

# The ERM experience of the Lombardy Region as a tool for improving the safety of the regional health care system

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## Abstract

The Regional Center for Healthcare Risk Management and Patient Safety of the Lombardy Region, with the technical partnership of Aon, designed an innovative *Healthcare Enterprise Risk Management Model* (hereafter HERM) to meet the following objectives:

- Improve the safety of the Regional Healthcare System through the implementation of methods and tools aimed to identify, analyze and manage in an integrated way all the risks to which are exposed the healthcare companies.
- Preserve the creation of "social value" in the medium-long term and the sustainable achievement of strategic and operational objectives.
- Optimize risk management costs.
- Reduce/mitigate adverse events in all business processes.
- Enable the ability to anticipate and react to changes.
- Establish sound long-term and risk-based strategies.

This paper describes the structuring of the overall HERM Model Framework, and the related information flows, the tools supporting the **Healthcare Enterprise Risk Management Methodology** (such as the *Risk Model* and the *Assessment Metrics*) and presents the preliminary result of first experience of Healthcare ERM in Italy.

## Background

The Lombardy Region is one of the 20 regions in Italy; and, through the Regional Health Service (RHS), ensures the healthcare management of 10.06 million inhabitants.

The Region implemented a risk governance system in public and private healthcare companies since 2004 (with the Circular 46/SAN), to assess the risks of each business unit, their causes, the elements of control implemented to reduce the unexpected events, as well as the average cost of claims (registered and settled).

The experience of the pandemic along with generalized increases in the cost of goods, services and utilities, uncertain institutional and regulatory framework for liability, as well as the significant introduction of digital technologies in the sector (such as Artificial

Intelligence and Telemedicine in care pathways), introduced new risk variables that make the Patient Safety Model insufficient for an effective management of health risks in healthcare public and private companies.

For this reason, the Regional Center for Healthcare Risk Management and Patient Safety of the Lombardy Region, with the technical partnership of Aon, designed an innovative *Healthcare Enterprise Risk Management Model* (hereafter HERM) to meet the following objectives:

1. Improve the safety of the Regional Healthcare System through the implementation of methods and tools aimed to identify, analyze and manage in an integrated way all the risks to which are exposed the healthcare companies.
2. Preserve the creation of "social value" in the medium-long term and the sustainable achievement of strategic and operational objectives.
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## Materials and methods

The Model was based on best practices and international standards for the effective implementation of Risk Management Processes within complex structures, such as:

- *Enterprise Risk Management Framework – Aligning Risk with Strategy and Performance (CoSO ERM Framework 2017)*: defined by the Committee of Sponsoring Organizations of the Treadway Commission, it represents a Reference Model for organizations wishing to adopt robust risk management processes that can best guide strategies based on performance.
- *ISO 31000:2018 Risk Management – Guidelines*: an international standard that provides general principles and guidelines for risk management. The standard, written by the International Organization for Standardization, provides an approach that is suitable for any type of risk and can be adapted to any organization and its context.

The first phase of the Model design involved the Framework definition, structured on three macro-components: Governance & Strategy, Risk Management Process and Risk Reporting (Figure 1).

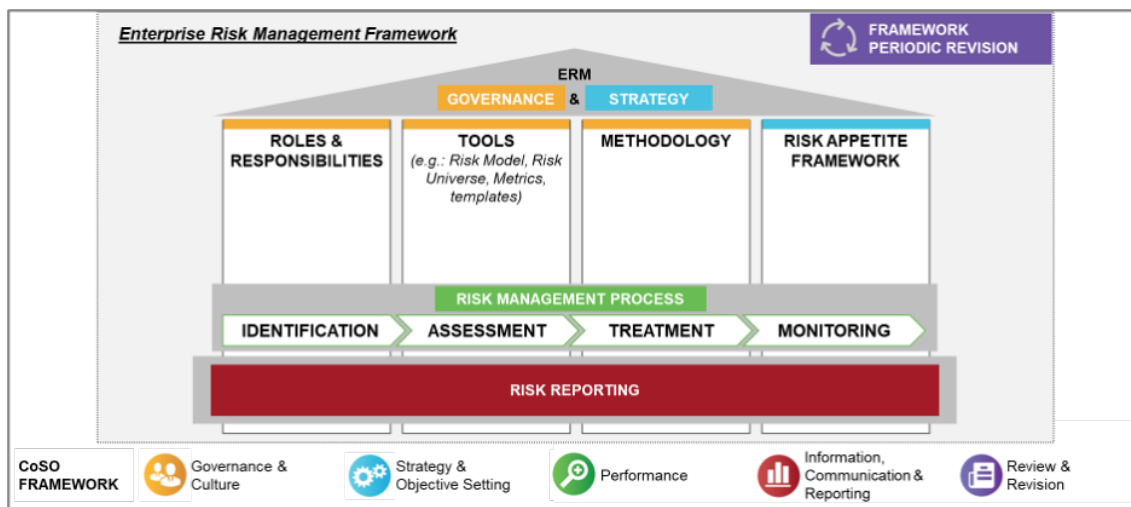


Figure 1 – HERM Model Lombardy Region | Framework

In terms of *Roles and Responsibilities*, the HERM Model of the Lombardy Region, is not limited to operate on individual healthcare companies, but involves the General Welfare Directorate at all levels: from the Councilor to the Risk Management Coordination Groups, passing through the different Operational Units.

Each of these subjects has a clear role within the entire HERM process, defined and assigned based on the levels and areas of responsibility entrusted within the General Welfare Directorate (Figure 2).

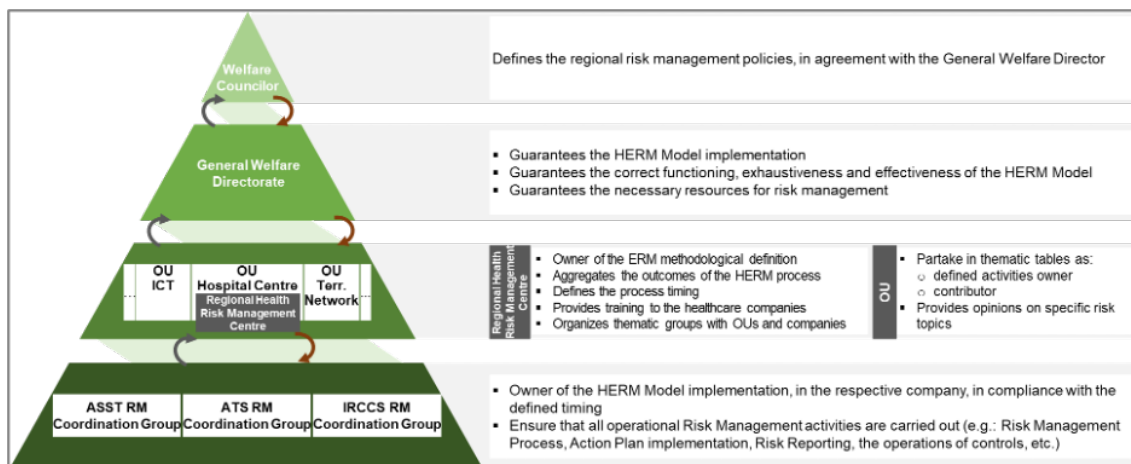


Figure 2 - HERM Model Lombardy Region | Roles and responsibilities

On these assumptions is based the structuring of multilevel information and reporting flows (Figure 3), defined to enable timely and integrated information flows throughout the pyramid and towards external stakeholders (e.g.: *National Observatory for Good Practices in Healthcare Safety*).

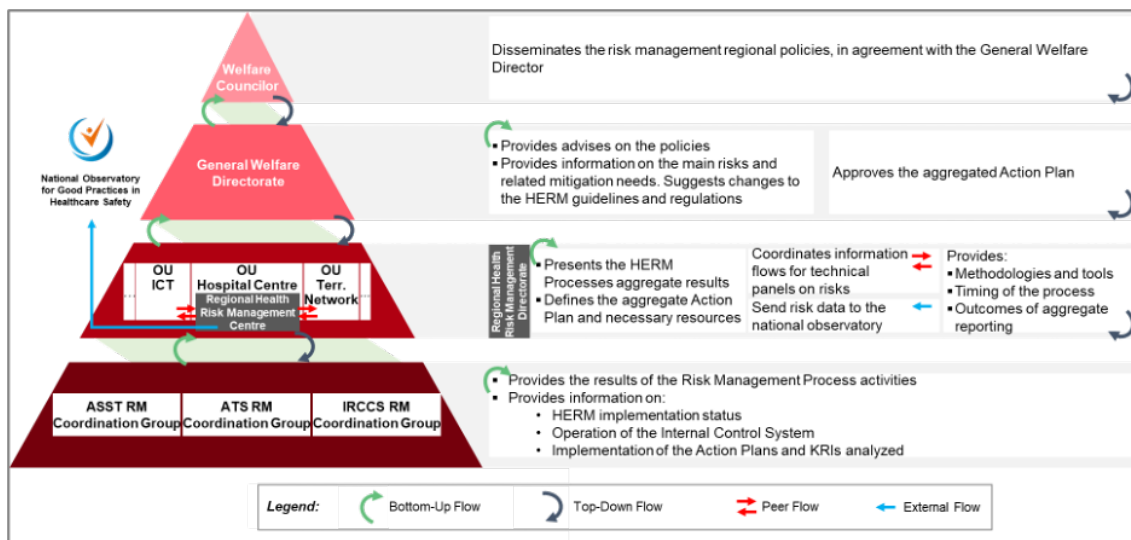


Figure 3 - HERM Model Lombardy Region | Information and reporting flows

Following the structuring of the overall HERM Model Framework, and the related information flows, the tools supporting the *Healthcare Enterprise Risk Management Methodology* (such as the Risk Model and the Assessment Metrics) were defined.

The Risk Model, or taxonomy of risks, a key element of the regional project innovation, enables the classification of risks according to standard and unitary categories/subcategories for the entire perimeter of the regional healthcare companies. This tool represents the reference for the classification of all risks detected in the different business areas/processes and, furthermore, it is designed to be shaped and revised according to the evolution of the external context and of the Regional Healthcare System (Figure 4).

CLINICAL & HEALTH RISKS		EXTERNAL RISKS	FINANCIAL RISKS	STRATEGIC RISKS	OPERATIONAL RISKS		COMPLIANCE RISKS
Aid policies	Anaesthesiology	Cyber security	Accounting and reporting	Communication and institutional relations	Activities and procedures	Information and reporting	Anti-corruption
Clinical trials	Diagnostic	Evolution of the regulatory context	Interest rates	Governance	Buildings and common spaces	Infrastructure assets and technology	Contracts and legal disputes
Documents drafting and management	Fall	External offences	Liquidity and credit	Image/ Reputation	Business Continuity	Internal wrongdoings	Ethical code
Infections	Ob-gyn & neonatal (including triggers)	National and regional socio-economic context	Property tax	Internal Control System	Communication and relationships	Management of drugs and medical devices	Information security and privacy protection
Patient identification	Prevention	Natural or accidental events	Tax	Investments and assets	Continuity and coordination of care pathways	Management of healthcare equipment	Internal regulations
Self-harm and suicide attempts	Surgery	Third Party Management		Strategic planning	Health, safety and environmental	People and culture	Regulations (regional, national, EU)
Therapeutic	Trasfusion						

Figure 4 - HERM Model Lombardy Region | Risk Model

The *Assessment Metrics* responds to the need of assessing risks on the base of the occurrence likelihood and on the several negative impacts that they could generate; for

this reason, the Assessment Metrics of likelihood and of the five main types of impact have been defined (Figure 5).

The risk assessment also depends on the effect of the mitigation actions that are part of the Internal Control System, i.e., implemented by the healthcare companies to reduce the impact and/or the likelihood of risk occurrence. To integrate this aspect into the methodological framework, respective metrics have been defined (Figure 5).

Scale		Evaluation	Category	Guideline
2	Negligible		Economic-Financial	<ul style="list-style-type: none"> <li>Economic impact (increase in costs/reduction in revenues)</li> <li>Financial impact (worsening cash flows)</li> </ul>
3	Limited		Reputational	<ul style="list-style-type: none"> <li>Relations with stakeholders (worsening relations/relationships)</li> <li>Event resonance in the national/international media and press</li> </ul>
5	Significant		Compliance	<ul style="list-style-type: none"> <li>Violation of contractual/regulatory obligations or deriving from financial liability</li> </ul>
7	Major		HSE	<ul style="list-style-type: none"> <li>Commission of crimes also resulting in cases of sanctions</li> <li>Accidents or deaths of employees at work</li> <li>Impacts on different environmental matrices</li> </ul>
10	Catastrophic		Operational	<ul style="list-style-type: none"> <li>Slowdown/interruption of operational processes</li> <li>Impacts on the services provided</li> </ul>

Scale		Evaluation	Guideline
2	Unlikely		The event is expected to occur in the long term
3	Not very likely		The event is expected to occur in the medium/long term
4	Moderately likely		The event is expected to occur in the medium term
5	Likely		The event is expected to occur in the short/medium term
6	Very likely		The event is expected to occur in the near term

Scale		Evaluation	Guideline
4	Alto		The controls operate effectively and efficiently, ensuring monitoring and containment of risks
3	Medio-alto		The controls operate effectively and efficiently, with slight deficiencies and limited exposure to risk
2	Medio		The controls operate with localized deficiencies with slight exposure to risk or for which a corrective/mitigation intervention is in place and is being concluded (e.g. procedure pending approval)
1	Basso		The control operate with significant deficiencies and moderate exposure to risk
0	Nulla		Total absence of control elements, or which presents serious critical issues, with high exposure to risk

Figure 5 - HERM Model Lombardy Region | Assessment Metrics

The final phase in the definition of the Lombardy Region’s HERM Model, involved the design of the Risk Management Process, consisting of the 4 stages shown in Figure 1 and discussed in more detail below (Figure 6).

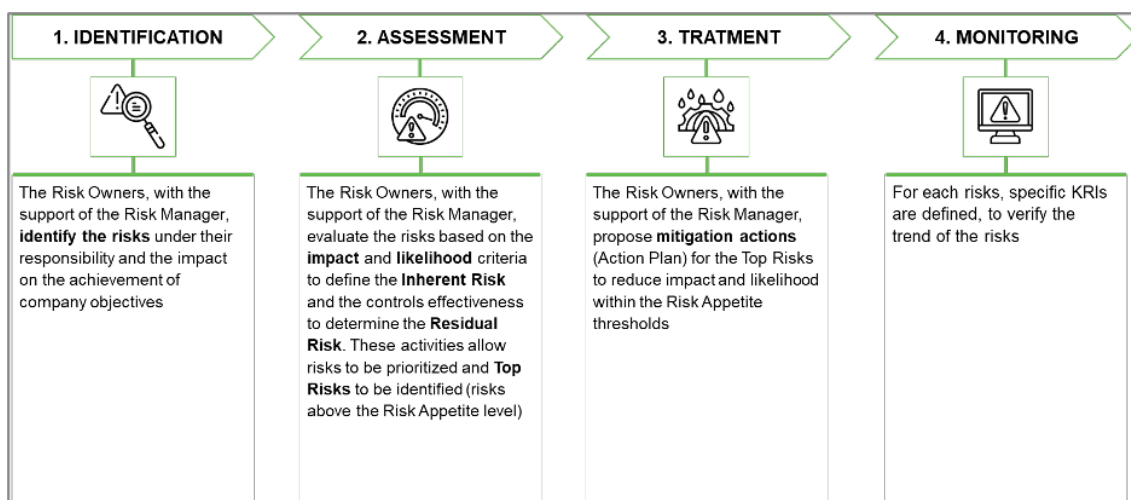


Figure 6 - HERM Model Lombardy Region | Risk Management Process

## Data Analysis

The implementation of the pilot Model is currently structured in 2 milestones: the first (completed) covered a total of 9 processes in 7 healthcare companies, the second (ongoing) extended the scope of the analysis to other processes in the same healthcare companies previously involved (Figure 7).

The implementation strategy of the Framework envisages that the healthcare companies involved in the pilot phase had a supporting role in Model definition, tools test and validation, and in verifying the coherence and the predictive validity of the Model, to contribute to its improvement.

Upon completion of the pilot implementation and after the methodology and tools consolidation, the remaining 33 companies of the Regional Healthcare System will be involved and provided with all the necessary tools and support in implementing the Model.

Process	ATS Milano	IRCCS Policlinico Milano	IRCCS San Gerardo	ASST Mantova	ASST Niguarda	ASST Pavia	ASST Valtellina
1. Diagnosis		✓	✓	✓	✓	✓	✓
2. Therapy		✓	✓	✓	✓	✓	✓
3. Public relations office	✓	✓	✓	✓	✓	✓	✓
4. Budget & reporting	✓	✓	✓	✓	✓	✓	✓
5. Purchasing	✓	✓	✓	✓	✓	✓	✓
6. ICT	✓	✓	✓	✓	✓	✓	✓
7. Clinical engineering		✓	✓	✓	✓*	✓	✓
8. Pharmacy		✓	✓	✓	✓*	✓	✓
9. Clinical trials		✓	✓				
10. Veterinary medicine & public health	✓						
11. Preventive medicine & screening	✓						

<b>Legend:</b>			
✓ Risk Model - clinical & health risks alignment	✓ Pilot phase	* For the ASST Niguarda, the activities are intended only for the HTA evaluation process	✓ 2023 extension

Figure 7 - HERM Model Lombardy Region | Scope

The pilot implementation was characterized by the creation of a working group by involving resources provided by 7 Health care Companies [1]: more than 80 people were interviewed, more than 450 documents analyzed and more than 250 risks identified. Figure 8 shows the provisional aggregate results obtained [2].

Process	Health Care Company 1	Health Care Company 2	Health Care Company 3	Health Care Company 4	Health Care Company 5	Health Care Company 6	Health Care Company 7
1. Diagnosis							
2. Therapy							
3. Public relations office	High	Low	Low	Low	Low	N/A	Low
4. Budget & reporting	Low	Low	Low	Low	Low	N/A	N/A
5. Purchasing	Low	Low	Low	High	High	N/A	N/A
6. ICT	High	High	High	High	High	N/A	High
7. Clinical engineering	High	High	High	High	Low	Low	Low
8. Pharmacy	High	Out of Scope	High	High	High	High	N/A
9. Clinical trials	High	Out of Scope	Out of Scope	Low	Out of Scope	Out of Scope	Out of Scope
10. Veterinary medicine & public health	Out of Scope	Low	Out of Scope	Out of Scope	Out of Scope	Out of Scope	Out of Scope
11. Preventive medicine & screening	Out of Scope	High	Out of Scope	Out of Scope	Out of Scope	Out of Scope	Out of Scope

Legend:	
Low	Low
Medium	Medium
High	High
Extreme	Extreme
Pilot phase	2023 extension Provisional data
Risk Model - clinical & health risks alignment	Data not yet available
Out of Scope	

Figure 8 - HERM Model Lombardy Region | Aggregate provisional results

## Discussion and conclusions

Since the Model implementation was conducted on 7 Healthcare Companies out of the 40 in the Lombardy Region, and the second phase is not yet completed, the exercise doesn't seem to present exhaustiveness and representativeness criteria.

However, the critical aggregate issues provisionally emerged are related to the following issues:

1. Generalized weakness of the IT security of the analyzed healthcare companies, with reference to data protection, vulnerabilities management in information systems, response to "IT security incidents [3]" (Incident Response and Business Continuity), Access Audit activities, registration and monitoring of virtual access, and, finally, user training and awareness on Cyber Security.
2. Purchase of drugs on foreign markets with packaging and instructions sheet not in Italian/English language. This aspect, together with the absence of a specific translation services, can facilitate errors in the preparation and administration of such drugs, posing a patient safety risk.

The findings suggested the needed improvement actions to ensure greater safety.

In-depth training for risk management personnel of public and private healthcare companies is nearing completion, as well as the system fine-tuning; the implementation of the HERM Model to the entire Lombardy Healthcare System will begin soon.

These actions are expected to result in a reduction of unexpected events and related riskiness as well as a reduction in the cost of related claims.



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[2] The tally and the main findings should be considered as provisional and not conclusive, as the activities of the second milestone are still ongoing.

[3] An IT security incident is defined as any event or set of events that imply a violation of ICT security policies, a source of damage to ICT assets or to the information assets of the organization, and because of which it is necessary to apply countermeasures and/or containment measures by the competent structures.