance: no action today, no cure tomorrow". The aim was to raise awareness among citizens and health workers about the importance of using antibiotics only when necessary and under the doctor's prescription, to ensure their effective use. In addition, it is advised to never discontinue therapy before the times indicated by the doctor or, in any case, interrupt it only after his advice and not to take antibiotics to cure viral infections (17-19).

### Surveillance of hospital infections

To control the phenomenon of health care-related infections, it is crucial to have a fast signaling system of events that require timely intervention. For example, in the case of legionella acquired in hospital, or tuberculosis not diagnosed at the time of hospitalization, immediate reporting allows the patient to be placed in hospital isolation. Timely detection of epidemic events, or infections sustained by microorganisms with antibiotic resistance profiles, allows an epidemiological investigation to identify the causes and to prevent further secondary cases.

The Ministry of Health issued two newsletters: "Indications containing carbapenemase-producing bacteria (CPB) infection prevention and control measures" of June 5, 2012 (20) and "Monitoring and control of infections from carbapenemase producing bacteria" of 26 February 2013 (21).

The first contained measures to strengthen: (a) the scrupulous use of precautions by health care staff, through increased hand hygiene, the use of gloves and overcoats, and the intensification of environmental hygiene.

The second contained guidelines on the following matter: a) passive surveillance through the detection of bacteremia from carbapenemase strains; b) active surveillance of the contacts with certain type of patients. These include infected or colonized patients, patients previously identified as infected or colonized who enter a hospital for the second time, patients from endemic countries (Greece, Cyprus, Pakistan, Colombia, India and Others), and patients who are admitted or transferred to risk departments such as intensive care, oncology, and transplant surgery.

Not having achieved significant results, with Law 28 December 2015, no. 208 (Stability Law for 2016) (22) the Ministry of Health has envisaged that public and private healthcare facilities should activate a monitoring, prevention and management and risk management utility (23,24).

Prevention programs can reduce infections. Two situations can occur: 1) the structure did not issue general prevention guidelines; 2) the directives were present but the department did not respect them. In the first case, the responsibility lies with the hospital managers (general manager and health director) and with the members of the Hospice Infection Committee, if constituted. In the second case, conversely, health care staffs are responsible for the non-application of prevention rules, for example: a doctor who does not regularly wash hands, etc.

Within healthcare facilities, there is a hierarchy that has to organize the department's health care, but it is also required to supervise it (25). Thus, even the head doctor may be considered co-responsible for a nosocomial infection, especially if he has not adopted appropriate measures and did not control compliance with prophylaxis measures.

### Responsibility of the medical doctor and the structure in case of infections

In the event of damage caused by hospital infections, the patient may sue the public or private hospital. When a patient enters the hospital, he stipulates with the facility a healthcare contract. The facility is obliged to ensure the

adequate presence of qualified medical, paramedical and auxiliary personnel, hygienic premises, and the proper functioning of the equipment.

Therefore, the structure is responsible for both events that depend on the structure itself, for example inadequate equipment, and for mistakes made by the doctor or paramedical personnel, such as forgetting a gauze in the abdomen. In case of litigation, the injured patient must prove that: 1) he had a contract with the hospital structure 2) he suffered damage 3) his health deteriorated because the facility did not properly perform the healthcare benefits it was contractually obligated.

The hospital must document that: 1) it has carefully observed all the technical requirements, e.g. correct sterilization of the operating rooms, 2) it has predisposed all the measures to ensure the patient's stay in a healthy environment 3) the infection derives from a cause not attributable to the structure (art. 1218 cc). It is undoubtedly difficult to reconstruct the moment an infection has arisen. For this reason, in order to confirm the existence of the causal link, the law uses a presumptive criterion because it takes a long time since the infection occurs when the judge has technical advice to ascertain the facts (26,27).

The judge also often uses the chronological criterion, i.e. he evaluates whether there is a correspondence between the time of infection and the period of hospitalization. On several occasions, counselors deny that the infection has occurred in the hospital because the time between dismissal and contamination is long.

In ophthalmic units, in most cases the infection has an external origin (28-30): the germ comes from the environment, affects the eyelid border and the tear film covering the palpebral and bulbar conjunctiva, besides the cornea. In addition, foreign bodies that penetrate the eye following perforating trauma or intraocular surgical procedures can carry the infection (31,32).

Endophthalmitis caused by surgical operations occur within 24 to 72 hours after surgery, with pain and sharp vision loss, eyelid swelling, redness, inflammation of the cornea and vitreous body (filling the eyeball). They may arise immediately after surgery, often in acute or late fashion. Generally, the primary causes are in this case the bacteria (33).

In its judgment of 9 March 2009 (34), the Court of Bari condemned the hospital because, after a cataract surgery, an infection of *Pseudomonas aeruginosa*, a pathogen diffused in hospital environment and particularly resistant to antibiotics, occurred (35). Its action can cause hemorrhage and necrosis of the tissue, and the destruction of the cornea within a few hours (36,37).

The doctor who performed the surgery had been acquitted because he had shown that he had used disposable devices and followed the prophylaxis of endophthalmitis prevention (38). In fact, he had sterilized the operating field and given the patient antibiotics already before surgery and at the time of dismissal. However, these cautions were not sufficient to avoid the infection because this bacterium is very resistant to antibiotics. The facility had, however, been convicted for failing to demonstrate that it had properly performed disinfection and sterilization of the operating rooms and sampling air in the operating rooms (38).

Infection also occurs very frequently in the birth room and recent chronicle cases (39) have pointed out how this issue can turn a moment that should only be joy into tragedy. In fact, still in the years 2000, delivery is not yet a safe event, sometimes for illnesses not yet well-known (40), other times for poor health care-related problems (41,42).

The Court of cassation with the sentence delivered on 1 March 2010, no. 24401 (43) convicted a hospital because a little girl had suffered at birth neurological lesions caused by cerebral hemorrhage due to a *Klebsiella* infection. The hospital had not demonstrated that it had properly disinfected and sterilized the operating room and the equipment used, nor had it shown that there was no causal relationship between the failure and the damage. For example, it had not shown that the infection was already in place when the mother was hospitalized.

To avoid condemnation, the hospital should have provided rigorous evidence for having taken all possible precautions to avoid the onset of the infection itself. It should have also demonstrated that nosocomial bacterial contagion was possible and predictable, but not preventable, because it was part of those cases that medical science considered as events that could escape the safety controls provided by healthcare facilities.

This "negative" evidence should have been provided through the "positive" evidence for having adopted all the measures that the research on the field had developed to avoid or, at least, reduce the risk of contamination. In this case, the judge could have considered the infection as a complication of intervention. In fact, the law agrees that in the case of an infection contracted by the patient as a result of a surgical operation, the hospital's liability does not exist if the onset of the disease is due to an unforeseen, unavoidable event and not imputable to doctors' conduct.

## Conclusions

The health-related infections (HRI) phenomenon in Italy is the sixth claim for compensation and the fourth cause for reimbursement. "Economic risk linked to HRI falls on regional and national health systems because infections increase the days of hospitalization and convalescence of the patient. Hospital infections are a complex issue, which can only be effectively countered if a HRI surveillance system is activated because it is demonstrated that, without monitoring, their incidence tends to increase with damage to both patient health and quality of care.

The law cases exposed here demonstrate not only the absolute necessity to adopt all the measures proposed by the laws and scientific guidelines on HRI prevention, but also the importance of documenting in detail the adoption of these technical directions. Otherwise, it is very likely that the healthcare provider and the medical practitioner will be convicted for professional or organizational responsibility and/or for submitting insufficient documentation, even if the technical advisor fails to identify the cause of the infection.

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