Patient safety between clinical risk management and medico-legal liability

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ABSTRACT

According to the Ministry of Health, clinical risk represents the probability that a patient will suffer an adverse event attributable to the care process, resulting from clinical factors,...

According to the Ministry of Health, clinical risk represents the probability that a patient suffers an adverse event attributable to the care process, resulting from clinical, organisational, technological or systemic factors. The management of clinical risk, within the broader framework of Clinical Risk Management, makes use of tools such as incident reporting, clinical audits, Root Cause Analysis (RCA), Failure Mode and Effect Analysis (FMEA), and the use of checklists and protocols.

These tools not only contribute to increasing patient safety, but also ensure the traceability of care activities. In fact, healthcare documentation, drawn up accurately and truthfully, constitutes evidence up to the point of being sued for forgery.

The role of the Clinical Risk Manager is therefore crucial, for the correct maintenance of the position of guarantee towards the patient. This multidimensional figure requires technical, organisational, communication and medico-legal skills, and is responsible for evaluating clinical and organisational processes (both proactively and reactively); monitoring adverse events and reports; implementing safety protocols; managing medico-legal disputes; and training staff on patient safety issues.

The risk manager and the healthcare facility can make use of information systems such as electronic health records (EHR/EMR), clinical decision support systems (CDSS), safe medication management technologies, electronic prescribing systems (CPOE) and predictive analytics tools to support clinical decisions and improve patient safety.

A key role in human resource management, aimed at preventing adverse events, is to

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understand the behaviour of professionals and their “error patterns”. Error analysis may include the observation of incorrectly performed actions, omissions, inappropriate decisions or violations of standard procedures.

The classification of human errors can be done not only through the well-known Swiss Cheese Model of Reason but also through the SRK model of Rasmussen, which distinguishes between:
- Skill-based errors (slips and lapses): skill-based errors;
- Rule-based errors: rule-based errors;
- Knowledge-based errors: knowledge-based errors.

This understanding is essential for implementing effective safety measures and evolves from the concepts of To Err Is Human (Reason, 1999) to those of The Human Contribution (Reason, 2008), which emphasise that practitioners are active players in complex systems and not simply responsible for individual faults or victims of complex systems.

From a medico-legal point of view, professional activity is also assessed in terms of individual responsibility, active decision-making and compliance with good practice. The Guidelines and Recommendations of Good Clinical and Health Care Practice are fundamental tools for complying with regulatory obligations, as envisaged by art. 5, paragraph 1, of Law no. 24 of 8 March 2017 (Gelli Law), always considering the specificities of each concrete case.

The National Guideline System (SNLG) of the Istituto Superiore di Sanità (ISS) represents the official platform for the production, consultation and dissemination of guidelines in the health care field. Established by Ministerial Decree of 27 February 2018, the SNLG offers evidence-based recommendations to professionals, managers, decision-makers, users and caregivers, constituting an indispensable reference for clinical practice and medico-legal risk management.

Professional responsibility is therefore on two levels: on the one hand, compliance with scientific evidence and good clinical practice, on the other hand, the ability to accurately and transparently document all phases of care. In the event of litigation, compliance with guidelines and healthcare documentation constitutes a fundamental evidentiary element, reducing the risk of legal sanctions and helping to demonstrate correct clinical and organisational management.

In conclusion, patient safety is the result of an integrated approach that combines clinical risk management, the adoption of advanced technological tools and the understanding of human behaviour, within a clear and evidence-based framework of medical-legal responsibility. The

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From the *no blame* culture, the system has evolved by affirming a more balanced paradigm, based on **individual accountability within complex systems** in which practitioners remain responsible for active decision-making, compliance with procedures and good clinical care practices. Empowerment is thus integrated with a culture of safety, promoting transparency, learning from mistakes and protection of professionalism.

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