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Clinical risk management, Areas of Intervention, Measures and Tools for Safety Places of Care

Maria Carmen Agnello*

Specialist in Health law, University of Bologna, Bologna, Italy

Corresponding author: Maria Carmen Agnello, Specialist in Health law, University of Bologna, Bologna, Italy**; E-mail:** agnelloc4@gmail.com

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ABSTRACT

In the current socio-economic context, health structures have to address the impact of emerging technological innovation and epidemiological changes on health risk management. In this context, the article analyses the regulatory framework and the set of programming measures and strategic actions in a comparative and diachronic way, in order to highlight what has changed and what needs to be changed in ensuring safety in health facilities. In this process, the turning point is identified in the implementation of the safety culture, through involvement and coordination between the institutional, professional and welfare levels.

Keywords:

Risk management, Planning, Measures and implementation tools, comparison

The multilevel analysis of clinical risk management: The preventive and proactive approach

The current evolution of health systems is aimed at improving the quality of care through conditions of maximum safety. In this context, the assessment and monitoring of the actual level of safety to be ensured for both patients and health professionals is of increasing importance within health organizations. This centrality of health risk management comes up against technological innovation and the social and welfare dimension, characterized by the constant growth of chronicity and co-morbidity. Similarly, in providing safe assistance, it is necessary to understand what needs to be changed in order to support the impact of such changes in terms of security. To this end, the general lines of health safety management will be set out below.

In places of care, safety includes two dimensions to protect the patient and health workers. The first concerns the concept of safety, which dimension of the quality of the assistance, to be guaranteed through the identification, analysis, and management of the risks also potential (sentinel events), the design and implementation of processes, which reduce the likelihood of adverse events occurring. Just as the safety of health professionals is part of the wider concept of "security", which is the dimension of the health facility in which they carry out their activities.

In this process, both safety and security-oriented, it was necessary to initiate prevention programs in the key areas of patient care and clinical and organizational management, learning from past mistakes as a source of knowledge to avoid recurrence in health care safety management. The guidelines of the evolution of risk management have been in one way to predict adverse events and prevent diagnostic and therapeutic errors through the analysis of criticalities and criteria based on epidemiological relevance and management variability and clinical risk.

On the other hand, a proactive approach has made it possible to develop diagnosis and therapy pathways through guidelines, able to identify and implement specific procedures for patient safety. These routes originate from the increasing attention not only to the improvement of the standards of welfare quality and to the reduction of the costs deriving from the claims compensation from malpractices and insurance guarantees but also in order to overcome the critical issues as set out below. The first issue concerns the existence of heterogeneous health services at the regional level, due to a lack of uniformity in the organizational models applied. At the organizational level, there is a lack of attention to applying scientific evidence recommendations and procedures, as well as limited resources (personnel and tools) to support safety. The regulatory framework is complex because of the variety of policy measures and organizational actions implemented at different levels, as set out below

Over the past decades, the challenge of security in health facilities has been addressed at different international, European levels and by the health systems of individual states. At first, the risk management approach was primarily geared towards preventing possible adverse events resulting from erroneous and/or incorrect management of diagnosis and treatment pathways, more frequent surgical and pharmacological treatments. At a later stage, soft law and good practice followed a proactive approach aimed at improving the quality of care, in the dual dimension of safety and security through containment and risk reduction.

Internationally, in 2004, the WHO launched the Alliance for patient safety to reduce the health consequences of medical errors in diagnosis and treatment. An essential element of this strategy has been the choice of an issue of major concern, relating to various aspects of risk in healthcare. This strategy was the first step in the path aimed at improving, through continuity criteria and the centrality of the person. This global program and subsequent international projects have encouraged countries to introduce solutions based on scientific evidence and to be adapted in a shared and multidisciplinary approach.

Available data show that Member States are at different levels in developing and implementing effective and comprehensive patient safety strategies. In the diversification of existing health service delivery models in Europe, soft law has also regulated clinical risk through a single framework of indications, in order to

standardize the assessment and management of adverse events. The priorities identified by the European Commission for the development of health have been the promotion of health and disease prevention, through the improvement of information, the ability to react to hazards and to address health determinants. The European Commission, in its White Paper "A Common Commitment to Health: EU Strategic Approach for 2008-2013» of 23 October 2007, includes patient safety as an area of action. For this purpose, the European Commission has disseminated actions in support of the exchange of information and experience.

The 2009 Recommendation of the Council of the European Union is based and complements the work on patient safety carried out by the World Health Organisation (WHO) through its World Alliance for Patient Safety, the Council of Europe. In this legal framework, the European Community has supported patient safety in health systems through "Information and Communication Technologies", included among the actions to be implemented the review and updating of best practices applicable to assistance, as well as the provision of information to citizens, sharing and comparing knowledge, experience and improvement measures.

The national health system the areas, measures and instruments for implementing

In the national health system, the Medical errors were tackled more comprehensively as a result of adverse events reported in 2000 by the Court of Patients' Rights. In the current phase, the management of clinical risk is to be contextualized with respect to the characteristics of the national health system in the regional diversifications and of the single sanitary structures located on the territory. The Decree of the Ministry of Health 70/2015, concerning "the quality and safety standards of hospital structures", indicated in point 1.1 the principles to be guaranteed the objectives of assistance effectiveness, the quality, and safety of care, the centrality of the patient and the humanization of care, with respect for the dignity of the person.

The National Health Plans and the implementation at the regional level have included a set of actions aimed at ensuring the quality of health services, through the improvement in clinical risk management. The path taken has been to address existing organizational and professional issues, from overloading, equipment malfunction, communication, through programming, shared procedures, monitoring, and evaluation of results. This paragraph covers the different stages of the evolution of clinical risk management in the national health system, though not only sector regulation, but also the set of measures and implementing instruments in the places of care.

The role of soft regulation

At first, the increasing attention to the above-mentioned issues formed the basis of the regulatory interventions of soft law through documents drawn up by ministerial technical commissions (recommendations, manuals, ministerial reports) which have outlined the path to be taken in the management of clinical risk in individual health structures.

The document edited by the technical commission established by the Ministry of Health on clinical risk "Risk management in health care. The problem of errors" (2003) has identified organizational models, aimed at reducing and managing risk through promotion, reporting and learning from errors, rather than identifying who is responsible.

In 2005 the Ministerial "Recommendations identified actions to be taken to prevent adverse events as well as alert situations regarding hazardous procedures. This method has provided tools to promote the assumption of responsibility of health care workers and thus promote an improved change, through greater awareness of the danger of certain events. In order to ensure the implementation of the above, 17 Ministerial Recommendations have been issued, setting up working groups in support of specific areas of Clinical Risk (D.D. 14 May 2005). The Patient Safety Group (D.D. 20 February 2006) explored the areas considered to be priority areas, such as monitoring of adverse-sentinel events, drafting recommendations; implementation of training policies; the involvement of patients and the analysis of legal and medical aspects.

In 2010, manuals "On the quality and safety of care in drug use were published. Recommendations, integration and training" and for "Safety in the operating room: Recommendations and checklists and a checklist questionnaire of the adoption of the checklist" including the 16 recommendations and checklist, developed by the World Health Organization in the "Safe surgery saves lives" program and adapted to the national context. These manuals indicate the method to guide the improvement of safety and quality, the application of which has been necessary at national health establishments, as well as monitoring at the regional level. As well as the manual of "Management of Clinical Risk and Safety of Treatment in General Medicine and Family Pediatrics" indicated a method to facilitate the choice of activities and measures to be taken for the safety of care, in the clinics of general medical practitioners and paediatricians and in order to carry out continuing training programs in this field.

The role of the planning and the project

This regulatory phase was followed by programming and design of the following second level, in order to overcome the critical issues and disseminate the existing good practices.

At the central programming level, the National Health Plan 2006-2008 for the management of clinical risk has provided a set of measures in support of the double dimensions of safety and security as fundamental objectives of the National Health Service (SSN). This has been pursued through multidisciplinary clinical risk management strategies, able to involve the widest range of professionals involved in the treatment paths.

Another objective pursued through programming has been to ensure uniform conditions for the consolidation of clinical risk. In this regard, in 2009 the Ministry of Health drew up the Protocol for the monitoring of sentinel events", by specifying uniform arrangements for monitoring and managing sentinel events to be shared on a national territory to ensure essential levels of assistance (LEA).

Under the cooperation agreement between the Ministry of Health and AGENAS, a project has been launched to identify best practices to improve the safety of care, through the cognitive tool of the activity report for the period 27 March 2009-26 September 2011, which collected the interventions carried out on the territory based on the evidence of effectiveness and cost analysis. The system for the dissemination and exchange

of best practice for patient safety has both been achieved, as demonstrated by the presence of the methods and tools for the dissemination and exchange of best practices tested in health organizations. The dissemination of good practice has been pursued through the promotion of regional programs based on the identification of measures, dissemination and implementation of patient safety projects, in cooperation with the national level.

Organization in places of care: Regulation and implementation tools

The most innovative aspect in the national health system has been to regulate clinical risk management in order to reduce insurance and legal costs related to malpractice, through the provision of specific instruments aimed at supporting the health organization.

In this regard, L. n. 189/ 2012 (c.d. "Balduzzi") has placed in charge of the sanitary Companies, without new or greater burdens on the public finance, the cure, the analysis and the adoption of the necessary solutions in order to manage the same risks, for the prevention of litigation and reduction of insurance costs". In favor of the safety of care and the monitoring and control of disputes concerning professional responsibility, the regions and autonomous provinces of Trento and Bolzano can provide, within health care facilities and within the human resources available, risk management functions that include, where available, forensic, occupational medicine, clinical engineering, and pharmacy skills, (as foreseen by L.stabilità 2013).

A Stability Law 2016 provided in the provision of health services, the mandatory establishment of the Risk Management office at public and private facilities, in preventing and managing adverse events, through the monitoring and evaluation of professionals' errors and the adoption of implementing measures.

In order to reduce the litigation and the phenomenon of "defensive medicine", L.n. 24/2017 ("Gelli-Bianco"), addressed safety in the double halving of security and safety, through the regulation of the operator's responsibility, the profession, and the public or private health facility. However, the magnitude of the cases not fully covered by the guidelines is an expression of the persistence of critical issues that do not allow to guarantee a high level of safety. As well as, the deficiencies of the l.n. 3 of 2018 to reorganize the health professions and the deficiencies of the decrees of successive implementations have not allowed to guarantee an application of l.n. 24/2017, as well as uniform application to reduce clinical risk litigation.

In pursuing the objectives of reducing costs resulting from clinical risk, it was necessary to implement the role of information and the use of IT tools, both at the central level and at the corporate level. At the central level, in 2009 the Ministry of Labour, Health and Social Policy established the SIMES (Information System for the Monitoring of Health Errors)means a centralized computer system capable of collecting information on sentry events and claims from health facilities in order to monitor such events.

The organizational implementation in the individual business realities has seen the start of a database system able to collect reports of adverse events, analyze them in preparing strategies and propose solutions. This information tool enabled"clinical risk management" to define the set of rules to maintain the security of care systems in individual structures. For the purposes of our analysis, we need to evaluate information and communication technology tools, such as electronic health records or electronic prescriptions, in helping to improve patient safety.

In this regard, the software Nirm (nursing Information Risk Management), developed by organizational experience has been an efficient response to the needs of staff and health care structure in ensuring the safety of care. The aim was to equip health facilities with high-tech, customizable tools that can support staff activities and at the same time have positive effects on resource management (human and) non-improving risk management by reducing risk factors, containing costs and improving the quality of services provided. The use of these IT tools has made it possible to implement a method that is capable of responding to the organization of the operational units. As demonstrated by the data obtained during the trial, the benefits for patients have been to improve the quality of services, for staff to simplify activities and for the health facility to reduce risk and contain costs, as it allows a quick and reliable comparison between the data acquired.

The perspectives: Integrated management and propulsive role of the culture of the risk

As the demand for health continues to grow, the issues of increasing public spending on health care and rational use of resources come up against risk management. In the current socio-economic conditions, The problem is reconciling health expenditure with the growing need to manage risk in the face of the disruptive role of innovation phenomena of epidemiological changes. Welfare benefits provided at health care facility medical equipment and devices, whose efficiency is the basis of safety for the user and professional.

The clinical Risk Management, as a dimension of clinical governance, requires the development of an integrated strategy, able to respond to the evolution of social welfare demand and the increasing impact on health budgets. The exposed affects the current methods and organizational models oriented to the proactive analysis, before the occurrence of the event(failure Mode And effects Analysis and failure Mode And effects criticality Analysis) and reactive, after the occurrence of an adverse event or a near-event (incident reporting, root causes analysis, clinical audit, review of medical records).

The perspective to be followed is two-fold.

At a company level, the answer is to optimize current risk management by integrating growth-enhancing measures and organizational tools, reduce the cost of services and thus facilitate the allocation of resources on interventions, aimed at developing safe and efficient health facilities. The analysis of the case studies allows identifying virtuous models where the integration of organizational levers has allowed making the structures more and more secure than the effect of technological innovation and chronic illnesses.

Welfare services provided in places of care use increasingly innovative medical devices and medicines, the efficiency of which is the basis of safety for the user and professional. In the face of technological innovation, collaboration with research institutions and the health industry is oriented to design in preventing and reducing the occurrence of adverse events in healthcare (as expressed in Council Recommendation 2009/C

151/01). Greater coordination between professional bodies, scientific societies, and the insurance industry can reduce the inequalities in clinical risk management that exist in the level of safety guaranteed between healthcare facilities.

The integrated circuit implemented by the ASL in Rome is an example of an integrated model between risk assessment, management and audit, which can be a reference point for other healthcare facilities. This organizational model has involved organizational levers where it has foreseen and implemented organizational tools to improve risk management, through the analysis and monitoring of company criticalities in order to reduce the level of riskiness in the most critical areas. At an illustrative level, we indicate among the implementing instruments: the Annual Plan of Risk Management (P.A.R.M.), coordination of the network of facilitators for clinical risk, internal reporting system (incident reporting), the GRC audit.

The second path is to foster a culture of risk. the report of the European Commission on the application of Recommendation 2009/C 151/01 has identified the priority of promoting the culture of security, not spread in a complete and uniform way in the 27 EU countries, with more critical issues related to patient empowerment and training of health care personnel. A further negative element is the distrust of users, as 53% (in Italy to 57%) fear possible damage in healthcare facilities. In the same way, as stated above, the European Commission pursues the primary objective of developing guidelines on how citizens are informed about the quality of care in order to increase not only their confidence but also their responsibility to involve them in the process of ensuring their safety. In overcoming these limits, a mentality sensitive to the principles of prevention of clinical risk is needed, ensuring the effective participation of users and professionals. This requires greater knowledge of the above instruments, with a view to raising awareness of best practices and/or security measures put in place and how to find information and have access to complaint systems.

Conclusion

The above has been regulated at the level of soft law through the recent guidelines of the Coordination of the Regions, which promote national health policies to support the development of the safety culture in regional contexts and health companies. The aim of the guidelines is to facilitate the application of the law in force in the sector, through uniform elements and common requirements to be applied at the regional level according to the context and organization of reference. The guiding principles identified in these guidelines concern “representativeness, inclusivity, integration and sharing” among the actors involved, as a soft power that can implement the measurement and evaluation of the level of safety guaranteed and thus improve the overall delivery of health services.

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