

Biological hazards and healthcare-associated infections in Italian healthcare facilities: some considerations on inspections and accountability

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Key words: HAI, biological hazards, liability, medical surveillance

Parole chiave: ICA, rischi biologici, responsabilità, sorveglianza sanitaria

Abstract

Healthcare-associated infections are a major clinical and public health problem that involve, in a variety of ways, healthcare professionals, hospital administrators and, above all, patients. In Italy, the incidence of infectious complications generally varies from 5-10% (hospitalized patients) to 1% (home care patients); 5-10% of such infections manifest epidemically, and infections caused by antibiotic-resistant microorganisms are becoming more and more common, with a mortality rate of 20-30%. Moreover, any "preventable deaths or serious injuries" attributable to a (concrete) causality resulting from a breach of rules, laws and regulations, as well as imprudence, incompetence or negligence by the operators will determine a possibility of a penal prosecution for manslaughter or grievous bodily harm, and also generate expenses for civil procedures and insurance compensation. The adoption of company policies covering appropriate risk assessment, epidemiological monitoring, implementation of guidelines, procedures and protocols, activity of the Hospital Infections Committee and proper communication between managers and facilities, training of healthcare personnel and medical surveillance of employees can help reduce the adverse phenomena of healthcare-associated infections.

According to data from the World Health Organization (WHO), 4,1 million patients are affected by healthcare-associated infections (HAI) in Europe each year, and this phenomenon may have significant implications even at a legal level. HAI are therefore a major clinical and public health problem that involve, in a variety of ways, health professionals, hospital administrators and, above all, patients. In fact, such infections are increasingly being perceived

as negligent offence in the context of social and healthcare legislation in Italy (1).

The overall frequency of HAI complications in Italy is thought to be approximately 10.5% in hospitalized patients, 5% in patients living in nursing homes and 1% in homecare patients. Moreover, since 5-10% of infectious complications take place epidemically, and HAI caused by antibiotic-resistant microorganisms are becoming more and more common, the current pneumonia

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mortality rate is estimated to have reached 20-30% (2, 3). From a legal point of view, some situations may be prosecutable under Section 438 of the Italian Penal Code: "*Whoever causes an epidemic through spreading pathogens is punished...*". According to the Court of Cassation, an epidemic is intended as an extraordinarily aggressive infectious and contagious disease, characterized by an elevated and uncontrollable diffusion ability. This term obviously refers only to diseases that affect people, given that those affecting animals only are defined in Section 500. The Penal Code, in practice, provides a hypothesis of negligent offence (breach of rules, laws, regulations, carelessness, incompetence, negligence), which is also the most plausible indictment (in theory) in cases involving HAIs, punishable by imprisonment from one to five years (as per Sect. 452 of the Penal Code).

From an etiologic point of view, HAIs are considered potential side effects that account for about 50% of hospital complications, causing an increase in costs for both the patient and the healthcare facility. HAIs are potentially avoidable in at least 30% of cases, with significant variations depending on the type of infection and the environment (incidence of preventable infections varies from 10 to 70% in different studies). Furthermore, infections contracted by healthcare workers during patient care should also be taken into account within this context (for example in correlation with non-compliance with the minimum preventive measures required by the Italian Legislative Decree No. 81/2008) (4).

The factors listed above lead to an initial consideration: combining a "preventable death or serious injury" to a (concrete) causality sustained by a breach of rules, laws and/or regulations, as well as imprudence, incompetence or negligence by the operators, will determine a possibility for penal prosecution for manslaughter or grievous bodily harm, allowing the authorities to

carry out investigations and surveillance with a mandate or delegation by the judicial authority or on their own initiative on the basis of reports or information received.

Some authors (1) have shown that in this respect, the recent increase in litigation associated with a progressively more favourable stance towards the affected individuals, has fostered attitudes of "defensive medicine" by medical professionals, who are being left increasingly uncovered by any form of legal protection. Various authors have also called for the implementation of new legislative measures inspired by the experience in other European countries.

Regarding HAI, the following considerations should also be made: *The risk of hospital infections is greater than in the past because of the increased use of invasive technologies, the prolonged survival of immunosuppressed and seriously ill patients, the larger quantity of hospitalized elderly patients, circulation of antibiotic-resistant bacteria in the hospitals, inadequate procedures and/or information and/or training (often in care homes) or the subsistence of highly obsolete facilities without up-to-date equipment.*

It must also be taken into account that, in Italy, there is a professional figure who is often overlooked in the prevention process, usually relegated to carrying out clinical and diagnostic tasks despite of possessing valuable expertise that could greatly benefit the preventive health and safety management process: the occupational health physician (OHP). The OHP participates in the risk assessment procedures and is considered a reference figure for the employer in terms of biological hazards, given both his/her *qualifications* (six years of medical school, followed by specialization and eventual a Master's degree) and the current Penal Code, which states that the OHP is *penally liable in the event of inadequate cooperation* with the employer in this context (Legislative Decree 81/2008, Section 25, Paragraph 1 A).

Several multicenter studies have been carried out on the *prevalence* of HAI; what should be noted is the fact that the presence of considerable variations between the “average” incidence of infections within diagnostic and care structures depending on the operators leads to a subsequent conclusion of inadequacy and the need for optimization of facilities, protocols, procedures, and assessment procedures, including employee monitoring. It should be highlighted that infections seem to be more frequent in small and mid-level structures (2), and that, according to a study by insurance companies, hospital infections in such settings cause death in 8.2% of cases, with an average cost of about 113,000 € per each deceased patient. Moreover, some incidence assessment studies shows that the department with the highest incidence of hospital infections is Orthopaedics and Traumatology (29.57%), and the proportion of penal procedures is obviously elevated in cases leading to the death of the patient (6.19% - 0.56% for lesions). The highest number of incidents seems to take place in Northern Italy (but perhaps this could be due to under-reporting in other regions), and, in line with the national trend, extrajudicial

practices are frequently resorted to (87.17%). These data are still relevant, even though penal procedures are less frequent than the national average (1% for infection - national figure about 8%) (5) (Table 1).

In the context of HAI prevention strategies, the factors currently considered important include:

- Risk assessment
- Epidemiological surveillance
- Implementation of guidelines, procedures and protocols
- Resolutions and actions of the Hospital Infections Committee and proper communications between managers and structures
- Training of healthcare workers
- Employee's health surveillance.

It must be kept in mind that the biological agents associated with HAIs *are included in the risk factor classification* of the Annex XIV of Legislative Decree No. 81/2008 on workplace safety and security, and that specific safety standards must be implemented in relation to *work environments, procedures and workers, since failure to observe the current regulations can be penally sanctioned, as per the provisions of Chapter X - Section I of the*

Table 1 - Statistics on the prevalence of HAI in Italy

	Cases	Prevalence
Zotti, 2000: Piedmont/entire hospital	9467	7.8%
Di Pietrantonj, 2000: Italy/entire hospital	1315	9.0%
Lizioli, 2000: Lombardy/entire hospital	18867	4.9%
Nicastri, 2001: Italy/entire hospital	2165	7.5%
Moro, 2001-2002: Emilia-Romagna/nursing home	1926	9.6%
Studio Spin, 2004: Veneto/entire hospital	6352	6.9%
Ippolito, 2002: Italy/entire hospital	3306	6.9%
Ippolito, 2003: Italy/entire hospital	3402	6.2%
Ippolito, 2004: Italy/entire hospital	3416	5.4%
Ippolito, 2004: Italy/entire hospital	2901	6.7%
Rodella, 2004: Tuscany/entire hospital	6631	4.5%

abovementioned Decree (Articles 266-286) and Annex IV on workplace hygiene. In summary, it is clear that the biological agents typically involved in HAIs are *not restricted to the affected person*. Moreover, the specific regulations for health and safety at the workplace are also used to verify the adequacy of procedures and defence methods against HAIs. Therefore, these regulations must be known, discussed and disseminated among all workers who can potentially become exposed to the risk of HAIs; thus it emerges an increasing need for interdisciplinarity.

It should also be noted that there is growing attention towards work-related diseases: a recent Memorandum of Understanding between the prosecuting authorities, local health authority (ASL), National Institute for Insurance against Accidents at Work (INAIL) and Provincial Employment Department (DPL) in Tuscany has been instituted for the management of work accidents and occupational diseases, also in order to establish improved channels for transmitting information during investigations on eventual professional liabilities (6).

Particular attention must be paid to any accountabilities while investigating HAI cases: the current tendency involves determining a liability through debasement of establishing the causal link and reversal of the burden of proof borne by the operator, with the concurrent rise of tougher sentences which - being more and more geared towards the protection of health - are often in favour of the patient. Within the context of civil implications and liabilities, a progressive weakening can be observed in the legal protection of the professionals involved in the implementation of prevention strategies, including occupational health physicians.

Also, in the health sector, it could be considered *negligence*, according to case law, for the operator to "tolerate" unsanitary situations, not denouncing the shortcomings, or - at best - "not to notice" situations of

degradation or lack of minimum standards in inadequate facilities during the course of routine inspections (by an OHP or medical director, for example).

The implementation of a Management System for Workplace Health and Safety (*Sistema di Gestione della Sicurezza sul Lavoro - SGSL*; defined in the Legislative Decree 81/2008) and an internal vigilance body (7) in a healthcare facility may constitute an appropriate control strategy for preventive measures since they:

- monitor the efficacy of the strategy, namely the consistency between the actual behaviours and the established model;
- evaluate the appropriateness of the strategy, i.e. its actual - and not merely formal - capacity to prevent illicit behaviours;
- analyze the continued compliance with the requisites of integrity and functionality of the strategy;
- ensure the necessary dynamic updates to the strategy, when the analyses carried out call for corrections and adjustments".

In this regard, the Regions Lombardy (8) and Lazio, in cooperation with the INAIL, have recently produced important guidance (9) for establishing a Managerial System for Occupational Safety in healthcare settings, also aimed at preventing occupational diseases, including HAIs.

In fact, ensuring the autonomy, independence and professionalism of a third-party body responsible for the overall assessment of the prevention strategy adopted can be an optimal solution for the improvement of preventive actions provided that "there is no affiliation between the evaluatee and the evaluator", that "interference and influences of economic or personal nature by the governing bodies are eliminated" (as per the decree of the Court of Milan [issued by the *Giudice per le Indagini Preliminari (GIP)*, or Preliminary Investigations Magistrate] on September 20, 2004); and that competent individuals responsible for inspection and consulting

activities are appointed to carry out statistical sampling and analyses, risk evaluation and containment, and to process and evaluate questionnaires.

In any case, what increasingly emerges is the evident need for close collaboration between risk managers, safety and prevention services and OHPs, SGSL, Hospital Health Direction (HHD) and the Employer. The steady increase in litigation, combined with a progressively more favourable stance towards the affected individuals, has fostered attitudes of defensive medicine (also by occupational health physicians) who often are left without adequate support for the creation of a full and comprehensive health and safety strategy. In such situations, a better risk management scheme that incorporates the implementation - as far as possible - of shared and validated procedures, guidelines and protocols is needed. This is essential to fulfil the edicts of the Italian Civil and Penal Codes, as well as the principles included in the Ethics Code of the International Commission of Occupational Health (ICOH) and those upheld by other professional orders, through the application of a set of principles derived from the assessment and best possible understanding of the risks, aimed at a proficient management of these factors.

The guidelines to be implemented should be, above all, endorsed by scientific organizations and evidence-based, since the Italian legislation implies, at least from a penal perspective, that adhering to guidelines that represent a tool based only on cost management, and not on the actual needs of the individual patient, does not fully satisfy the requirements of the constitutional provisions on the right to health (10, 11). Moreover, in medicine, the guidelines endorsed by scientific organizations are designed to optimize the quality of care procedures that can carry risks for the patient and the operator. Such guidelines make up a systematically developed set of recommendations and behaviours, based on

existing scientific evidence for or against a particular type of intervention, aimed at all health professionals. Recommended guidelines have an important role in the verification of eventual cases of suspected professional negligence in implementing the appropriate health and safety requirements. The guidelines “normally contain the most complete and detailed indications based on current scientific knowledge in a specific sector” and in legal proceedings involving negligence (especially in the medical field) guidelines are often emphasized, since they can provide essential elements for the identification of the appropriate response behaviours, to the extent that the Legislative Decree No. 81/2008 includes a procedure for the identification, collection, codification, dissemination and implementation of guidelines and good practices in order to attest to the validity and the scientific nature of the recommendations through an actual selection process (12).

On the other hand, protocols, intended as a set of professional actions with a specific aim (e.g. safety or radiological protocols etc), are documented operational instructions that define the modalities used to complete a specific activity through planning, management and control of processes that could have an impact on occupational safety and hygiene.

Even though these protocols should be simple, understandable, repeatable, applicable, subject to continuing education, and adaptable following testing, they are still not always evidence-based and often obsolete, lengthy, not implemented, untested and non-adapted to specific situations. These deficiencies frequently affect administrative responsibilities, both in the civil and in the penal context. Yet such protocols should be issued in all situations where the absence of precise instructions can cause hazardous conditions for workers, and preferably issued or validated by the health and safety manager and collaborating experts (e.g. risk managers or directors) in cooperation with any personnel with detailed knowledge on

the specific risks (directors, supervisors) and applicable to employees and third parties at risk of potential exposure to occupational hazards, acting on behalf of the facility or in it.

Monitoring of environmental matrices can be particularly useful, also for legal proceedings, to demonstrate the adequacy of the controls, as well as the attention afforded to hygiene issues (e.g. ambient air, and, above all, surfaces), to verify the efficacy of decontamination methods and the asepsis levels, and to rule out biological agent contamination outside of the containment areas provided (13, 14).

Regarding HAIs, we would like to mention the launch of some specific legal actions over the past 10 years, involving the insurgence of cases of Legionellosis (caused by facilities incompatible with guidelines), for cases of Aspergillosis in hospitalized patients, caused by failure to implement precautions (absence of health and safety protocols during interior renovation work), for *Klebsiella pneumoniae* infections in physicians and nurses (due to non-compliance with guidelines) and, in particular, for deaths from *Pseudomonas aeruginosa* in hospitalized patients (again, due to the lack of implementation of guidelines and appropriate sanitation procedures). For some HAIs, despite the inability to pin down the causal event with certainty due to the difficulty of "tracing" the penetration and presence of microorganisms, there have nonetheless been outcomes determining violations and potential liabilities by the local health authority, as well as repercussions on the official licensing of the facilities involved, and civil liabilities by healthcare workers and operators. In some cases, even after an initial negative medico-legal report refuting direct responsibility of the hospital department, the request for dismissal of the proceedings by the prosecutor has been rejected with the order for further investigations to analyze the compliance with occupational hygiene standards and assess any FURTHER

responsibilities (by supervisors, directors, health and safety managers, or occupational health physicians).

Furthermore, in several cases, situations of significant degradation and inadequate conditions, incompatible with the minimum requirements for healthcare facilities (Presidential Decree of the Italian Republic, 1997) (15) have been exposed during investigations. In other words, part of the original inspection reports on the equipment, facilities and operating rooms had been unlawful in light of the emergence of the HAIs and the Legislative Decree No. 626/1994 (16). Moreover, the state of incompatibility with the requisite for healthcare delivery to be carried out under appropriate safety and hygiene conditions is even more significant where restructuration requests have been made in the past, or, in other words, where reports of inadequacy have motivated the release of funds for remediation of the critical aspects, as an alternative to shutting down such facilities (even in the presence of very incomplete and inadequate risk assessment documentation, not providing any detailed statements on the procedures to be adopted for the adequate control measures targeting biological hazards, including those with the potential to affect third parties).

A previous study, carried out in 2011, assessed inferior court verdicts issued by the Civil Court of Rome during the period between 2001 and 2009 (17). Out of the 2478 verdicts analyzed, 30 involved cases of nosocomial infections, including 23 cases of Staphylococcus, four of Pseudomonas, one of Staphylococcus and Yersinia, and one case of Proteus. In 73% of these 30 cases, the claim for damages was successful, while being rejected in 23% of cases, and partially accepted in 4% of cases. It was also estimated that the average time from the claim notice to the verdict submission was about 4 years, and that the discipline most frequently involved was Orthopaedics (68%

cases, mostly following surgical reduction of fractures with plates and screws). In most cases (41%), the surgeon and healthcare facility were sued, while in two cases, the infectiologist was also cited, and in other two cases, the claims were made against the surgeon and the University.

*The conduct ascribed to the cited healthcare workers was deemed commissive and omissive in 52% of cases, omissive in 38% of cases, and commissive in 10% of cases. In 40% of cases, the infection process was found to be attributable to surgical therapeutic error, in combination with inadequate hygiene and sanitation, in 30% of cases to inadequate hygiene and sanitation (imputable to the healthcare facility), in 18% of cases to clinical diagnostic error, and in 12% of cases to surgical therapeutic error. In this series of cases, the average compensation paid for nosocomial infections amounted to 32,000 Euros, and 13 verdicts also awarded moral damages for an average amount of 14,000 Euros. In two distinct clusters of hospital infections by *Pseudomonas aeruginosa*, two cases of epidemic *Legionella pneumophila*, a cluster of *Aspergillosis* and in an event involving two cases of *Klebsiella pneumoniae*. infection, varying degrees of responsibility for failing to implement preventive measures were attributed to employers, directors, OHPs and health and safety managers, especially in situations where inadequacies were identified within the facilities and management strategy; the involvement of supervisors, workers and attending physicians was generally lesser, except in the case of inadequate implementation of existing protocols.*

Conclusions

Any physician assigned to care for patients in healthcare facilities and hospitals should vigilantly observe the evolution of the patient's condition in order to immediately

intervene in case of complications (18), should not take into consideration interests, impositions or conditioning (e.g. related to politics or even teaching activities), nor provide services at odds with the principles of science and conscience (as per the Article 4 of the Italian Code of Medical Ethics).

Any structural inadequacies identified during inspections by the OHP (or other responsible personnel, including those from the Health Direction) should also be communicated to the employer, especially if significant degradation is detected within the facilities (*in compliance with the ICOH Code of Ethics as stated in Section 39 of the Legislative Decree No. 81/2008*). Moreover, the ICOH Code also states that in case of uncertainty or differences of opinion concerning the risk factors or the risks involved, the accountable personnel in charge of prevention strategy implementation and OHPs should provide explicit assessments, avoiding ambiguous communications, and resort to advice from other professionals where necessary. At that point, and in case of refusal or unwillingness of the facility director or manager to take action to remove an undue risk or to remedy a hazardous situation with potential health or safety implications, the physicians must submit their clearly written concerns to the accountable officer with utmost urgency, underlining the need to take due account of the scientific knowledge and appropriate application of the health and safety standards, calling the employer to observe its obligations in implementing the law and regulations to protect the health of their employees. The workers and their representatives should also be informed and, where necessary, contacts with the competent authorities should also be established (19).

On the other hand, not all HAIs are preventable: it is, therefore, opportune to selectively monitor which cases can be attributable to care quality issues. It is usually possible to prevent infections

associated with specific procedures through elimination of unnecessary steps, selection of safer instruments, and implementation of patient care measures aimed at ensuring aseptic conditions. One of the key aspects for further reflection is the limited acceptance and use of personal protective equipment (PPE) compared to conventional medical and surgical equipment providing a barrier effect.

Riassunto

Rischi biologici e infezioni correlate all'assistenza nelle strutture sanitarie : alcune riflessioni in tema di indagini e responsabilità

Le infezioni correlate all'assistenza sono un rilevante problema clinico e di salute pubblica che vede coinvolti, a vario titolo, gli operatori sanitari, gli amministratori delle aziende ospedaliere e soprattutto le persone assistite. In Italia la frequenza con cui compare una complicanza infettiva è mediamente variabile dal 5-10% (ospedale) all'1% (pazienti assistiti a domicilio) ma il 5-10% delle complicanze infettive si manifesta in modo epidemico e sono sempre più frequenti le infezioni sostenute da microrganismi antibiotico resistenti con mortalità attribuibile pari a 20-30%. Ed eventuali "decessi prevenibili o lesione grave" collegabili ad una causalità (concreta) sostenuta da violazione di norme, leggi, regolamenti oltre che ad imprudenza, imperizia o negligenza degli operatori possono determinare ipotesi di reato per omicidio colposo o lesioni personali gravi, oltre a comportare costi per procedimenti civilistici ed indennizzi assicurativi. Adozione di policies aziendali che contemplino adeguata valutazione dei rischi, sorveglianza epidemiologica attuazione di linee guida, procedure e protocolli, una attività del Comitato Infezioni Ospedaliere e una corretta comunicazione tra responsabili e strutture, la formazione del personale sanitario e la sorveglianza sanitaria dei dipendenti possono contribuire a ridurre fenomeni avversi costituiti dalle infezioni correlate all'assistenza.

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