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Review

Litigation in Cardiovascular Surgery: Risk Management Considerations in the Italian Context

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Abstract: Background/Objectives: Malpractice in cardiovascular surgery was addressed from the forensic pathology perspective, offering reflections on risk prevention in the Italian context. Litigation and risk management in healthcare, following the Italian law on safety of care, clinical risk management and professional liability, should be viewed in an integrated manner. Methods: We conducted a narrative review on litigation data and the principal areas of complaint in Italy regarding the cardiovascular field. The aim is to discuss human, communicative, organisational, technological and regulatory factors that may play a role in this phenomenon. Results: We discuss the importance of information and consent and the management and monitoring of competences, particularly in specialised activities, given the current human capital deficit. Furthermore, we focus on the centrality of the surgical indication focusing on benefit-risk balance in light of clinical guidelines and team-based evaluation, such as by an emergency heart team, to better tailor care to patients. At the facility level, the minimum volume of activity and the requirements for human resources, specialisations, technologies and organisation standards needed for health activity authorisation are highlighted as foundational to risk prevention. Furthermore, we discussed the availability of the minimum diagnostic and care tools in compliance with guidelines and the role of company clinical and organisational protocols. Conclusions: In the surgical, time-sensitive, highly specialised and technologically advanced sector, the importance of enterprise risk prevention and broad, value-based governance to ensure healthcare quality and safety is emphasised.

Keywords: medical malpractice; litigation; professional liability; risk management; quality and safety; cardiac surgery; adverse events

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1. Introduction

Malpractice significantly impacts patient outcomes and healthcare costs, and Montisci et al. has addressed the topic of malpractice claims in cardiology and cardiac surgery from a forensic pathology perspective [1].

Exploring crucial topics such as the surgical approach indication and more frequent adverse events in cardio-vascular surgery, the adequacy and exhaustiveness of information, patients' expectations and disability or survival expectancy could promote professionals' awareness and patient-centred decision-making in clinical practice. However, the phenomenon is more complex and social and needs to be studied in a broader way. Considering the prevalence of cardiovascular pathology in the population, healthcare planning and organisational needs and the effects and costs determined by adverse events and litigations

in this field, an integrated and multidisciplinary perspective of analysis involving professionals, middle management and strategic management is central [2,3]. It is crucial for all parties to identify risks and prevent adverse events [4].

Feelings of harm usually prompt either criminal or compensatory action by patients. The Italian law from 8 March 2017, n. 24, titled "Rules on the safety of care and patient, as well as on professional liability", revised the legal framework in order to facilitate patients' ability to sue healthcare facilities for compensation instead of the professional, with simpler evidentiary burden and longer limitation statute. The law emphasised the role of guidelines in the assessment of punishability of the professionals' conduct in the criminal context. Primarily, the law addresses human error and fallibility, promoting clinical risk management and incident reporting without providing additional financial resources [5]. According to the Italian insurance reports, cardiovascular surgery ranks after orthopaedics, obstetrics-gynaecology, emergency and general surgery in terms of litigation rates [6–8]. However, claims in this field often involve high-value settlements, usually around the big-claim threshold (500,000 euro), impacting healthcare funds and risk reserves. In addition, as seen in obstetrics-gynaecology, the significant emotional impact of severe adverse events on families hinders conciliation in compensatory claims and may lead to criminal proceedings against professionals. Heavy media exposure of the healthcare service and emotional and professional burden of healthcare providers must be also considered.

This review discusses adverse events and litigation in cardiac surgery, focusing on the Italian healthcare system from organizational and regulatory perspectives.

2. Brief Narrative Review

According to the currently available literature on cardiac surgery and litigation in Italy [1,9–13] and looking for comparison worldwide [14–20], certain sub-fields and procedures are more frequently involved in litigation cases. These include the following:

i. Management of acute coronary syndrome and differential diagnosis, particularly distinguishing myocardial infarction from acute aortic dissection;
ii. Coronary angiography and cardiac catheterization;
iii. Pacemaker-defibrillator implantation;
iv. Outcomes of valvular surgery; and
v. Treatment of congenital diseases.

The primary causes identified in the perioperative phase include poor fit or securement of prosthetic valves, surgical site infections, perfusion-related complications, failure to diagnose or treat complications in a timely or appropriate manner and vascular perforation, dissection or thrombosis.

In the postoperative phase, issues such as bleeding or tamponade, infective endocarditis and sepsis are reported. Issues related to information and communication have also emerged as significant factors [21,22].

These findings must be contextualised within broader demographic trends, such as increased preoperative risk [23]. Other contributing factors include a higher prevalence of intravascular implants, increased use of advanced technology, heightened patient expectations, rising life expectancy and more frequent use of minimally invasive surgical approaches for complex cases [24,25]. Additionally, the notable shortage in both the quality and quantity of healthcare professionals, as well as recent changes in healthcare funding and organisational structures, should be considered [26].

3. Discussion

Based on the main causes of claimed adverse events and the pathological, social and organisational context of the healthcare service, an in-depth analysis can be conducted in key areas of interest. This analysis aims to highlight opportunities for improvement and existing strategies to ensure patient safety, as well as the quality and appropriateness of care.

3.1. Information and Consent

A primary consideration is the information that healthcare professionals provide to patients. Tools such as informative brochures (now enhanced with QR codes linking to explanatory videos) and preoperative consultations can be extremely useful, even though they may sometimes seem time-consuming in daily clinical routines [27–29]. Effective doctor-patient communication fosters compliance throughout the care pathway and improves the overall quality of care [30]. However, practitioners see informed consent disclosure as either an absolute disclaimer or a useless bureaucracy, in particular when information and communication must be traced in writing [31]. Examining litigation outcomes, it is evident that the written format of informed consent does not fully achieve its purpose of involving the patient, partly because it is primarily a component of a broader communication process aimed at reducing legal complaints. Secondarily, in the case of a death related to an adverse event, it is the legal heir who initiates a complaint, while the information and consent has been obtained from the entitled person. Heirs or next of kin are obvious involved in the informative disclosure differently than the patient, even if they have been engaged since the beginning. Nevertheless, appropriate information and communication given to the entitled subject and the family members, with documentation in the medical records, foster trust and could further prove diligent and collaborative professional behaviour. Communication with the patient and family is also crucial in the event of surgical complications and in general for adverse events during hospitalisation [32]. Communicating frankly and clearly, in a team with, for example, another medical or nursing figure, in a discreet environment, about both the operative indication and any intra-procedural complications can be an effective model for strengthening the relationship with the patient and family. This approach allows information to be managed carefully, enabling explanations of errors when necessary and reducing the likelihood of event misinterpretation or a search for blame, especially in cases of serious complications or death [22]. Meanwhile, to prevent unauthorised transfer of health information or violations of patient self-determination, it is essential during the admission phase to identify the individuals involved in the communication process, any advanced directives (such as blood transfusion preferences) and any legal representatives [33]. Another common issue in litigation related to informed consent omissions is the brief presentation of therapeutic alternatives and their associated risks. Clinical indications should be based on best practices and the highest standards, and, where possible, patient preferences—such as choices regarding the type of valve prosthesis—should be included to facilitate shared decision-making and personalised care.

3.2. University Training and Competence Monitoring

University-level post-graduate specialisation and subsequent professionalisation training are other central issues, especially in highly specialised fields such as electrophysiology, transcatheter valvuloplasty and robot-assisted procedures. The Italian Decree n. 145/2018, called the Calabria decree, and the later reforms from the SARS-CoV-2 pandemic onwards have allowed hiring in derogation non-specialised professionals (residents) in the National Health Service (NHS). These residents represent a hybrid professional category with limited autonomy in case management [34]. This situation creates a need for university and health facility tutors to document the resident's progressive acquisition of skills and autonomy, according to the specialisation class, to settle the resident's autonomy. This documentation forms the basis for assessing liability, establishing the required level of diligence in performing assigned tasks. Specialisation should be understood as the ability to control risk and anticipate and manage potential adverse outcomes. In court, it is not valid to argue defensively that a resident lacked competence simply because they were in training; once a resident assumes responsibility for a patient's care, they are fully accountable for that care. In the face of hyper-specialisation, healthcare professionals must be aware of the limits of their expertise and the challenges these may present [35]. In the cardiovascular field, for example, the physician in specialist training must have interpreted

1000 electrocardiograms to be considered trained and thus autonomous as a specialist; further, they must have performed 150 coronarographies and 100 coronary angioplasties as a first operator. A cardiac surgeon in training is required to complete 300 minor surgeries, with at least 100 as the primary operator, and 60 high-complexity surgeries, including at least 10 as the primary operator [36]. The case volumes at university-affiliated health facilities, particularly for certain specialised approaches, are central to ensuring adequate training and must be verified. Healthcare facilities are required to track the acquisition, maintenance and updating of competencies for all practitioners, including specialists and managers. In surgery, for example, this is achieved by allocating and managing privileges for lead surgeons and by implementing outcome feedback and auditing systems. If a professional assumes an excessive risk, they bear the criminal liability individually. However, in civil law, the healthcare facility assumes responsibility for any imbalance in a professional's risk assessment—unless the professional's actions deviate significantly from standard practice [37,38]. Risk prevention activities are ineffective if there is no clear delimitation or achievement of the required skills, including managerial and organisational ones [39].

3.3. Competences and Risk Knowability

A recent ruling by the Italian Supreme Court reported a case where the Court of Appeal excluded the liability of a general abdominal surgeon who lacked expertise in laparoscopic procedures and specialised solely in open approaches. "The Court of Appeal found that the complication (intestinal adhesion syndrome in a laparotomic approach) was neither foreseeable nor avoidable by the surgeon" [40]. Notably, the surgeon was not held responsible for this complication, as a less invasive approach with a lower risk of adhesion was not an option at all due to their lack of training in laparoscopy. This statement is open to discussion, as the court did not evaluate the average skills and knowledge expected of a general surgeon. However, risk prevention and liability assessment are typically based on the ordinary diligence of an average practitioner, considering their experience, specific training and the context of patient care [41,42]. Importantly, the central factor in determining the right to health and the benefit-to-risk ratio is the patient, not the surgeon [43].

Complications in this case could have been foreseeable and potentially avoidable if another surgical option, practitioner or healthcare facility had been chosen. It is therefore crucial to train professionals on the consequences of taking on risks beyond their competence, as well as to consider structural and organisational resources known or accessible to the practitioner. Case law assigns liability to practitioners who perform procedures without the necessary equipment specified by guidelines, both for standard management and complication management [44,45]. Similar concerns arise with blood transfusions, where re-evaluation during preoperative time-out, additional specialist support during surgery or altered postoperative care fall under the healthcare professional's responsibility. Otherwise, these omissions are classified as technical [46]. Clinical guidelines, which standardise medical practices based on current scientific evidence, must be implemented by healthcare organizations to ensure adequate training for all medical personnel. Furthermore, any unjustified deviation from institutional protocols and procedures constitutes a violation [47,48]. In a ruling of the Court of Auditors, a healthcare team was found grossly negligent for failing to perform a gauze and instrument count, a violation of essential risk prevention protocols [49].

3.4. Surgery Indication with Risk Imbalance

A correct and well-documented assessment of the risk-benefit ratio is essential, especially for certain complex diagnostic procedures and treatments, as it considers both preoperative risks and likely outcomes [50]. The use of multidisciplinary team evaluations, such as the emergency heart team for surgical indications or the endocarditis team for selecting the best treatment for infective endocarditis, serves as an excellent model for scientific comparison and standardisation [51]. In Italy, clinical guidelines are those formally registered in the National System for Guidelines, though few have been uploaded to date; otherwise, reference should be made to the best available evidence [52,53]. These references also guide professional conduct in court cases concerning liability. Methodological criticisms have been raised across distinct levels [54]. For example, the "Guidelines on the proper use of transcatheter aortic valve implantation" are endorsed by the Department of Epidemiology of the Italian Region Lazio and are significantly outdated, while the guidelines on thoraco-abdominal aorta pathologies were developed only by the scientific societies of vascular surgeons and radiologists and date back to 2022 [55]. In cases involving potential guideline deviations or complex cases with comorbidities, multidisciplinary team assessments ensure that treatment is tailored to the patient. Additionally, scoring systems that direct cases toward specific treatments provide support that practitioners may otherwise need to justify after the fact [56]. In suspected cases of myocardial infarction, health professionals must prioritize timely management and ensure rapid transfer to a referral centre with the necessary facilities, including a haemodynamic laboratory for angioplasty and an on-call cardiac surgeon [57]. Similarly, in cases of aortic dissection, the diagnosis and treatment timelines, along with the availability of diagnostic tools such as ultrasound for suspicion and angio-CT for confirmation, are crucial. This requires not only having access to an angio-CT but also ensuring that a timely report is available, even at 2 a.m. on a holiday weekend; otherwise, a safe transfer must be managed [58].

3.5. Clinical Risk Management Issues

In the specific context of cardiovascular surgery, many foundational concepts of risk prevention and outcome standardisation are applied inconsistently, often due to high staff turnover. Basic concepts such as identifying high-risk, look-alike-sound-alike (LASA) drugs or following safety recommendations to prevent gauze retention or patient misidentification are widely recognised, but their implementation varies significantly across healthcare facilities. These concepts must therefore be verified and reinforced through training. In today's increasingly technological environment, it is necessary to reduce the burden of documentation, procedures, and repetitive tasks to enhance efficiency and support lean professional management. Risk management methods also need regular updating to adapt to changing contexts [59]. For instance, using automatic drug dispensers with specific dosages at the patient's bedside, verified by barcodes, could simplify and improve the accuracy of repetitive tasks with high error rates, such as drug administration [60]. Conducting audits on cases of death or serious adverse events is also valuable for objectively reconstructing events, reviewing surgical indications, and evaluating patient management and team communication. Furthermore, there is an increasing need for indicators to measure cross-cutting risks, such as social factors. Poor socioeconomic and family conditions can significantly impact health outcomes, leading to poor patient compliance, unhealthy lifestyle habits, and limited access to care—even in countries with high levels of health coverage. The lack of continuous documentation and informational consistency regarding patient care still leads to delays, whether due to pharmacological reconciliation, incomplete medical history, or unavailability of radiological exams, especially in emergency settings [61–63]. Unstructured health records, fragmented data and inconsistent indicators—varying by specialty and facility—are prone to error and hinder effective benchmarking [64,65].

3.6. Regulatory Compliance and Good Enterprise Organisation

From the perspective of healthcare management and stakeholders, there are significant organisational and regulatory issues, particularly concerning minimum activity volumes and outcomes in specialized areas. These metrics serve as indicators of the healthcare facility's performance, aligning with (but not limited to) the minimum standards defined by the Ministerial Decree of 2 April 2015, No. 70, which outlines the quality, structural, technological and quantity standards for hospital care [66]. These standards have a substantial impact on the organisation of both public and private healthcare companies, affecting their approach to organizational accountability and risk prevention. Healthcare structures are viewed as enterprises, with liability distributed among administrative and top healthcare management [67]. Otherwise, the functional comeback of responsibility would disappear in a law system attributed impersonally to the legal entity, as an abstract entity.

A key focus is compliance with health requirements, a responsibility shared by top management (general directors or legal representatives) and chief medical officers. Examples include adherence to authorisation requirements for healthcare activities, such as the construction and operation of operating theatres, disinfection and sterilisation practices, and the management of workflows and risk levels. Equally important is the availability of essential instruments for preoperative assessments or procedures (such as ultrasound-guided cannulation as per guidelines) and for managing intraoperative complications [68]. The overall capability of a facility to handle complex cases, including rare complications, is also critical—particularly the availability of post-surgical intensive care and the ability to convert minimally invasive surgeries to traditional approaches when necessary [69]. Additionally, the role of technology in healthcare is now prominent, encompassing everything from implantable devices to semi-automatic algorithms for radiological interpretation, telemedicine, telesurgery and even decision support for surgeries. The selection of these tools is critical, as it has far-reaching implications for responsibility [70,71]. In infectious disease management, particularly for infective endocarditis, the distinction between community-acquired and healthcare-related infections is complex, especially when patient history is fragmented, complicating its legal application [72]. Comparisons between infective endocarditis and surgical site infections highlight the distinct contributions of healthcare organisations and professionals and the typical impact on the healthcare facility itself [10,73]. Typical responsibilities of healthcare facilities include managing staffing and room flow to maintain temperature, humidity and airflow; ensuring compliance with procedures—especially anti-sepsis protocols; managing air systems for opportunistic waterborne pathogens; and properly locating equipment, such as heater-cooler units, to prevent *Mycobacterium chimaera* infections [74,75]. Additionally, healthcare facilities are responsible for contracts related to cleaning and disinfection services, surface contamination monitoring and comprehensive infection prevention and control policies, as well as overseeing meal delivery and waste disposal [76–80].

3.7. Allocation of Responsibilities

These topics are of significant legal interest, as liability in the health sector has been addressed in the Italian legal framework through the law of 8 March 2017, n. 24, from a social perspective to establish a specific legal system that respects various external and overarching factors—organisational, structural and technological [5]. Although healthcare professionals occupy an intermediate position within the hierarchy of health policy and organisation, they are ultimately the direct providers of care to patients and act as guarantors of the right to health. It should be noted that the healthcare professional has only an instrumental obligation to fulfil the duty towards the patient. Thus, criminally, the healthcare professional is solely responsible for patient care and safety. Today, safeguard systems limit criminal punishment to cases of gross negligence, though the emotional burden on healthcare providers remains high [81]. From the civil law side, responsibility is assessed with regard to internal relationships and the limited capacity of individual practitioners to influence healthcare organisation and the broader care delivery system. This framework

directs claims for compensation primarily toward healthcare facilities, even the largest and best-organised, rather than individual professionals [82]. Excluding cases of clearly imprudent, reckless or negligent behaviour by the practitioner, human actions are appropriately contextualised within the specific dynamics of the healthcare organisation, where individuals or teams have limited causal influence over the comprehensive management and care of patients [83]. In cardiovascular surgery, it is particularly important to consider actions that could have been taken earlier in terms of prevention and chronic disease management. Poor patient compliance with overall health recommendations should also be considered, as many patients focus solely on the curative aspects of surgical intervention without adapting their lifestyle, nutrition, rehabilitation, medication adherence, smoking habits or routine check-ups [19]. Health policies must also be carefully designed, particularly regarding time-sensitive care networks and the geographic distribution of healthcare facilities, to ensure that minimum organisational, structural, technological, volumetric and staffing requirements are met. Regulatory compliance in these areas is foundational to ensuring safe, high-quality and appropriate care—an essential basis for every risk management strategy and then for proper accountability allocation.

4. Key Strategies

- ✓ Address the patient and seek out the family to better understand all information needs;
- ✓ Define the professional who is to do the informing and who has good communication skills, particularly in cases of high-risk interventions or serious adverse events;
- ✓ Provide simple information material before admission and encourage discussion with respect to health expectations;
- ✓ Trace the expression of consent;
- ✓ Define residents' autonomy and progressive competence gaining;
- ✓ Define and monitor performance indicators for all professionals;
- ✓ Define the identification, monitoring, training and acquisition of the privileges of all professionals;
- ✓ Educate new professionals regarding the specifics of the context and practice;
- ✓ Define ways of periodical auditing, peer-review and feedback;
- ✓ Map the main risk areas according to the volume and type of activity of the structure in its network, according to resources and human capital;
- ✓ Document the surgical indication according to guidelines and/or good practice, sharing with the patient and, in complex cases, through a multidisciplinary assessment (e.g., endocarditis heart team);
- ✓ Document alternative care options and where possible shared choice with the patient;
- ✓ Guarantee and monitor the minimum volumes and resources of the facility;
- ✓ Define the identification, monitoring and improvement actions for clinical, process and organisational outcomes;
- ✓ Enhance multidisciplinary work, inter professionals' comparison and evaluation and transparency of assessment at every level;
- ✓ Promote, monitor and improve the standardisation of pathways and processes according to best evidence;
- ✓ Promote continuous scientific update and inter-facility interaction;
- ✓ Train on the value and modalities of communication and non-technical skills.

5. Conclusions

Risk management and adverse event prevention should be understood as a collective responsibility, involving all stakeholders to enhance patient safety and healthcare services, particularly in time-sensitive, high-risk and surgical settings such as cardiovascular surgery. Achieving this requires the seamless integration of clinical, organisational and regulatory actions to mitigate risks effectively. Litigation related to malpractice serves as an additional source of insight, highlighting the role of causation and human factors in adverse events, which are often viewed as system errors. In the cardiovascular field, the primary areas of

complaint underscore the importance of this integrated approach, revealing how adverse and harmful events frequently stem from systemic factors.

With the adoption of organisational models that identify and prevent the risks of illicit and harmful events, clinical risk management must be complemented by robust enterprise risk management and regulatory compliance to support professionals, ensure patient safety and strengthen the healthcare system. Well-designed governance structures, collaborative and communicative organisations, transparent benchmarking and skill development not only mitigate risks but also add value to healthcare delivery.

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