Clinical Risk Management framework, strategy and action plan

Phase 3

Support for improving quality of healthcare and patient safety in Slovenia

RFS REFORM/SC2020/021
AARC - Consortium

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ABBREVIATIONS

CPD	Continuous Professional Development
CRM	Clinical Risk Management
CRMP	Clinical Risk management Plan
FMEA	Failure Mode and Effect Analysis
ICT	Information Communication Technology
HFMEA	Healthcare Failure Mode and Effect Analysis
MoH	Ministry of Health
OECD	Organisation for Economic Cooperation and Development
OWG	Operating Working Group
PS	Patient Safety
QoC	Quality of Care
RM	Risk Management
RMIS	Risk Management Information System
RPN	Risk Priority Number
RSK	Razširjeni strokovni kolegij (Specialty profesional collegium)
SA	Situational Analysis
SWOT	Stength, Weaknes, Opportunity, Threat
WHO	World Health Organisation

Glossary is provided in Appendix F.

1. INTRODUCTION

Unsafe care exerts a significant burden on health systems, communities, and societies. Unforeseen and undesirable events can occur in any setting where health care is delivered. Each tenth patient in Europe encounters an adverse event in hospitals, producing suffering and misfortune over the patient and their families. It takes a high monetary cost for social insurance frameworks.

Most human activities lead to some safety risks. Some risks may be more urgent and severe, while others may not require any external policy or approach to handling them. Nonetheless, it is vital to effectively prevent, identify, address, and mitigate risks, which requires a robust risk management policy. Robust risk management is vital to the healthcare field. A small clerical error or treatment oversight could harm a patient and even cause death. The lack of procedures to effectively address and mitigate these risks can lead to more significant problems in the future.

Every contact of a patient with a process of care can comprise an intrinsic risk. **Risk management** is about being aware of the potential of things that can adversely affect healthcare service/function **(risks)** and putting in place actions **(controls)** to make sure that the likelihood of them occurring is reduced as is reasonably practicable. A **risk** is something that **could** happen. An **incident** is something that **has** happened.

Without a proactive approach, without dealing with critical points in the structures, processes, and professional behavior an avoidable adverse event can occur. Avoidable adverse events have many profound implications for patients/families, involved healthcare staff, and a healthcare organization reputation.

Incident reporting and analysis provide information about past incidents. However, their retrospective nature has a limitation. Apart from being reactive, other reporting limitations are also shown, such as incomplete data, hindsight bias, unreliable error classifications, and merger of risk outputs in a comprehensive picture (1, 2).

Incident reporting itself is also not likely to help identify risks relevant to the system issues that have contributed to most error occurrences. The reporting process is necessary since it enables increasing awareness and creates a safety culture, but it should not be taken as the most meaningful Patient Safety (PS) tool (3).

Clinical Risk Management (CRM) is a specific form of risk management focusing on clinical processes, directly and indirectly, related to the patient. Therefore, a uniform process for managing CRM is helpful. CRM is a proactive system specifically concerned with improving the quality and safety of health care services by identifying the circumstances and opportunities that put patients at risk of harm and then acting to prevent or control those risks (4). CRM is a part of the patient safety system and also a part of quality management as it can improve clinical indicators, especially processes and outcomes.

CRM is proactive analysis, looking ahead, which aims to identify and mitigate hazards before problems occur. The proactive analyses should be used when looking ahead to anticipate and evaluate potential adverse events in the future. In addition, CRM seeks out structural hazards and resulting difficult processes, contributing to avoidable adverse events.

Getting ahead of harm before it happens. (6)

Healthcare systems are inevitably and intrinsically hazardous by their nature. Therefore, it is essential to identify and assess all potential risks before ultimately leading to harmful incidents. To have a successful risk identification process within the scope of risk management, information and experience are two critical inputs needed. To reach such inputs, traditionally, incident reporting is the common tool used in healthcare.

The distinction between the retrograde PS approach and CRM as a proactive methodology has practical implications.

A uniform process for managing CRM is helpful. CRM is a proactive system specifically concerned with improving the quality and safety of health care services by identifying the circumstances and opportunities that put patients at risk of harm and then acting to prevent or control those risks.

The overarching objective of this project, of which CRM is a part, is to contribute to institutional, administrative, and growth-sustaining structural reforms in Slovenia, in line with Article 4 of the SRSP Regulation.

The **goals** of Phase 3 of the project are to support the Slovenian Ministry of Health in capacity building, developing a comprehensive CRM system, including strategy and action plan for CRM

This document briefly describes the generic risk management requirements and their components, a short overview of health care risk management, detailed CRM, strategic goals, and action plan with responsibility and accountability.

2. METHODOLOGY

2.1. Compilation of information

A non-exhaustive **literature review** on CRM showed that CRM is a part of generic risk management and part of healthcare management systems. The components of generic, healthcare risk management, and CRM are described below in section 3.1.

The results of the situation analysis (SA) regarding CRM in Slovenia were considered as described in Deliverable 2 of the project "Support for improving quality of healthcare and PS in Slovenia". They revealed that there was no fulfillment of the National policy requirement from the year 2006 for a proactive approach for reducing PS incidents either at the national or healthcare organization levels (5).

Risk management in Slovenia started with introducing the international accreditation system and ISO 9001 certification in the year 2010/2011 in healthcare. The system is voluntary. Accreditation standards require the creation of a framework, procedure, and documented process that addresses risk management related to the safety of patients and personnel, the strategic, operational, and financial integrity of the healthcare organization. As a result, internationally accredited healthcare facilities have developed risk management policies, guidelines, tools, criteria, risk matrices, risk registers, and actions to respond to risks. ISO 9001 is not specific to healthcare. The requirements for risk management are more generic, and much less elaborated than in accreditation standards.

In Slovenia some terminology regarding PS and CRM are not used properly and not explicitly explained, like patient risks, patient safety risks to safety, and thus may confuse healthcare staff and other stakeholders.

2.2. Comparative analysis of CRM systems used in EU and other countries

State of the art of CRM in three states and two regions was studied: Tuscany (Italy), Ireland, Catalonia (Spain), Australia, and Denmark. The review describes health system organisation, governance structures, plans and strategies, CRM, and PS. The details are provided in a complementary document in PDF format name: *SRSS QoC and PS - T3.2. Comparative analysis* and in the Appendix E.

2.3. Workshops

The first workshop with OWG (representatives from University clinical Center Ljubljana, Community Healthcare Centre of Ljubljana, and Agency for Medicinal Products and Medical Devices of the Republic of Slovenia) was conducted in Slovenian on 16th September 2021 at the MoH as part of the celebration of World Patient Safety Day together with Phase 4: "Improvement Patient Safety and safety culture) – T.4.1: "Design a National Action Plan". Also, the SA was presented to all working groups and invited people. Then the introduction on CRM, PS, and PS culture were presented to OWG. The task for the OWG was, following the inception report, to collect and review the elements of the risk management system available in Slovenia. The members of OWG clarified what has been done so far and what is still needed to be done about

risk management. A generic analytical framework proposal was shown to the group to find out the key achievements and the key outstanding issues and collect and review key documentation using the framework and validation with the OWG. Likewise, a short questionnaire about RM and CRM in their facilities was distributed to the members of OWG.

The questionnaire (appendix A) was answered by 4 members of the group and all came from hospitals. Results are shown in Appendix A and reflect their perceptions/ opinions about the issue. All of these facilities were accredited by international standards and certified by ISO 9001 but not ISO 31000 and thus all have to comply with the accreditation standards of risk management. One hospital has almost everything depicted in the questionnaire in place, according to the results of the questionnaire. However, not all relevant documents were provided that can confirm alignment with the answers in the questionnaire.

Identified risk management documentation and guideline in some of the accredited hospitals in Slovenia are comprised of:

- Purpose
- Definitions
- Diagram of basic activities with responsible administrator-guardian and required documentation
- Description of the process of risk management, criteria
- Risk matrix
- Risk register with the calculation of risk score
- Actions to respond to risks

In 2013 Information Communication Technology (ICT) support for Healthcare Failure Mode and Effect Analysis (HFMEA) was developed with a practical approach to medication management in one Slovenian hospital. Unfortunately, it had not been adopted or adapted in the healthcare system due to a lack of proper governance and no robust system of spreading good practices (6).

A **comprehensive CRM** has not been developed on the national level according to MoH. There is no national policy, strategy and action plan and no guidance to develop CRM in healthcare facilities and even accredited healthcare organisations rarely use CRM as noticed in the surveyed healthcare organisations by the international accreditation body.

The second workshop with OWG was held on 9th November 2021 with the aim of discussing the proposal for an analytical framework for a CRM system in the Slovenian healthcare system.

There was 30 minutes presentation on:

- Generic risk system with principles, framework, and process based on ISO 31000
- Risk management in healthcare
- CRM definition, methods and tools based on HFMEA with an example from real life
- Strategy and example of an action plan for healthcare facilities

- Future workshop for consensus regarding deadlines and responsibilities for each action plan

In the discussion the following items were emphasized:

- The structure for CRM has to be incorporated in existing structures for quality and patient safety, especially for smaller healthcare facilities
- The responsibilities and accountabilities of top leadership should be explicitly required
- External evaluation of CRM system in healthcare facilities is necessary
- Training for CRM has to be planned and implemented
- System for spreading of good practices must be developed

Note 1: the requirement for training and spreading of good practices will be incorporated in the action plan for phase 4 together with the training for patient safety.

Note 2: another workshop or focus group will be necessary to determine responsibilities and deadlines of action plans for CRM.

3. GOAL, CONTENT, AND OBJECTIVES OF THE CLINICAL RISK MANAGEMENT SYSTEM

The **goal of the document** is to present the strategy and action plan for CRM in the Slovenian healthcare system that will facilitate closing the gaps in the existing risk management efforts in healthcare organisations/providers of healthcare services.

The **objectives of the CRM framework** are to describe CRM principles, prepare strategic goals and action plans, establish a process for CRM, decide on responsibilities, required resources, develop a communication plan, design tools, and propose an organizational chart.

3.1. Generic risk management requirements and their components

Risk management is about being aware of the potential of things that can adversely affect a service/function (risks) and putting in place actions (controls) to make sure that the likelihood of them occurring is reduced in so far as is reasonably practicable.

The **generic risk management ISO 31000 standard** has three main components of risk management:

1. A set of **principles** that guide risk management activities (see figure 1)
2. The **risk management framework** - the overall structure and operation of risk management across the organization, similar to the plan/do/study/act (PDSA) cycle (see figure 2)
3. The **risk management process -** how are risks identified, analyzed and treated (see figure 3) (9)

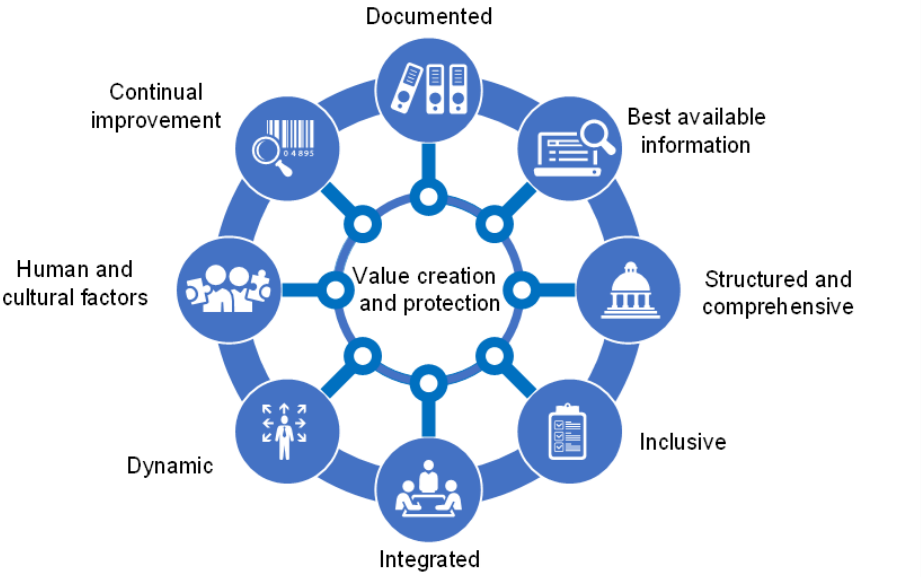

Figure 1. Risk management principles

Source: adapted from ISO 31000—2018

Risk management principles features are:

1. Framework and processes should be customized and proportionate
2. Appropriate and timely involvement of stakeholders is necessary
3. A structured and comprehensive approach is required
4. Risk management is an integral part of all organisational activities
5. Risk management anticipates, detects, acknowledges and responds to changes
6. Risk management explicitly considers any limitations of available information
7. Human and cultural factors influence all aspects of risk management
8. Risk management is continually improved through learning and experience

The purpose of the **risk management framework** is to support an organization in integrating risk management into its essential activities and functions. The effectiveness of risk management will depend on its integration into the organization's governance, including decision-making. It should include:

1. **Risk architecture:** roles and responsibilities of individuals and committees that support the risk management process (who “owns“ different risks?)
2. **Strategy:** objectives of the risk management activity in the organization
3. **Protocols:** how the strategy will be implemented and risks managed (procedures, indicators, risk reporting and escalation procedures) monitoring and review

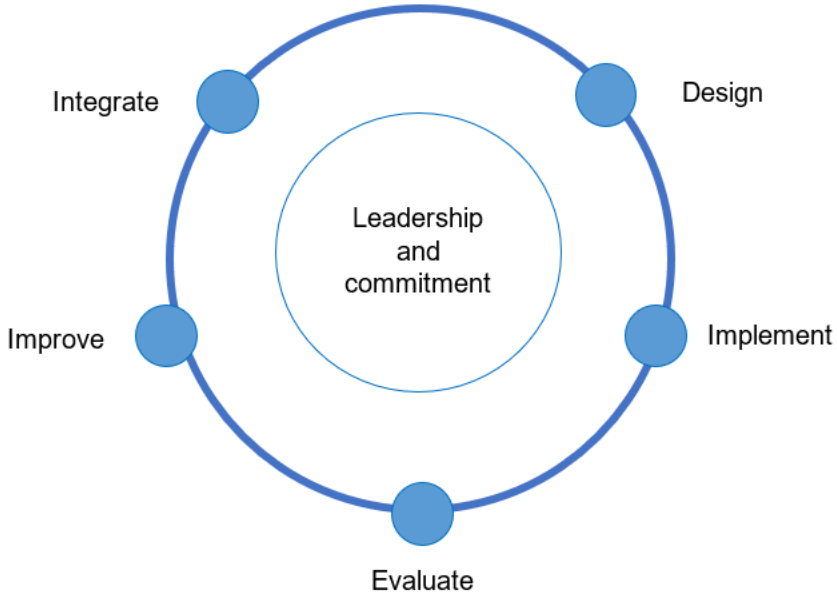

Figure 2. Risk management framework

Source: adapted from ISO 31000—2018

The **risk management process** (see figure 3) should be an integral part of management and decision-making and integrated into the organization's structure, operations, and processes. It can be applied at strategic, operational, program or project levels.

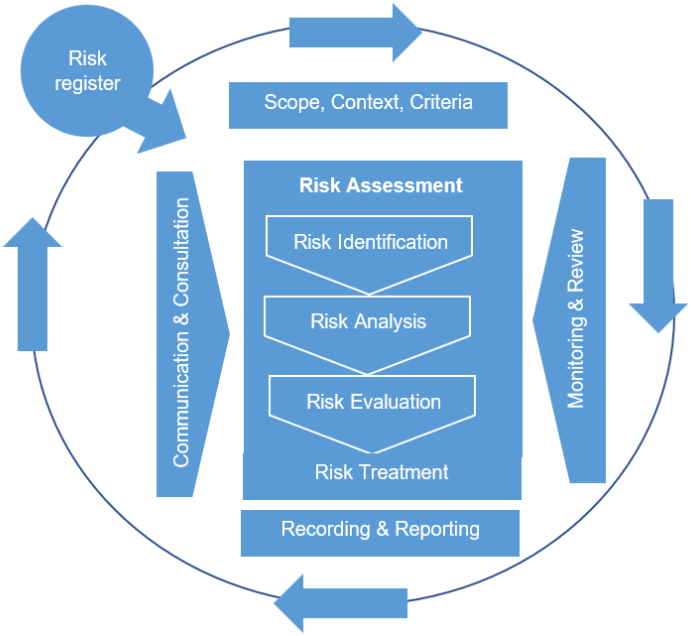

Figure 3. Risk management process

Source: adapted from ISO 31000—2018

The detailed risk management process is described below as depicted in figure 3:

a) Risk communication and consultation

Means for communicating risk information may include existing committees or forums within the organisation or dedicated risk management committees.

Early on, it helps understand stakeholders' interests and concerns and checks that the risk management process focuses on the correct elements. Later on, it helps explain the rationale for decisions and specific risk treatment options.

Communication and consultation aim to:

1. **Bring different areas of expertise together** for each step of the risk management process
2. Ensure that **different views are appropriately considered when defining risk criteria and when evaluating risks**
3. Provide sufficient **information to facilitate risk supervision and decision-making**
4. Build a **sense of inclusiveness and ownership** among those affected by risk

b) Risk assessment

Risk assessment phase is critical for the CRM process. Risk assessment should be conducted systematically, iteratively and collaboratively, drawing on the knowledge and views of stakeholders. It should use the best available information, supplemented by additional information as necessary.

It is vital to have a template for recording appropriate information about each risk. Table 1 shows the range of information that may need to be recorded.

#	Item	Description
1	Name of the risk	• Unique identifier or risk index
2	Scope of risk	• Scope of risk and details of possible events, including a description of the events, their size, type and number
3	Nature of risk	• Classification of risk, the timescale of potential impact and description as a hazard, opportunity or uncertainty
4	Stakeholders	• Stakeholders, both internal and external, and their expectations
5	Risk evaluation	• Likelihood and magnitude of the event and possible impact or • consequences should the risk materialize at the current level
6	Loss experience	• Previous incidents and prior loss experience of events related to the risk
7	Risk tolerance, appetite	• Loss potential and anticipated financial impact of the risk • or attitude • The target for control of risk and desired level of performance • Risk attitude, appetite, tolerance or limits risk
8	Risk response, treatment	• Existing control mechanisms and activities and controls • Level of confidence in existing controls • Procedures for monitoring and review of risk performance
9	Potential for risk improvement	• Potential for cost-effective risk improvement or modification • Recommendations and deadlines for implementation • Responsibility for implementing any improvements
10	Strategy and policy	• Responsibility for developing strategy related to the risk • Responsibility for auditing compliance with controls

Table 1. Information template that might be recorded

Source: adapted from Airmic, 2010

The objective of a template is to enable the information to be recorded in a table, risk register, spreadsheet or a computer-based system. Although a simple description of risk is sometimes sufficient, there are circumstances where a detailed risk description may be required to facilitate a comprehensive risk assessment process.

As part of the risk assessment process, there are the following steps and we propose to use HFMEA tool (Appendix B):

- **Risk identification:** What could prevent healthcare teams and healthcare organisations from achieving the objectives**.**
- **Risk analysis:** Understanding the sources and causes of the identified risks; studying probabilities and consequences given the existing controls to identify the level of residual risk.
- **Risk evaluation:** Comparing risk analysis results with risk criteria to determine whether the residual risk is tolerable.
- **Risk treatment:** The purpose of risk treatment is to select and implement options for addressing risk by changing the magnitude and likelihood of positive and negative consequences to achieve a net increase in benefit. Risk treatment involves an iterative process of:

    1. Formulating and selecting risk treatment options
    2. Planning and implementing risk treatment
    3. Assessing the effectiveness of that treatment
    4. Deciding whether the remaining risk is acceptable
    5. If not acceptable, take further treatment

c) Monitoring and review

The purpose of monitoring and review is to assure and improve the quality and effectiveness of process design, implementation and outcomes. Therefore, ongoing monitoring and periodic review of the risk management process and its outcomes should be a planned part of the risk management process, with responsibilities clearly defined.

d) Recording and reporting outcomes

The risk management process and its outcomes should be documented and reported through appropriate mechanisms:

1. Communicate risk management activities and outcomes across the organization
2. Provide information for decision-making
3. Improve risk management activities
4. Assist interaction with stakeholders, including those with responsibility and accountability for risk management activities

e) Risk registers

Risk registers are a tool that can be used to assist the prioritization of risks and the appropriate allocation of resources. The registers must be kept up to date and regularly reviewed according to the individual risk rating. The organization's risk register must be available for auditors.

The **objectives of the healthcare risk register** are to:

- Achieve greater visibility of exposures and threats that may prevent a healthcare organisation from achieving its objectives
- Implement a thorough basis for decision making and planning
- Create a record of the identification and control of key organisational risks
- Achieve a more effective allocation and use of resources by prioritizing risk
- Respond more effectively when potential risks occur
- Assess and monitor if management controls or resources are adequate to manage risks
- Achieve pro-active, rather than reactive, management and therefore reduce the likelihood that risks will occur
- Continue and further develop the integrated approach to risk management, whether the risk relates to clinical, nonclinical, financial or organisational risk
- Ensure all significant risk management concerns are properly considered and communicated to the Governing Council

The **main elements of the risk register** are:

1. **Dates:** it is important to record the date that risks are identified or modified. Optional dates to include are the target and completion dates
2. **Description of the risk:** a phrase that describes the risk
3. **Likelihood of occurrence:** provides an assessment on how likely it is that this risk will occur
4. **The severity of effect**: provides an assessment of the impact that the occurrence of this risk would have on the project/organization
5. **Countermeasures**: actions to be taken to prevent, reduce, or transfer the risk. This may include the production of contingency plans
6. **Responsibility/owner**: the individual responsible for ensuring that risks are appropriately engaged with countermeasures undertaken
7. **Status**: indicates whether this is a current risk or if risk can no longer arise and impact the project
8. **Other columns**

The content of these registers may originate from two primary sources since a 'top-down/bottom-up approach is in place. Risks descend from the top by means of objectives and directives to the organisational level of management below. Second, the owner of the risk register is the person with ultimate accountability for a defined area of responsibility.

3.2. Risk management in healthcare

Risk management in healthcare includes the clinical and administrative systems, processes, and reports engaged in detecting, monitoring, assessing, mitigating, and preventing risks. The **system of risk management in healthcare** covers **eight risk domains** (figure 4). The possible impact of risks can affect one or several of the aspects of healthcare operation and organizations should consider clinical, human resources, information technology, finances, business practices, the environment and reputation, loss of community confidence and nonconformity with mission and values (10).

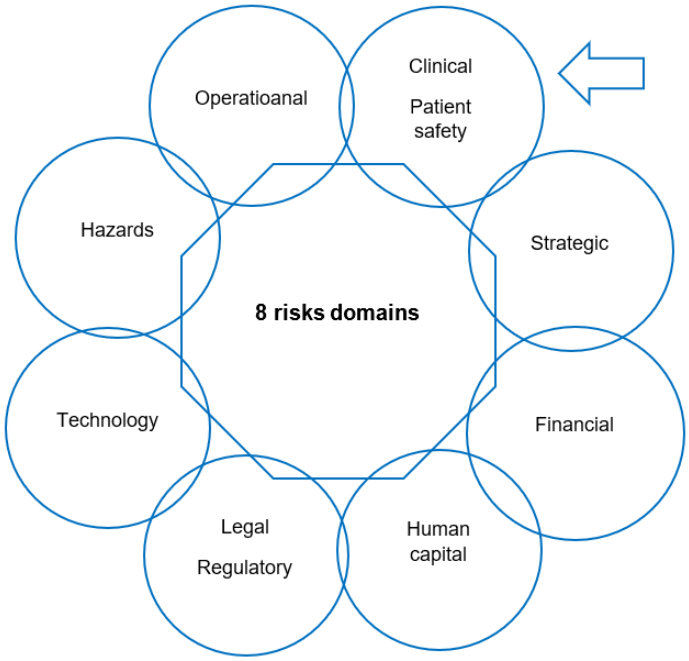

Figure 4. Risk management in healthcare. The arrow shows the domain of CRM

Source: adapted from American society for healthcare risk management, 2020

4. CLINICAL RISK MANAGEMENT

In clinical environments, the risk is defined as the combination of the probability of the occurrence of harm, the severity of that harm, and the detectability of possible harm. (6)

Sufficient information to help assess and appropriately treat the risk is essential and may involve data collection, literature review, historical records, and relevant expertise. Engaging key stakeholders who bring appropriate skills and expertise to assessing risks is critical to ensure a comprehensive analysis of the risk-related issues. Risk-relevant data should be gathered and used proactively and reactively. Thus, CRM is closely connected with retroactive identification of avoidable adverse events and near misses.

The risk analysis process can be undertaken using qualitative or quantitative analysis methodology.

Principles of CRM are similar to the principles of the generic RM system but applied in the context of healthcare with the objectives to eliminate avoidable adverse events to patients, staff and visitors.

4.1. Principles for CRM

CRM principles are:

a) Protects patients, staff, visitors and others

CRM contributes to the achievement of healthcare objectives through the continuous review of its processes and systems.

b) Decision making

The process of CRM assists decision-makers in making informed choices, identifying priorities and selecting the most appropriate action.

c) Address uncertainty

Through identifying potential risks, a healthcare organistaion can apply controls and treatments to maximize the chance of gain instead of the chance of loss.

d) Systematic, structured and timely

The process of CRM should be consistent across the entire healthcare organization to ensure efficiency, consistency and the reliability of results.

e) Based on the best available information

To effectively manage risk, it is essential to understand and consider all available information relevant to an activity and to be aware that there may be limitations on that information. It is then important to understand how all this information informs the risk management process.

f) Tailored

A healthcare organization risk management framework needs to include its risk profile and consider its internal and external operating environment.

g) Take into account human and cultural factors

Risk management needs to appreciate the contribution that people and culture have on achieving healthcare services objectives.

h) Transparent and inclusive

Engaging stakeholders, both internal and external, throughout the risk management process that communication and consultation is key to identifying, analysing and monitoring risk.

i) Dynamic, iterative and responsive to change

The process of managing risk needs to be flexible. The challenging environment we operate in requires agencies to consider the context for managing risk and identify new risks that emerge and make allowances for those risks that no longer exist.

j) Facilitate the continual improvement of organisations

Healthcare organizations with a mature risk management culture are those that have invested resources over time and are able to demonstrate the continual achievement of their objectives and integrate CRM into general healthcare RM as all risks can influence PS and patients outcomes (9).

4.2. A framework of clinical risk management

The sample framework (see figure 5) applies to any healthcare organization and can be adapted to meet their needs.

Figure 5. A sample framework for CRM is for the national and healthcare providers levels

Source: Prosunt©

4.3. Clinical risk management policy

A **national policy of CRM** is a part of quality and PS policy and is an organized effort by Slovenia to promote and plan PS and QoC improvement. CRM policy forms an external framework for the implementation of a risk management system and is the foundation of a risk management strategy.

The purpose of the CRM policy is to shape the commitment of the healthcare system in Slovenia to proactively manage clinical risks in line with principles of risk management.

CRM policy at **healthcare facilities** is the crucial system to improve patients' outcomes, patient, staff, and visitors' safety.

4.3.1. A national CRM policy

The national quality and healthcare facilities strategy are ultimately determined to achieve better health outcomes and improve health system performance in quality dimensions such as effectiveness, safety, patient-centredness, timeliness, efficiency, and equity. Achieving these goals requires policy formulation to create an enabling environment, addressing gaps in the delivery system. In addition, the policy should integrate the improvement and measurement efforts of disease-specific and population-specific health programs that exist in the country.

The purpose of the CRM policy is to shape the commitment of the healthcare system in Slovenia to proactively manage clinical risks in line with principles of risk management. The policy applies both to public and private healthcare that must be aligned to and consistent with the policy and procedural guidance requirements. The policy provides a clear roadmap and outlines "how" the policy will come to reality with components, methods and tools of risk management. Risk policy formulates principles or guidelines for basic handling, not only of risks but also of opportunities. It forms the external framework for implementing a risk management system and is the foundation of a risk management strategy. The policy involves proactively identifying risks that threaten the achievement of objectives – the delivery of high-quality and safe care, compliance with legal and regulatory requirements and putting in place actions to reduce risks to an acceptable level.

Policy statement: *the CRM principles, framework and processes as outlined in this paper are to be used within the Slovenian healthcare system. The policy supports the delivery of the CRM strategy and actions to decrease or avoid preventable adverse events. The policy is to be available to all healthcare providers and it applies to the management of clinical risks in connection with patient, staff and visitors' safety.*

CRM is obligatory in all healthcare providers, public and private. The responsibilities for implementation are established in strategy and action plan. Healthcare providers are encouraged to use HFMEA method for a proactive approach to avoidable adverse events.

4.3.2. CRM policy at healthcare organisations/providers of healthcare

All healthcare organisations/providers of healthcare are expected to develop CRM policies, public and private.

An example of the policy statement in a healthcare organization: CRM is the crucial system to improve patients' outcomes and patient, staff, and visitors' safety. Through this system of internal control and accountability of the top management, it fulfills their responsibility and accountability. Governing Council realizes its responsibility of stewardship. Critical systems are fully embedded at every level of the organisation and ensure compliance with current and future CRM related standards and legislation.

The policy should involve:

- Statement of the attitude of the organization to risk (risk strategy)
- Description of the risk-aware culture or control environment
- Risk management training topics and priorities
- Development of a robust approach to the assessment, identification and understanding of the risks inherent within the delivery of health services:
  - Risk management and arrangements (risk architecture)
  - Details of procedures for risk recognition and ranking (risk assessment)
  - List of documentation for analysing and reporting risk (risk protocols)
  - Risk mitigation requirements and control mechanisms (risk response)
  - Level and nature of risk that is acceptable (risk appetite)
- Identification of resources available to support the implementation
- Definition of the roles and responsibilities for CRM
- Outlining the process to be adopted at all organizational levels requires that risks are identified, assessed using the risk management tools, and thereby prioritized for action
- Ensuring that all risks have clear ownership and that the actions are identified to minimize risk. Risks are recorded, assigned an action to the owner and have a due date for completion
- Risk management and internal control objectives (governance) – compliance monitoring is the sine qua non of the CRM and criteria for monitoring and benchmarking risks
- A formal communication to staff across their organization is in place
- Risk activities and risk priorities for the coming year

Resources should be allocated to manage risk issues appropriate to the size and scope of the organization and the consequences of failure to manage the risk. Resources may include financial resources, human resources, and physical resources.

4.4. Clinical risk governance

Ministry of Health (MoH), the National independent body for QoC and PS, and healthcare service providers' governing bodies are accountable for CRM.

A framework for healthcare governance defines five mutually exclusive pillars: transparency, accountability, participation, integrity and capacity (11).

For strong PS governance and therefore also for clinical risk governance, it should be required from the government to consider key findings of OECD study (12):

1. Requirements for **aligning clinical risk governance with overall health system governance and financing** align its individual components and functions
2. **Inclusion into all healthcare settings**
3. Enforcement **people-centeredness** in safety governance
4. Fostering a **culture of openness and trust** among health professionals and regulators
5. Enabling **continuous learning** from both harm and success
6. **Incorporating other policy areas**, notably data privacy/security policies and workforce preparedness

Health service provider governing bodies are accountable for CRM and must ensure that a local risk management policy, framework and any other supporting documentation is developed and includes:

- Defined processes to identify, assess, treat, monitor, review, record and report clinical risks
- Risk review frequency requirements
- Supervision requirements for the governing council and/or dedicated risk and audit sub-committee
- Risk ownership and acceptance decisions for risks at each risk level are specified in the local policy
- Risk identification and continuous monitoring of the risk profile occurs on an ongoing basis
- Risk management requirements are formally communicated to staff across the organization
- Processes are in place to build staff awareness and risk understanding through education and training

4.5. Strategic goals and action plans for CRM

The strategic goals describe the implementation of principles, and policy, and process of CRM. The format of a CRM action plan varies by organization and depends on the analysis of existing systems and historical data as well as the unique characteristics of each healthcare entity.

Some **fundamental components belong in all healthcare CRM plans**:

- **Education and training**: Clinical Risk Management Plans (CRMP) need to detail employee training requirements, including new employee orientation, ongoing and in-service training, annual review and competency validation, and event-specific training
- **Purpose, goals, and metrics:** CRMP should outline the purpose and benefits of the CRM. Specific goals to reduce liability claims, preventable adverse events, including sentinel events and near misses
- **Communication plan:** while it is critical that the healthcare risk management team promote open and spontaneous dialogue, information about how to communicate about risk and with whom should be provided in the CRMP. It is also essential that the plan detail reporting requirements to departments and top management. Furthermore, the plan should promote a safe, "no-blame, no-shame" culture and include anonymous reporting capabilities
- **Reporting protocols:** every healthcare organization must have a quick and easy-to-use system for documenting, classifying and tracking possible risks and adverse events. These systems must include protocols for mandatory reporting
- **Response and mitigation plans**: include collaborative systems for responding to reported risks and events, including acute response, follow-up, reporting, and repeat failure prevention

The CRMP is a **living document** that is regularly updated and improved based on emerging risks, lessons learned, new information, and changes in the healthcare system and practice of medicine.

The **action plan** defines clear milestones and tasks that must be undertaken, clarifies roles and responsibilities, sets clear timelines, and addresses financial and resource considerations. An action plan can significantly aid the dissemination and execution of the strategy and ensure the document does not simply "sit on the shelf and gather dust". It may also help translate the national strategy of CRM into healthcare providers' action plans to promote ownership across the system, highlighting the need for close linkages between national and healthcare facilities plans. While the strategy itself plans to build consistency across stakeholders in the health system, align quality goals and priorities, and identify key levers to achieve these quality goals, the action plan goes a level deeper to define explicit tasks, roles, timelines, and financial considerations.

An action plan should answer the following questions:

- What are the tasks or actions that must be undertaken?
- How should tasks or actions be prioritized if available resources are limited?
- Who are the persons who have the responsibility for each of these tasks or actions?
- What is the timeline in which these tasks or actions must be completed?
- How much and what kind of resources must be provided to complete each task or action?

- What should specific performance measures be collected (for example, quarterly) throughout the length of the action plan to evaluate the success and effectiveness of the plan?

Strategic objectives and action plans of CRM are part of the strategic objective of safe clinical processes described in Phase 4 of the project. CRM for safe and reliable clinical processes is described below in table 2. Action plans for a national independent body for quality and PS would be the responsibility of MoH f this body is not established or if there is a dealy in its creation. The setting of incentives/penalties is a matter of discussion between MoH, Health insurance institute of Slovenia with the participation of healthcare organisations/providers of healthcare.

Strategy 3.1 Identify all risk-prone clinical procedures and mitigate their risks, taking account of national and local priorities		**Responsibility**	**Deadline**
Actions for government	a. Set out the **policy systems and processes** that are required to ensure that risks are managed consistently across Slovenian healthcare governance **and develop a system for monitoring and controlling CRM system at the providers level**	Ministry of Health	31.09.2022
Actions for National independent body for quality and patient safety	a. **Review evidence to identify risk-prone clinical procedures** in collaboration with professional bodies, experts, academia, and patient and family representatives, and other relevant stakeholders and partners	National body	30.06.2023
	b. Establish a **range of clinically-led patient safety improvement programs each yea**r consistent with the national patient safety plan and strategy that target systemic themes (patient identification, diagnostic safety); patient groups (dementia patients, pediatric patients); health care settings (primary care, nursing homes); sources of harm (venous thromboembolism, sepsis, and patient falls); clinical practice domains (surgical care, obstetric services, critical care, emergency medical services, radiotherapy); and mental health and public health programs (immunization, reproductive health, maternal health)		31.12.2022 and renewed each year
	c. Create **expert groups** to identify, assess, map and widely communicate the information on key areas and sources of avoidable risk and harm in each domain of clinical practice		30.06.2022
	d. **Create and regularly update a database** of knowledge and tools to enable organisations and health care professionals to mitigate the risks and manage harm associated with clinical processes		30.06.2023

Strategy 3.1 Identify all risk-prone clinical procedures and mitigate their risks, taking account of national and local priorities		Responsibility	Deadline
Actions for National independent body for quality and patient safety	e. **Develop assessment tools and guidance** to identify and mitigate these risks, for example in the areas of diagnostic safety, patient falls, and hospital-associated venous thromboembolism	National body	30.06.2023
	f. **Develop patient safety improvement programs** that target systemic themes, patient groups, different health care settings, sources of harm, clinical domains and public health programs		31.12.2023
	g. **Provide guidance and leadership** support to annual patient safety improvement programs, evaluate them and disseminate lessons learned with overall safety and quality improvement programs in the health sector		30.06.2023
	h. Develop **standards criteria and indicators** for the evaluation of CRM system, including the implementation of policy, strategy, tools, number and quality of HFMEA projects and implement regular evaluation of CRM system		31.12.2023
	i. **Collate and disseminate best practices** and success stories and develop **training** for healthcare professionals and stakeholders		6 months starting 31.12.2022
Actions for health care organisations	a. Designate or appoint **clinical risk managers or patient safety officers** in large health care facilities. Incorporate it into existing risk management, quality and patient safety structure	Director	30.6.2022
	b. Establish a **healthcare risk unit** at a healthcare organization that can be part of the quality and patient safety unit	Director	30.6.2022
	c. Establish a **clinical leadership group** within the organization to adapt and drive forward the annual national patient safety improvement priorities together with local priorities for clinical services	Quality Committee	30.6.2022
	d. Specify a **system for information communication** from different sources such as audit committee, CRM committee, patient safety committee, drug and therapeutic committee, utility committee, infection prevention committee, accreditation reports etc.	Quality Committee	30.6.2022

Strategy 3.1 Identify all risk-prone clinical procedures and mitigate their risks, taking account of national and local priorities		Responsibility	Deadline
Actions for health care organisations	e. Establish or upgrade and maintain a risk registry	Quality Commission	30.6.2022
	f. Formulate a **CRM programme**	Professional councils of all professional groups	30.6.2022
	g. Identify **key clinical service areas** requiring focused patient safety improvement based on national and local health priorities, the criticality of delivered services, and safety incidents reported	Quality committee and professional councils of all professional groups	31.10.2022
	h. Identify all risk-prone clinical procedures within the spectrum of care delivered to patients by the organization and develop a package of actions for risk mitigation	Professional councils of all professional groups	30.6.2022
	i. Apply basic principles for quality management and utilize **improvement science methods** for improving clinical services and outcomes	Quality commission	31.12.2022
	j. Implement **CRM activities to improve patient care**, for example, to address venous thromboembolism, falls and pressure ulcers, patient identification and communication during transitions of care	Professional councils of all professional groups	30.6.2022
	k. Promote the **wider use of validated standard operating procedures** in all clinical areas in consultation with clinicians	Quality Committee	Every year starting 30.6.2022
Actions for[1] stakeholder	a. Encourage and facilitate professional organizations to systematically identify the sources of risk and harm in each area of clinical care, and to formulate patient safety solutions for different health care settings and share their expertise	Collaboration with professional chambers associations and RSKs	Every year starting 30.06.2022
	b. Collaborate with National independent body to develop or revise national guidelines for CRM	Professional chambers associations and RSKs	Every 2 years starting 30.06.2023

[1] Stakeholders are depicted in the column of Responsibility.

Strategy 3.1 Identify all risk-prone clinical procedures and mitigate their risks, taking account of national and local priorities		Responsibility	Deadline
Actions for stakeholder	c. Support health care providers in prioritizing clinical safety programs based on context, burden and feasibility	Professional chambers associations and RSKs	Every year starting 30.6.2023
	d. Advocate inclusion of, incorporate and prioritize patient safety components in national and international public health programs	Professional chambers associations and RSKs Inform National independent body for quality and patient safety	Every year starting 31.12. 2022
	e. Form collaborative working arrangements with private sector partners to identify and mitigate risks inherent to their products and services	Regular meetings professional chambers associations and RSKs	Every year starting 2022

Table 2: CRM for safe and reliable clinical processes

Source: adapted from World Health Organization (WHO). Global Patient Safety Action Plan 2021–2030. Towards Zero Patient Harm in Health Care. Geneva: WHO, 2021 (13)

4.6. Implementation of the action plan

Implementation of the system of CRM can follow SMART recommendations and is equally relevant for all four groups described in strategy 3.1.

a) **S**pecific

The objective of CRM is to improve PS and patient outcomes. The goal is to establish a system of CRM as a part of more general risk management in healthcare. CRM is essential to proactively deal with possible preventable adverse events and avoid the suffering of patients and families. It is necessary to express precisely the task and what it will achieve. In CRM, everybody is involved and responsible. The governance and technical management are located at the governing council and the top management. Units and departments are responsible for the management of CRM. Human and financial resources must be provided.

b)Achievable

When the goals and action plan for CRM is set, the determination of a realizable goal is necessary so that CRM system is successful. A plan to reach these goals has to be in place. When setting the goals, consider financial and human resources. Prepare a SWOT analysis to determine if the objective is achievable. Understand challenges and threats to goal attainment to identify solutions.

c) **M**easurable

Strategic goals and action plan realization must be measured yearly. The risk register can help in viewing data and producing relevant statistical analysis. Based on the results, corrective actions are introduced. Choosing appropriate measures depends on the specific system or process that is evaluated.

When the goals and action plan for CRM are set, the determination of a realizable goal is necessary so that the CRM system is successful. A plan to reach these goals has to be in place. When setting the goals, consider financial and human resources. Prepare a SWOT analysis to determine if the objective is achievable. Understand challenges and threats to goal attainment to identify solutions.

d) **R**elevant

The goals of CRM must be accepted by the top and middle management and be explained to all staff why the goals are worthwhile, is in alignment with the patient safety system, and that it is applicable not only for accreditation and certification but predominantly for patients and staff safety. The unit for quality and patient safety should have control over the goals.

e) **T**ime-bound

Each goal and action needs a target date so that there is a deadline to focus on. The time must be realistic and the intermediate goals have to be checked. Can the objective be completed within the allocated timeframe? What is the timeline? Has an identifiable start and stop date been identified? Can you build in a time window for unexpected interruptions?

For patients and providers, CRM is the most crucial activity. The emphasis is on clinical risks that involve failure to follow the evidence-based practice, diagnostic, therapeutic, preventive, rehabilitation, palliative, and health-promoting processes that can lead to adverse events due to

- Equipment and infrastructure failures
- Standards, rules, and policies
- Workforce management
- Training and education

4.6.1. Implementation of the action plan for Ministry of health

Goal: all providers are informed about the policy, monitoring and controlling CRM system

Indicators:

1. The policy is published at the deadline
2. Human, technological resources for CRM are provided to healthcare providers

Accountability: to the Parliament

4.6.2. Implementation of the action plan for the national independent body for quality and patient safety

Goals: lead the system of CRM at the national level

Indicator: fulfills the action plan at the deadlines

Accountability: to the founder

4.6.3. Implementation of the action plan for healthcare organisations/providers of healthcare

The implementations for healthcare organisations/healthcare providers are described in more detail as it is obvious that practical CRM is occurring at healthcare organisations/providers.

Goals: implement the action plans into the daily practice

Indicator: fulfills the action plan at the deadlines

Accountability: to Ministry of health

The implementation experience of the action plan in a day to day healthcare drives policy and strategy development and thus can build a sense of ownership among those implementing it. In practice, implementation-informed policy and strategy development require sustained and meaningful engagement with stakeholders across the health system throughout the process, recognizing there need not be an inherent dichotomy between “top-down” and “bottom-up” approaches to improve quality (14) (see figure 6).

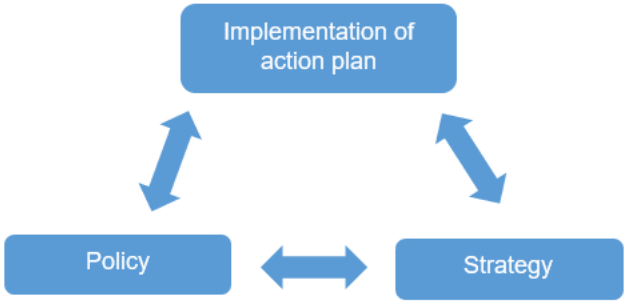

Figure 6. Policy, strategy and implementation plan as a cycle rather than a linear model

Source: Adapted from WHO Handbook for national quality policy and strategy

Implementation of CRM programs at all levels of an organization is a challenge for all clinicians and managers alike (15). The challenge for management is to support and encourage CRM by:

- Communicating and demonstrating support for CRM
- Trusting and empowering all staff to identify, analyse, report and manage risks
- Acknowledging, rewarding and empowering good CRM practices
- Identifying and managing systemic problems as they occur
- Encouraging organizational learning
- Developing positive strategies to reduce the likelihood of recurrence of the problem and/or consequences rather than responding by introducing restrictive controls

Successful implementation of a risk management initiative is an ongoing process that involves working through four components of activities: planning, implementation, measurement and learning:

a) Plan

1. Identify the intended benefits of the CRM initiative and gain governing council support
2. Plan the scope of the CRM initiative and develop a common language of risk
3. Establish the CRM strategy, framework and roles and responsibilities

b) Implement

4. Adopt suitable risk assessment tools and an agreed risk classification system
5. Establish risk benchmarks (risk criteria) and undertake risk assessments
6. Determine risk appetite and risk tolerance levels and evaluate the existing controls

c) Measure

7. Evaluate the effectiveness of existing controls and introduce improvements

8. Embed risk-aware culture and align CRM with other activities in the organization

d) Learn

9. Monitor and review risk performance indicators to measure CRM contribution
10. Report risk performance in line with obligations and monitor improvement.

4.7. Integration in healthcare organisations/providers of healthcare

The ultimate aim of healthcare risk management is to achieve better health outcomes and improve all six dimensions of quality. Integration with technical and disease-specific programs allows the healthcare organisations to leverage the already existing quality-related strengths and capabilities of technical programs and ensure that those programs are not left functioning outside the strategy (16). Options are:

- The integration of data and measurement systems from the technical program into the national measurement framework and quality data systems
- Ensuring cross-learning between quality-related efforts in different technical programs through strategic oversight provided by a national drive on the overall quality
- Development of a plan for alignment and integration, including an agreed joint program of work, consideration of budgetary challenges and opportunities, or a timetable for further consultation

The fundamental goal of CRM is to provide safe health care for patients, and safety for the staff, visitors and others. CRM is an integrated part of the PS system and PS culture and QoC.

4.8. Responsibilities and accountabilities for clinical risk management for healthcare organisations/providers of healthcare

Responsibilities and accountabilities for CRM for MoH and National body for quality and patient safety are described in section 4.6.

Responsibilities and accountabilities for CRM for healthcare organisations/providers of healthcare should be formally defined for the overarching risk management program, risk-specific programs, and identification, analysing, and reporting of risk issues. The governing council should define the communication and requirements for risk information by following governance standards. The governing council and leaders should ensure that at the same time as concentrating on strategic and important matters, they also need to be sure that all risks are effectively controlled and managed and attention is focused on the core reasons for existing of the organization – to care for and treat patients. Accountabilities and responsibilities should be defined for all stakeholders, including the governing council managers, employees, clinicians, contractors and service providers. Responsibilities for key risk categories should also be assigned – for example, infection control, quality improvement, patient and staff safety, etc. (17).

Every staff member is responsible for identifying risk with the context of their work. Everybody is a risk manager for their area of responsibility. The importance of leadership in creating an environment where quality and safety are seen as a priority cannot be understated. It is the development of positive staff attitudes and behaviors towards quality and safety that can make a critical difference with workplace safety. They place importance on learning and improvement. They are concerned with risk, quality and safety and strive to proactively reduce risk and incidents through vigilance and identifying opportunities to strengthen the systems of work.

4.8.1. CRM responsibilities for the top management team and Governing Council[2]

- Determine strategic approach to risk
- Establish the structure for risk management (Appendices D1 and D2 show an example of organisational structure for CRM)
- Understand the most significant risks
- Manage the organization in a crisis
- Control/audit the CRM functions

They place importance on learning and improvement. They are concerned with risk, quality and safety and strive to proactively reduce risk and incidents through vigilance and the identification of opportunities to strengthen the systems of work.

4.8.2. CRM responsibilities for the departments and units heads

- Build risk-aware culture within the unit
- Agree on risk management performance targets
- Ensure implementation of risk improvement recommendations
- Identify and report changed circumstances/risks

They are safety aware and vigilant and demonstrate and reinforce this attitude with staff and they do not assume that everyone is constantly aware of the safety situation. The staff is assured to speak up and ask about the possibility of a risky situation. The healthcare and other teams are constantly engaged in conversation about safety and risks.

4.8.3. CRM responsibilities for individual employees

- Understand, accept and implement risk management processes
- Report inefficient, unnecessary or unworkable controls

[2] The responsibilitis for governing and control functions in the Appendix D2 are the same as for Governing Council.

- Co-operate with management on incident investigations

4.8.4. CRM responsibilities for the risk manager

- Develop the risk management policy and keep it up to date
- Document the internal risk policies and structures
- Coordinate the risk management (and internal control) activities
- Compile risk information and prepare reports for the governing council

4.8.5. CRM responsibilities for internal audit manager

- Develop a risk-based internal audit programme
- Audit the risk processes across the organization
- Receive and assure the management of risk
- Report on the efficiency and effectiveness of internal controls (15)

4.9. Investment into risk management information system

Investment in RMIS at the national level is the responsibility of MoH or the Health insurance institute of Slovenia for the public sector. Healthcare providers in the private sector are responsible for RIMS investment-.

Information technology is a necessity to ease and support efforts of daily CRM and has integrated with other patient safety, quality, and clinical programs. Multiple platforms for reporting and managing risk are on the market. These systems provide tools for documenting incidents, tracking risk, reporting trends, benchmarking data points, and making industry comparisons. RMIS can greatly enhance risk management by improving performance through available and reliable systems while providing overall cost reduction by automating routine tasks. The best tools integrate patient safety, CRM and quality. It is of note that in 2013 the ICT system for CRM was successfully used in one of the Slovenian hospitals (6).

The prototype of ICT for HFMEA considered (6):

- User-friendly interface
- Easy and quick access to information through one entry point
- Use classifications and standard procedures
- Use of modern technology

- Possibility of recording deviations from the planned process
- Possibility of preventing illogical orders and procedures

The researchers use HFMEA method with an example of medication management. Standard sets of procedure were used: patient personal data; hospitalization data; diagnosis; procedures/ interventions; drug therapy; diet; vital signs; fluid balance; lab reports; x-ray; other diagnostic tests; allergies; infections; activities/physiotherapy; nursing care; consultant reviews; and general observations. They have also conducted the impact of corrective actions on critical factors. For example, the computerized drug medication dose calculation method corresponded to a 67 percent reduction of the identified causes of errors (human attention, knowledge and experiences, critical thinking). Corrective actions to reduce risk factors were part of humans' understanding and integrating data and consultation with colleagues. On the segment of ICT it was a computerized calculation of the medication dose. Risk assessment before corrective action on the HFMEA hazard matrix was 12 and after correction 4. Thus the impact on reducing errors with human and ICT correction was 67% (6).

4.10. CRM tools for healthcare organisatons/providers of healthcare

Proactive analyses require the use of models and tools to guide the analyses. A model gives a basic concept underlying a system and should be used to understand the context, purpose and goal(s) of proactive analysis. There are many different approaches to implementing risk management in healthcare. Accredited by international accreditation standards and/or certified by ISO 9001 or ISO 15422 healthcare facilities in Slovenia use the risk management standard and healthcare facilities are free to choose the methodology, but the methodology must be consistent. However, there is not enough emphasis on CRM, as has been shown in accreditation surveys.

A very suitable tool for CRM is Healthcare Failure Mode and Effect Analysis (Appendix B), one of the most widely adopted techniques for conducting a proactive risk assessment. HFMEA also replaces the risk priority number (RPN) calculation with a **hazard score** read directly from the Hazard risk matrix. In addition, HFMEA provides severity and probability ratings, hazard matrix, decision tree and action types. The findings of each HFMEA are to be incorporated into the existing risk registry of a healthcare organisation.

The essential tools for HFME are process flow charts, brainstorming, cause and effect diagrams, a severity rating, probability rating, the occurrence of frequency, qualitative risk matrix, hazard scoring matrix, decision tree, clinical risk hierarchy, the effectiveness of measures to reduce the severity, evaluation of the new process, and sustainability. A practical guide for HFMEA is described in Appendices B, B1 and B2.

4.11. Monitoring and review

MoH is responsible for monitoring and control of CRM systems in the country. For healthcare organisations/providers of healthcare, it is the responsibility of the health service providers' executive team (QoC, PS and CRM committee) to monitor and evaluate all aspects of the organizations' CRM framework including, accountability arrangements, development,

implementation and organization of CRM policies and processes, training and professional development for staff, clinical and organizations' outcomes and internal audit findings.

Health service providers should develop and apply mechanisms to evaluate the outcomes and impact of risk management systems at all levels of the organization. The organization should develop and implement **performance indicators** to demonstrate the effectiveness of the organization's risk management system (18, 19). A Proposal for monitoring and review of CRM is provided in Appendix C.

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6. APPENDICES

6.1. Appendix A - Workshop on 16th September 2021

Answers of 4 members of the OWG

Questions	Yes	No	Don't know
1. Are you certified by ISO 9001:2015?	4		
2. Are you accredited by international?	4		
3. Is there a commission for risk management?	1	3	
4. Do the members of the commission certified as competent for RM	1	3	
5. Is there a risk manager in your facility?	1	3	
6. Are you using ISO 31000 for RM?	1	3	
7. Are responsibilities for CRM in place?	1	3	1
8. Do you use the HFMEA tool for CRM?	2	1	1
9. Do you have a risk register in your facility?	4		
10. Is the staff informed about the values, vision, and mission of CRM?	2		2
11. Is there a policy, strategy, and action plan for CRM?	2	2	
12. Is Governing council in your facility informed about the number of conducted HFMEA and actions for the improvement at least quarterly per year?	2*	1	1
13. Is there regular training for CRM in your facility?	2	2	
14. Is there a process for communication of results of HFMEA	2	2	
15. Is there a budget in place for delivering CRM		4	

Table 1. Answers of 4 members of OWG

*Once a year

Note: These are subjective opinions. therefore, it should be taken cum grano salis as all the relevant required documents were not delivered.

6.2. Appendix B - Healthcare Failure Mode and Effect Analysis (HFMEA)

a) Introduction

Historically avoidable adverse events prevention has not been a primary focus of medicine that was misguided reliance on “faultless” performance by healthcare professionals. Healthcare systems were not designed to prevent or absorb errors; they just reactively changed or even forget about patient safety incidents and were not typically proactive.

b) What is Failure Mode and Effect Analysis?

Failure mode and effect analysis (FMEA) is a team-based systematic and proactive approach for identifying how a process can fail, why it might fail, the effects of that failure, and how it can be made safer. The goal is to eliminate or minimize the potential for failures, stop failures before harm reaches the patient, or minimize the failure's consequences (1).

Failure: when a system or part of it performs in a way that is not intended or desirable.

Mode: how something, such as a failure, can happen or what could go wrong?

Effect: the results or consequences of failure mode

Analysis: the detailed examination of the elements or structure of a process

Healthcare failure mode and effect analysis: is a prospective assessment that identifies and improves steps in a process, thereby reasonably ensuring a safe and clinically desirable outcome. It is a systematic approach to identify and prevent product and process problems before they occur. HFMEA adds a decision tree to FMEA. It also replaces the calculation of the RPN with a hazard score that is read directly from the Hazard matrix (2,3).

HFMEA aims to prevent a tragedy, not simply responding to it, does not require previous patient safety incidents, and makes the system more fail-proof.

c) Why use HFMEA?

The fundamental reason healthcare organizations should conduct HFMEA is that it has been proven to reduce the risk of error and increase the successful performance of a process.

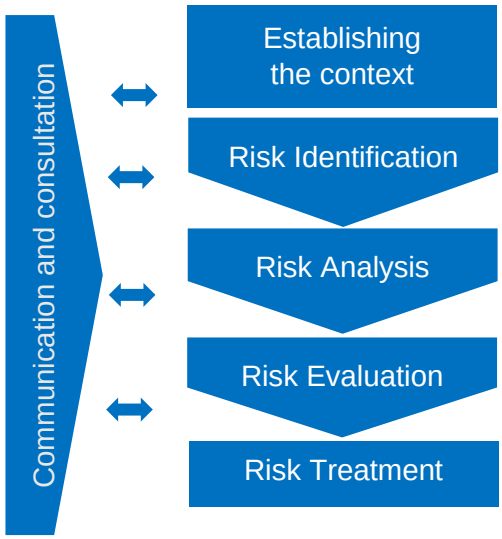
HFMEA follows a generic risk management process (4), (figure 1).

Risk Identification	What could prevent us from achieving our objectives?
Risk Analysis	Understanding the sources and causes of the identified risks; studying probabilities and consequences given the existing controls, to identify the level of residual risk.
Risk Evaluation	Comparing risk analysis results with risk criteria to determine whether the residual risk is tolerable.
Risk Treatment	Changing the magnitude and likelihood of consequences, both positive and negative, to achieve a net increase in benefit.

Figure 1. Generic RM process

Source: adapted from ISO 31000

Communication and consultation are important at the start of the HFMEA and later on for the risk treatment options (figure 2).



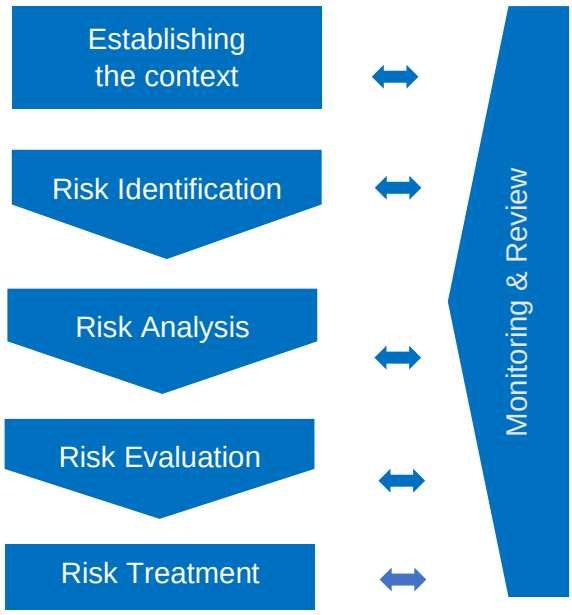
Communication and consultation
Early on: helps understand stakeholders' interests and concerns, to check that the risk management process is focusing on the right elements.

Later on: helps explain the rationale for decisions and for particular risk treatment.

Figure 2. Communication of risks

Source: adapted from ISO 3100

Monitoring and review help to assure and improve the quality and effectiveness of process design, implementation and outcomes. Ongoing monitoring and periodic review of the risk management process and its outcomes should be a planned part of the risk management process, with responsibilities clearly defined (figure 3).



Measure risk management performance against indicators, which are periodically reviewed for appropriateness

Check for deviations from the risk management plan.

Check whether the risk management framework, policy and plan are still appropriate, given organizations' external and internal context.

Report on risk, progress with the risk management plan and how well the risk management policy is being followed.
Review the effectiveness of the risk management framework.

Figure 3. Monitoring and review

Source: adapted from ISO 31000

d) 4 Practical steps in HFMEA

There are 5 major steps in HFMEA (see figure 4):

Figure 4. Steps in HFMEA

Source: adapted from VHA National Center for Patient Safety

1. Define the topic

Context helps to define the necessities for and limitations on effective risk management within the organisation. The core obligation for all health service providers is to deliver safe and effective patient care. The risk management program should be relevant to the clinical services provided to ensure safe, quality care and services. For example, the risks associated with obstetric services are different from those in elderly care services; hence risk management strategies would vary accordingly.

Define the topic of the HFMEA along with a clear definition of the process to be studied (table 1). When selecting the topic, narrow the scope of the analysis by being specific about the process or product to be studied. The team may look at systems, designs, processes, services, and software to help conceptualize a topic to analyze. In step one, the topic is chosen, the scope is defined and the topic statement is written.

For patient and staff safety and patient outcomes, the identification of clinical risk requires staff to have a thorough understanding of the components illustrated in table 2.

Risks	Examples
The main cause of the clinical risk has the potential to result in harm	Lookalike packaging of medications
The event or incident that could occur if the risk is not managed and the impact on the organisation or its internal/external stakeholders	Wrong medication is administered to a patient
The other causes(what and why) for the presence of the clinical risk or hazard of the event occurring	Lack of checking processes
Identification of the potential result or outcome of the clinical risk on the organisation or its stakeholders	A clinical incident where the patient is harmed from being too long on the waiting list
When and where the clinical risk or hazard could occur	In the operating room

Table 2. Definitions and examples of possible risks

Possible methods of choosing topics or identifying clinical risks are incident register data, complaint data, accreditation standards, ISO 9001 survey, internal and external peer reviews, process maps and critical control points, internal and national clinical audits, brainstorming, etc.

The topic should represent a high-risk and/or vulnerable area and needs to include a clear definition of the process to be studied. Topics might include problems with patient safety identified during the root cause analysis process; review and/or trending of patient safety event reports or other event reporting systems; assessment of patient complaints; concerns from staff about hazards which are likely to cause injury; evaluation of risks with new or existing products, processes, and systems that have a potential to fail, review of the national or international sentinel events list; vulnerabilities from reports of other healthcare facilities, etc.

Setting **the scope** and boundaries of an application of CRM involves:

- Defining the location, process, project or activity and establishing its goals and objectives
- Specifying the nature of the decisions that have to be made
- Defining the extent of the project activity or function in terms of time and location
- Identifying any scoping or framing studies needed and their scope, objectives, and the resources required
- Defining the depth and breadth of the CRM activities to be carried out, including specific inclusions and exclusions

After the topic is identified, consider further investigation to find out appropriate if the appropriate **scope** has been identified. The team should define clear boundaries for the process to be examined. The complexity of the process and the availability of the team members should be considered. For example, if the process is facility-wide, the team may choose to focus on high-priority or high-risk areas.

After identifying a potential scope, the patient safety officer or clinical risk manager can gather facts, data, and material about the scope to include consideration of events that have occurred at

other facilities. **The topic statement** should include a description of the topic being analyzed and the scope of what will be covered. Consider the following guidelines when drafting a topic statement:

The topic statement should:

- Describe what process is being analyzed
- Define the boundaries or scope of what will be analyzed
- Be clear, definitive, concise, and leave no room for misinterpretation
- Be brief, consisting of one or two sentences

Example: “Handover of mental health patients from emergency to arrival on acute care”.

CRM is guided by the creation of a framework that defines the CRM process and ensures the feedback on the performance of the process is used for monitoring and reviews.

2. Assemble a team

The team should be multidisciplinary and the number of people on a team depends on the scope of the process being reviewed (5). There should be at least one representative from each employee group involved in the process. There are many tasks for the team ahead and each of the team has special responsibilities.

Advisor. Typically, the organisation patient safety officer or clinical risk manager serves as the team’s advisor. The primary responsibilities of the advisor are to define the project topic and scope, assemble the project team, orient team members to the process, and provide consultation to the team throughout the process. The advisor should provide the team with a clear vision of the task. The advisor initiates the process and works with hospital leadership to gain support and escalate issues as necessary. Understanding the HFMEA requirements is an important characteristic of an effective advisor.

Specific responsibilities of the advisor include:

- Identifying the high-vulnerability topic/process (in consultation with top management of healthcare organisation)
- Obtaining leadership support to ensure the topic aligns with leadership goals
- Assembling a multi-disciplinary team with subject matter experts (and individuals who are unfamiliar with the process)
- Completing the charter memo and obtaining the director’s agreement
- Requesting supervisor support for team member participation
- Providing orientation/overview of the HFMEA process to team members
- Supporting the team with ongoing consultation

Team Lead. The advisor appoints the team leader and ensures a clear understanding of the processes being reviewed. The team leader guides the team and serves as the project manager.

It is important that the team leader understands the HFMEA process and can facilitate the team, as needed. The team leader's responsibilities include:

- Arranging meeting times and location
- Setting and maintaining ground rules for meetings
- Keeping the team on task and within the timeline
- Using the HFMEA tools
- Facilitating the use of materials (e.g. flipcharts and sticky notes) for flowcharts and diagrams
- Summarizing the work completed and identifying the next steps
- Writing the final HFMEA summary for leadership review
- Consulting with the advisor

Subject Matter Experts. Staff who have immediate experience with the process being analyzed or who bring additional knowledge, experience, or points of view that will benefit the team. If possible, subject matter experts should be included from multiple shifts to gain a true perspective of the topic being analyzed. The experiences of staff working during the day may be much different than what happens during the evening and night shifts (5). The staff selected to serve as the subject matter experts members should have day-to-day responsibilities for completing one or more steps in the process under analysis.

Effective subject matter experts team members:

- Have personal knowledge of what happens in the process, including differences between work as performed and as planned
- Are vital to the project's success
- Must be allowed a flexible schedule to participate fully in team meetings and work required outside of recurring team meetings

Recorder. The recorder is responsible for documentation during the working sessions, taking minutes, and distributing the information to the team. The recorder is responsible for:

- Updating flip charts, worksheets, and process flow diagrams throughout the working sessions and between meetings
- Notating the process flow diagram and documenting the hazard analysis decisions
- Recording the actions and outcome measures
- Using the HFMEA numbering scheme
- Recording any necessary information
- Assisting the team leader to stay on the timeline

HFMEA cover sheet. The cover sheet is used to record the administrative information about the HFMEA. Administrative information includes the topic statement, dates started and completed team members and designations, and other information. When completing the topic sheet, teams should include the following information:

- The final topic statement
- A list of all team members, their position titles, and contact information
- Designation of team leader and team recorder
- Self-certification that all affected areas of the process being examined are represented on the team
- Self-certification that members at various levels within the organization with different types of knowledge are included on the team
- Annotation of the official date the HFMEA was started and the date it was completed

A template for starting the HFMEA process (steps 1 and 2 is shown in Appendix B1 and step 4 and 5 in Appendix B2).

3. Draw the process, picture of the process flow

After the topic is defined the team will create a graphical representation of the process being examined. The goal of graphically describing the process being examined is to break the entire process into small pieces, arrange them in a logical order, and construct a process flow diagram that the team will use to build the analysis. The team will identify the main process steps, subprocess steps, and assemble them in sequential order. To begin the graphic description of the process, it is important to have several resources available to the team. Important resources may include individuals who are subject matter experts, relevant policies, standard operating procedures, and any resource that guides the team to help identify each step in the process being analyzed. The HFMEA process flow diagram follows the work routinely done during the process being reviewed. This is different from the retrograde analysis of patient safety incidents where a flow chart is constructed as it had happened and not as in routinely performed work. The different types of flowcharts and symbols used are described elsewhere (6,7).

Figure 5 shows the main steps of a simple generic flow chart with main processes and subprocesses.

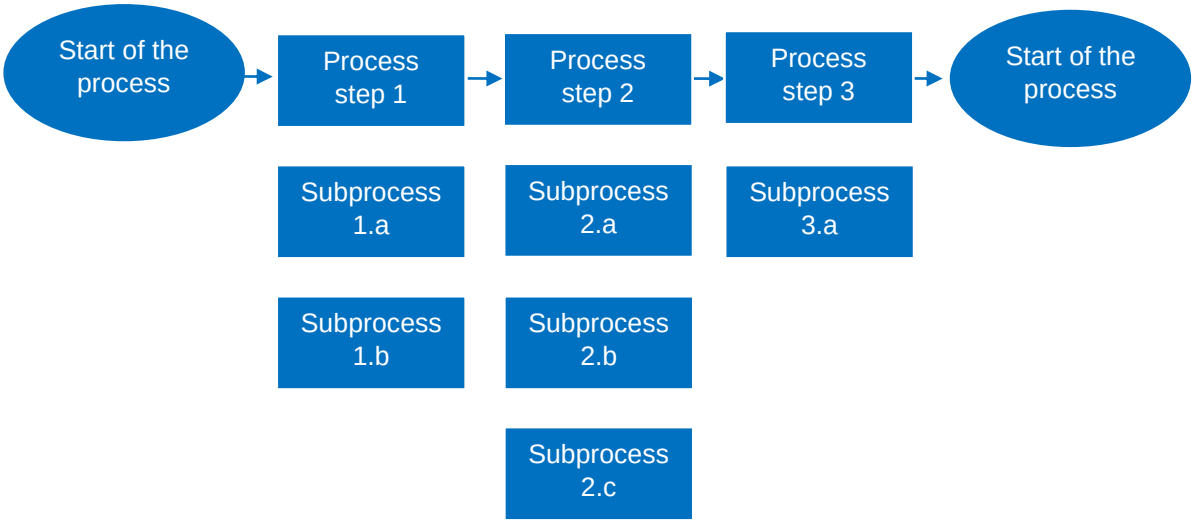


Figure 5. Flow chart diagram of a simple process with its subprocesses

Source: Prosunt ©

When the process flow diagram is completed, visit the area to observe the process and validate if the diagram is correct. If it is not, adjust it to reflect what was observed.

Drawback: Limiting the description to what happened on a specific day. Remember, the description must reflect what is routinely done.

4. Conduct hazard analysis

Hazard analysis is the process of collecting and evaluating the information on hazards associated with the selected process. The purpose of the hazard analysis is to develop a list of hazards or vulnerabilities that are of such significance that they are reasonably likely to cause injury or illness if they are not effectively controlled. Step 4 will describe the concepts of failure mode, failure mode cause, a severity rating, probability rating the hazard matrix, and the decision tree.

e) Failure Modes and Failure Mode Causes

A **failure mode** is defined as one of the various ways that a process step or subprocess step can fail to accomplish its intended purpose. For example, for the subprocess step of identifying a patient the lumbar puncture, potential failure modes would include:

1. Patients were not identified by using two identifiers
2. Patient consent form not completed
3. Pre-procedure timeout not completed

Failure modes describe what could go wrong or how the process could fail. A failure mode may be unique to a single sub-process step or it may apply to multiple subprocess steps. The risk could be different depending on which part of the process it occurs.

A **failure mode cause** is defined as the reason why a potential failure mode might occur. A single failure mode will typically have more than one potential cause. For the example in failure mode - patient not identified by using two identifiers - potential causes would include:

1. Lack of a written policy requiring the use of two identifiers for lumbar puncture
2. Lack of staff training on the use of two identifiers
3. The patient is not able to provide two identifiers

Failure mode causes describe why something might go wrong or what vulnerabilities could cause the failure mode to occur.

f) HFMEA hazard analysis sequence

The hazard analysis process helps the team determine potential failure modes and failure mode causes significant enough to develop actions and outcome measures.

Act I: *Identify and list the potential failure modes for each subprocess step within the overall process. action*

Systematically list all potential failure modes for each process step and subprocess step within the process. Starting with the first subprocess step, the team should **brainstorm** what potential failure modes would prevent each subprocess step from succeeding. As failure modes are identified, they should be numbered following the overall numbering sequence (e.g. 1a(1), 1a(2)). The team should utilize various sources and tools to help determine how each process step might fail. It is common for teams to discover one or more failure modes for each subprocess step. Failure modes may involve many aspects such as process, technology, information, human factors, product quality, or anything else that may cause a process to fail. You can use a **fishbone diagram** to help you find potential failures. The Conceptual Framework for the International Classification for patient Safety - ICPS (8) can help to classify the potential causes that are divided into 10 high-level classes:

1. Incident Type
2. Patient Outcomes
3. Patient Characteristics
4. Incident Characteristics
5. Contributing Factors/Hazards
6. Organizational Outcomes
7. Detection
8. Mitigating Factors
9. Ameliorating Actions
10. Actions Taken to Reduce Risk

Act II: *Assign a hazard score to each failure mode using the HFMEA Hazard Matrix (severity and probability).*

When the team has identified the potential failure modes for each subprocess step, the next step is to begin the analysis of each failure mode. The analysis starts by assigning a hazard score to the failure mode. The four possible severity ratings are Catastrophic (4), Major (3), Moderate (2), and Minor (1). The four probability ratings are Frequent (4), Occasional (3), Uncommon (2), and Remote (1). Definitions of each severity and probability rating are shown in Tables 3 and 4. A hazard score is assigned to each failure mode by reviewing the severity and probability definitions then selecting the appropriate severity rating and probability rating using the HFMEA Hazard Matrix, which is shown in Table 4.

Use table 3 to assign a **severity rating** when determining the hazard score of a failure mode or failure mode cause.

Use HFMEA hazard matrix to select a hazard score based on the assigned severity and probability of a failure mode or failure mode cause (table 3 and 4). The scores used here would be the best to use in Slovenia in all healthcare facilities; however, as accredited and some other facilities are already using different scores, it is no problem as long as scoring is consistent.

Table 4 HFMEA Hazard matrix (multiply severity- table 3 with probability - table 4). The risk team review events to make the decision using the hazard matrix for the decision-making process. The hazard matrix is designed as a tool, not a solution. It is only quantifying the result and organizations need to work on interpreting the decision.

Event Rating	Patient outcome	Visitor outcome	Staff outcome	Equipment/facility
4 Catastrophic	*&**Death, major permanent loss of function, suicide, rape, hemolytic transfusion reaction, surgery or procedure on the wrong patient or wrong body part	Death; or hospitalization of 3 or more visitors	A death or hospitalization of 3 or more staff	Damage equal to or more than 250.000 €. Any fire that grows larger than an incipient stage
3 Major	*Permanent lessening of bodily function, disfigurement, surgical intervention, increased length of stay or level of care for 3 or more patients	Hospitalization of 1-2 visitors	Hospitalization of 1-2 staff, 3 or more staff with lost time or restricted duty injuries/illnesses	*** Damage equal to or more than 100.000 €

Event Rating	Patient outcome	Visitor outcome	Staff outcome	Equipment/facility
2 Moderate	Increased length of stay or increased level of care for 1 or 2 patients	Evaluation and treatment for 1-2 visitors (less than hospitalization)	Medical expenses lost time or restricted duty injuries or illness for 1-2 staff	Damage between 10.000 € and 100.000 €. A fire at an incipient stage or smaller
1 Minor	No injury, nor the increased length of stay nor the increased level of care	Visitor evaluated (no treatment or treatment refused)	First aid only (no lost time, restricted duty injuries or illnesses)	***&**** Damage less than 10.000 €. Loss of utility system with no adverse outcome

Table 3. HFMEA Severity Ratings

Source: adapted from VHA National Center for Patient Safety

*Loss of function to include sensory, motor, physiologic, or intellectual function

**Also includes infant abduction or infant discharged to the wrong family

*** Fire events are not applicable for major and minor categorizations. They will be categorized as major or moderate events.

****Power, natural gas, electricity, water, communications, transport, heat/air conditioning

The following table 4 is HFMEA Probability Ratings. Use this table to assign a **probability rating** when determining the hazard score of a failure mode or failure mode cause.

HFMEA probability rating	
4 Frequent Event	Likely to occur immediately or within a short period (may happen several times in one year)
3 Occasional Event	Probably will occur (may happen several times in 1 to 2 years)
2 Uncommon Event	Possible to occur (may happen sometime in 2 to 5 years)
1 Remote Event	Unlikely to occur (may happen sometime in 5 to 30 years)

Table 4. HFMEA Probability Ratings

Source: VHA National Center for Patient Safety

HFMEA hazard matrix				
	Severity of effect			
Probability	1 Minor	2 Moderate	3 Major	4 Catastrophic
4 Frequent Event	4	8	12	16
3 Occasional Event	3	6	9	12
2 Uncommon Event	2	4	6	8
1 Remote Event	1	2	3	4

Table 5. HFMEA hazard matrix

Source: VHA National Center for Patient Safety

Act III: *Use the HFMEA Decision Tree (figure 6) to determine if each failure mode warrants further attention.*

Assigning a hazard score for each failure mode is only a part of the analysis. The next step is to triage the item using the **HFMEA decision tree**. The decision tree is an algorithm that will prioritize each respective failure mode or failure mode cause and inform the HFMEA team if further action is warranted. The decision tree is one of the key components distinguishing HFMEA from traditional FailureMode and Effect Analysis (FMEA). It provides supplementary logic and introduces three important decision points: *criticality, absence of effective control measures, and lack of detectability*. These decision points are treated as yes or no questions used to guide the team's decisions. When used correctly, the decision tree is a powerful tool to quickly identify which potential failures will be addressed. The following definitions are the basis of using the HFMEA decision tree.

Single Point Weakness (Criticality). A single point weakness measures whether the entire system will fail if an individual part or step of the process fails. If a step in the process is so critical that its failure would result in a system failure or adverse event, it is considered a single point weakness. For example, the absence of a specimen label poses a single point weakness for many processes involving laboratory specimens. There may be more than one single point weakness in a single process or there may be none.

Effective Control Measure. An effective control measure is an existing barrier that eliminates or substantially reduces the likelihood of a hazardous event from occurring. Identifying whether an effective control measure is already in place requires knowledge of the process being analyzed. Effective control measures may come in many forms, including but not limited to checklists, system

interlocks, redundancies, and mechanical or electronic forcing functions. For example, the pin standard for medical gases is an effective control measure that physically prevents medical gases from being inadvertently interconnected. Care should be taken to consider the strength of existing control measures. Weaker actions such as documentation, training, or double-checks do not constitute effective control measures (9).

Obvious Hazard (Detectability). An obvious hazard is something obvious enough that it will be discovered before the failure occurs or before the effect of the failure results in a system failure or adverse event. Obvious hazards may often incorporate visual information, warning indicators, or other mental signs that are clear and evident to the user. For example, for processes involving alarms, teams should consider whether the alarms are distinguishable in their context of use and if they provide enough information to the appropriate personnel. Alarms are not the only source of detectability. Obvious hazards may include any scenario that is highly unlikely to go unnoticed by the users prior to failure or harm.

Act IV: *Identify and list the potential failure mode causes for each failure mode that warrants further attention (based on the HFMEA Decision Tree). Assign a hazard score to each failure mode cause using the HFMEA Hazard Matrix and use the HFMEA Decision Tree to determine if each failure mode cause warrants actions and outcome measures.*

For failure modes, the decision tree determines if the team must identify potential causes of the failure or not. For failure mode causes, the decision tree will determine if the team must determine actions and outcome measures for each respective cause.

Even if the hazard score is 7 or lower, the team will still be asked to assess for **single-point weakness** (criticality). If a hazard score is 8 or higher, the hazard is deemed dangerous enough that it should be further analyzed even if it is not a single point weakness. In this case, the team will skip the single point weakness (criticality) decision point and move to review existing control measures as indicated in the decision tree diagram.

The next feature observed in the decision tree is that there are two automatic “STOP” questions.

If a failure has an effective existing control measure in place or is estimated detectible, the team

should “STOP” and focus their attention on other failures. Whenever the team chooses to “STOP,” they should document that decision in the HFMEA worksheet and briefly describe the effective control measure in the explanation.

By the end of the decision tree, the team will have systematically determined if the failure should

be addressed. After each failure mode and failure mode cause has undergone a decision tree analysis, the team will have a prepared list of failures and potential causes for which solutions will be created in HFMEA Act 5 – Actions and outcome measures.

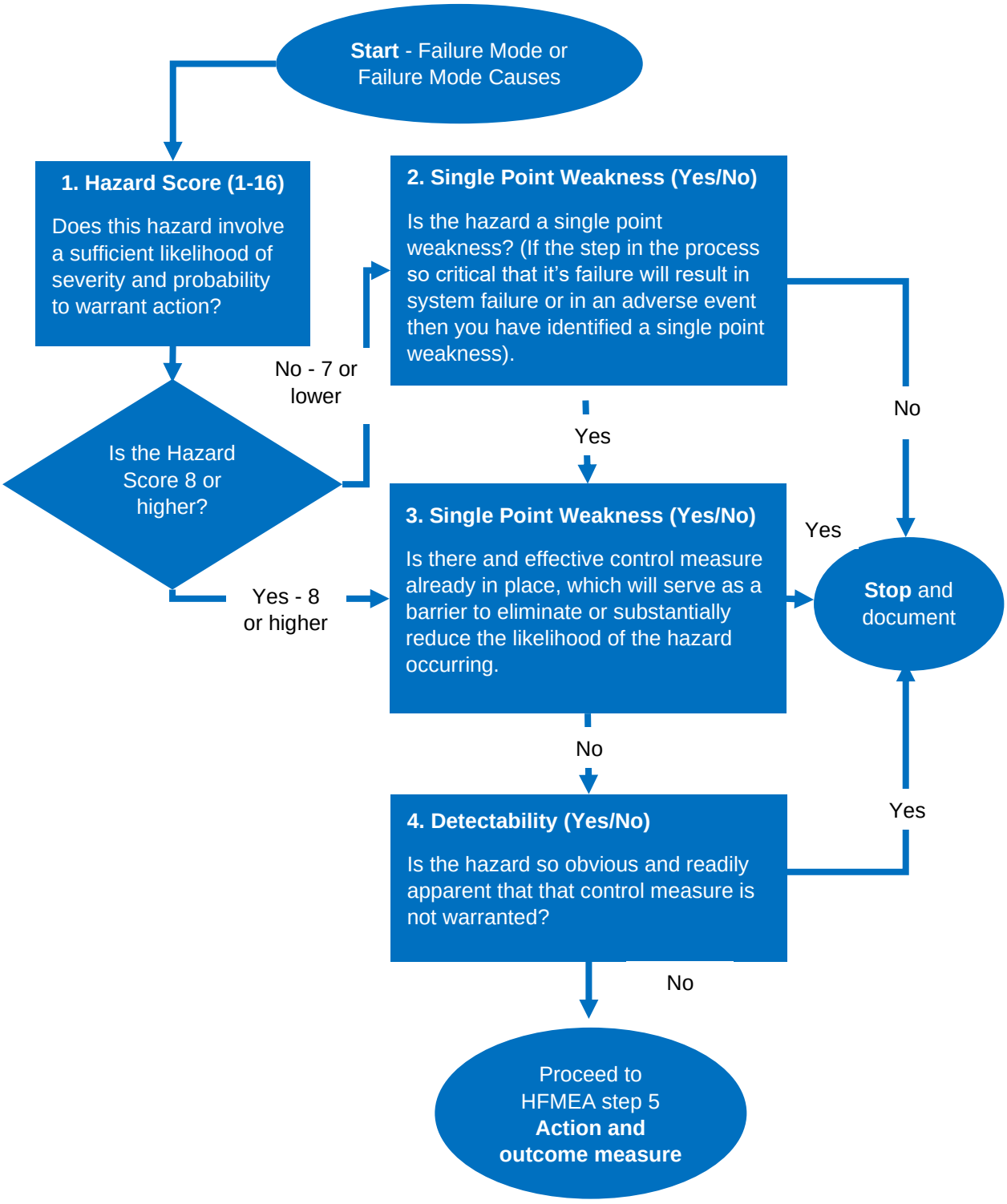


Figure 6. HFMEA Decision Tree

Source: adapted from VHA National Center for Patient Safety

***Act V**: Actions and Outcome Measures*

a) Action types

The team will decide whether to eliminate, control, or accept the failure mode causes identified.

- **Eliminate**: to prevent all future occurrences by removing the failure point
- **Control**: to minimize all future occurrences by implementing mitigating factors
- **Accept**: to acknowledge and accept known risks

The most effective option is to eliminate the failure mode cause or failure point, which may require one or more strong actions. If the failure mode cause cannot be eliminated, the best option may be to control the failure mode caused by using one or more actions. Sometimes the team may decide to accept a failure mode cause if there are no remedies available.

Teams will select an action type for each failure mode potential cause that scores to proceed (Appendices B1 and B2) and document it on the worksheet. If the team chooses to accept the failure mode cause, a brief rationale is required on the worksheet.

Reasons why a clinical risk may be deemed as acceptable include:

- The likelihood and/or consequence of the risk being so low that specific treatment is inappropriate given the available resources
- There is no treatment available for the risk
- The opportunities presented outweigh the threats to such a degree that the risk is justified

For example, surgical interventions will always be associated with high risks so it is important to ensure that all controls (e.g. surgical checklists) are in place and operating to prevent or mitigate causes and effects of all known risks.

Teams will develop specific actions and outcome measures to minimize or prevent the identified.

causes from happening. The team will ensure the actions are **directly linked to the failure mode causes** and the outcome measures are linked to the actions.

b) Pilot Testing

Consider starting the pilot on the unit with the most willing volunteers who may be able to identify the gaps in the process. Ask staff and patients what worked well and what could be done to improve the new process. Build time for pilot testing into the overall action plan and the outcome measures time frame.

c) Action Strength

Understanding action strength is important to ensure the desired outcome. The team should strive to develop at least one strong or intermediate action for each failure mode cause. However, weak

actions are sometimes necessary to complete the steps in the process. Weak actions can be used as a complement to intermediate and strong actions.

The strength of actions and examples has been described in the manual " Errors in health care – Systematic analysis of errors root causes and their prevention (9) and are for the sake of completeness describe below.

Stronger actions aim to permanently remove an identified vulnerability by reducing reliance on human memory, and emphasizing permanent, physical, or architectural changes, interlocks, simplification, or standardization*. Examples:* simplify the process and remove unnecessary steps,

standardize on equipment or process, high-reliability training (simulation, competency evaluation

Intermediate actions are intended to increase detectability, prevent, or minimize the recurrence of events. *Examples:* checklists, cognitive aids, improved communication, system redundancies, or software configuration.

Weaker actions may be used to complement stronger and intermediate actions. *Examples:* double checks, warnings, and labels, memoranda, additional study.

d) Risk treatment

Risk treatment involves identifying the range of options for treating risk, assessing those options and preparing and implementing risk treatment action plans. Where risks cannot be accepted a treatment option may involve avoiding the risk, improving the risk controls or sharing or transferring the risk. Each treatment option should be evaluated for effectiveness. A combination of options may be considered.

When preparing treatment action plans, staff should document how the chosen treatment option will be implemented. Each clinical risk analysis and clinical risk treatment action plan should ideally outline individual responsibilities, schedules, the expected outcome of the clinical risk treatment process, budgeting and performance measures and a mechanism for monitoring and reviewing the outcome of the treatment process.

e) Avoiding the activity/event associated with the unacceptable risk

A health service provider may avoid the clinical risk by deciding either not to proceed with an activity that contains unacceptable risk, choosing an alternative activity that has less risk for the organisation, or choosing an alternative less risky methodology or process to complete the desired activity.

f) Reduce the risk by improving controls

Reducing the level of risk involves the reduction of the likelihood or consequences of risk or both. Hospitals/health services may reduce the likelihood of clinical risk through the enhancement of existing controls or additional controls. Examples of how health service providers may reduce risk include revision of documented policies and procedures, quality assurance, training, supervision, and environmental monitoring.

g) Transferring the clinical risk

Transferring the clinical risk may involve sharing the risk with another party. As a general principle, risks can be transferred by contract, legislation or administrative processes to another party. For a clinical risk, this could take the form of transferring the activity completely to another hospital or provider.

h) Retaining the clinical risk

Retention of the clinical activity with a high risk within the organisation may take place in circumstances where it is either impossible or too costly to avoid, reduce or transfer the risk to another organisation. Where clinical risks which would normally be considered unacceptable are retained, the decision and rationale should be carefully documented. Retained clinical risks should be listed on a centralised clinical risk register, monitored, and contingency plans developed.

i) Outcome Measures – Outcome indicators

Once the action has been identified for implementation, it is important to measure whether it was effective and if any unintended consequences occurred. Outcome measures should measure if the action was effective. Each of the treatment options should be evaluated based on the extent of clinical risk reduction, and the benefits or opportunities created.

The outcome measure should be quantifiable. Outcome measures show the effectiveness of the action not completion of the action. For example, if a new fall assessment tool is implemented, the outcome should measure fall rates and not the percentage of staff trained to use the assessment tool. The sampling strategy should be specific and include a time frame for the measurement. *For example,* a random sample of 15 charts per quarter will be reviewed for four consecutive quarters. The performance threshold identified should be reasonable and attainable.

The following question can be determined if actions were successful:

- How would you know if an action made a difference or not?
- How would you measure it?

Always consider the measures which are already in place for outcome measurement. This will help to maximize existing opportunities instead of creating new or duplicate work. *For example:* if a leadership team already conducts walking rounds consider adding observation related to the outcome measure developed by the team (6). If medical records of interest are already being audited or reviewed, ask if additional questions related to the outcome measure can be added.

REFERENCES - Appendix B

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6.2.1. Appendix B1 - Process of HFMEA

This template can be adjusted to the needs of your healthcare organisation.

Process steps 1 and 2:

Step 1. Select the process you want to examine. Define the scope (be specific and include a clear definition of the process, product, system, or equipment to be studied). Narrowing the scope or focus is important because of human factors that could contribute to the process or system vulnerabilities.

HFMEA Focus

Click or tap here to enter text.

Step 2. Assemble the Team

Name of the HFMEA project: Click or tap here to enter text.

Number:Click or tap here to enter text.

Date Started:Click or tap here to enter text.

Date Completed:Click or tap here to enter text.

Team Members - The multidisciplinary team should include members from each service involved in the process and at least one or more unfamiliar with the process.

List of team members:

1. Click or tap here to enter text.
2. Click or tap here to enter text.
3. Click or tap here to enter text.
4. Click or tap here to enter text.
5. Click or tap here to enter text.
6. Click or tap here to enter text.

Team Leader: Click or tap here to enter text.

Are all affected areas represented? YES ☐ NO ☐

Are different levels and types of knowledge represented on the team? YES ☐ NO ☐

Who will take minutes and maintain records:Click or tap here to enter text.

6.2.2. Appendix B2 - An example of HFMEA process (step 4 and 5)

Step 4 – hazard analysis										Step 5 – Actions and outcomes				
#	Description of the risk	#	Potential causes	Scoring Table 2, 3,4			Decision tree analysis				Action type Control Accept Eliminate	Action or reason for stopping	Outcome measure	Person responsible	Management agreement
				Severity	Probability	Hazard score	Single point weakness?	Existing control measures?	Dectebility	Proceed?					
1a		1a													
1b															

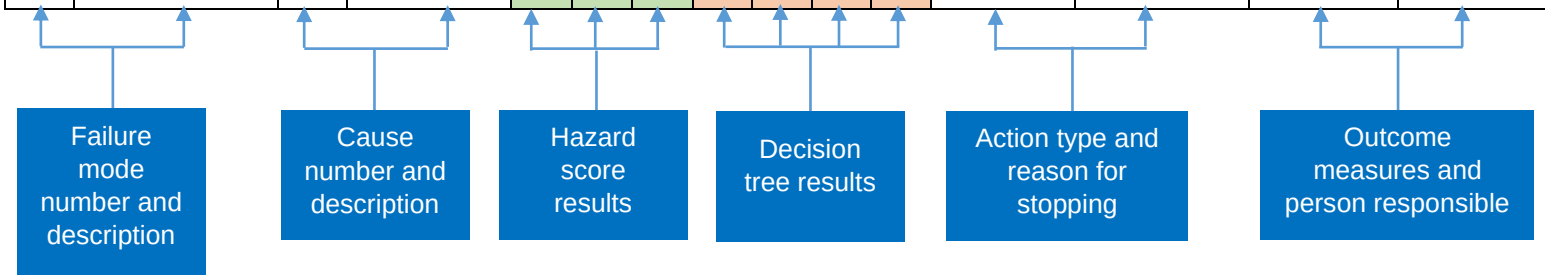

Table 6. An example of HFMEA process

6.3. Appendix C - Proposal for monitoring and review of CRM

Element	When	Completed	Approved
CRM infrastructure	Annually or when changes occur	Medical director and director of nursing	Director
Budget for CRM	Annually	Director	Governing Council
CRM policy, strategy and action plan	Annually	Quality/risk committee	Governing Council
Risk register	Biannually	Internal audit commission	Director Medical director and director of nursing
Responsibilities for CRM	Biannually	Internal audit commission	Internal audit commission
Education for CRM	Annually	Quality risk committee or external educators	Director

Table 7. Proposal for monitoring and review of CRM

6.4. Appendix D – Proposals for organisational structure and process

6.4.1. Appendix D1 - Proposal for organisational structure and process for CRM for the larger public or private healthcare organisation

Appendix D1 shows the structure and process of CRM for secondary and tertiary levels of healthcare and for primary healthcare that is organized at the level of the larger town's municipality, like healthcare center Ljubljana, or regional primary healthcare, like primary healthcare for Gorenjska. Top management and governing council are responsible for policy, strategy and action plan that is built with all relevant stakeholders. Quality, PS and CRM commission implement the strategy and action plan and the Audit /utilization commission controls it. Clinical and other units executed daily activities link to programs, projects and research. The main actions are shown at the bottom of the figure and are not exhaustive.

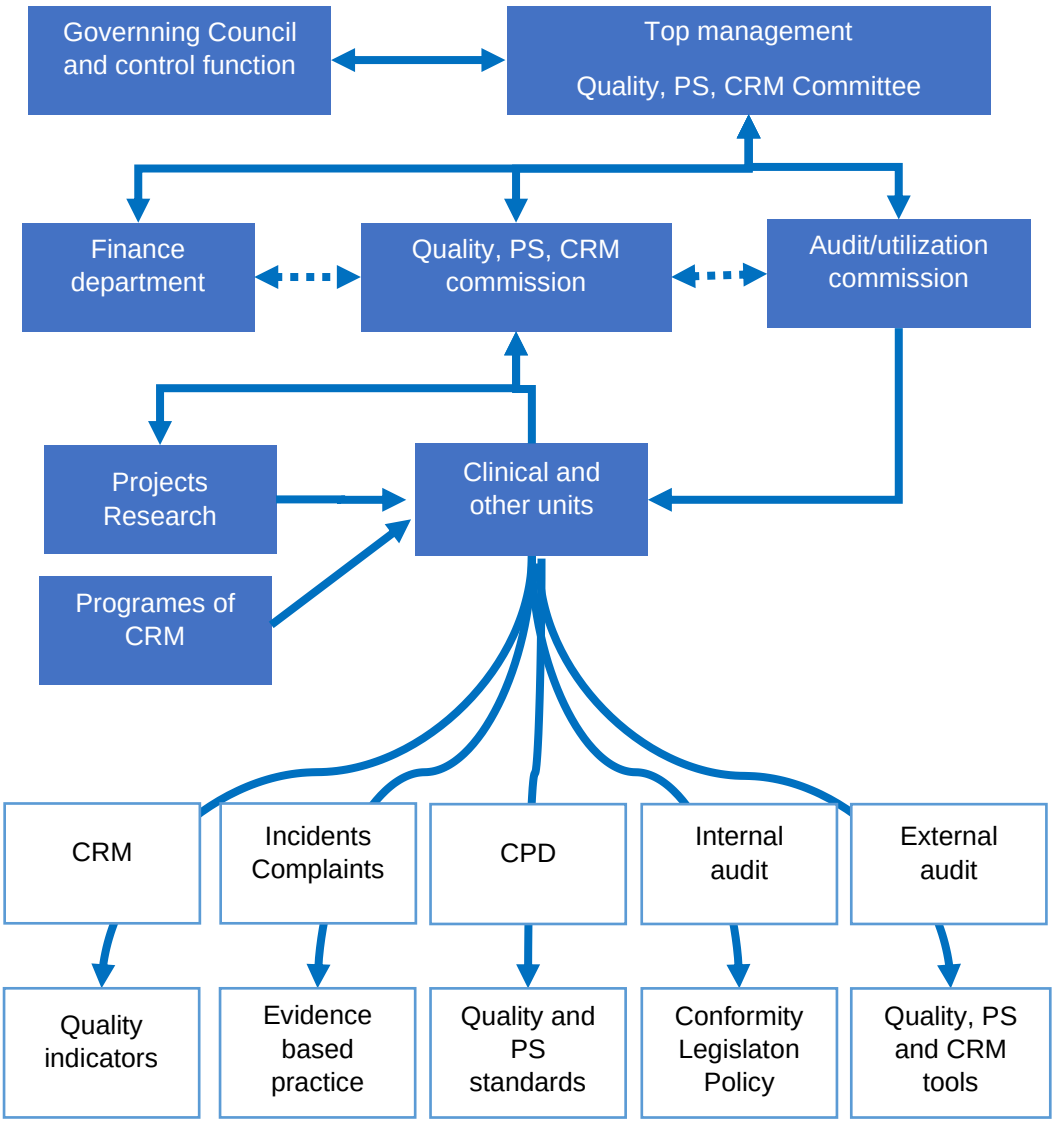

Figure 7. Proposal of organisational structure and process (I)

6.4.2. Appendix D2 - Proposal for organisational structure and process for CRM for smaller municipality healthcare center, practices with concessions at primary or outpatient specialties, public or private

Top management and governing and control function is responsible for policy, strategy and action plan that is built with all relevant stakeholders. Quality, PS and CRM commission implement the strategy and action plan and the Audit /utilization commission controls it. Clinical and other units executed daily activities link to programs, projects and research. The main actions are shown at the bottom of the figure and are not exhaustive.

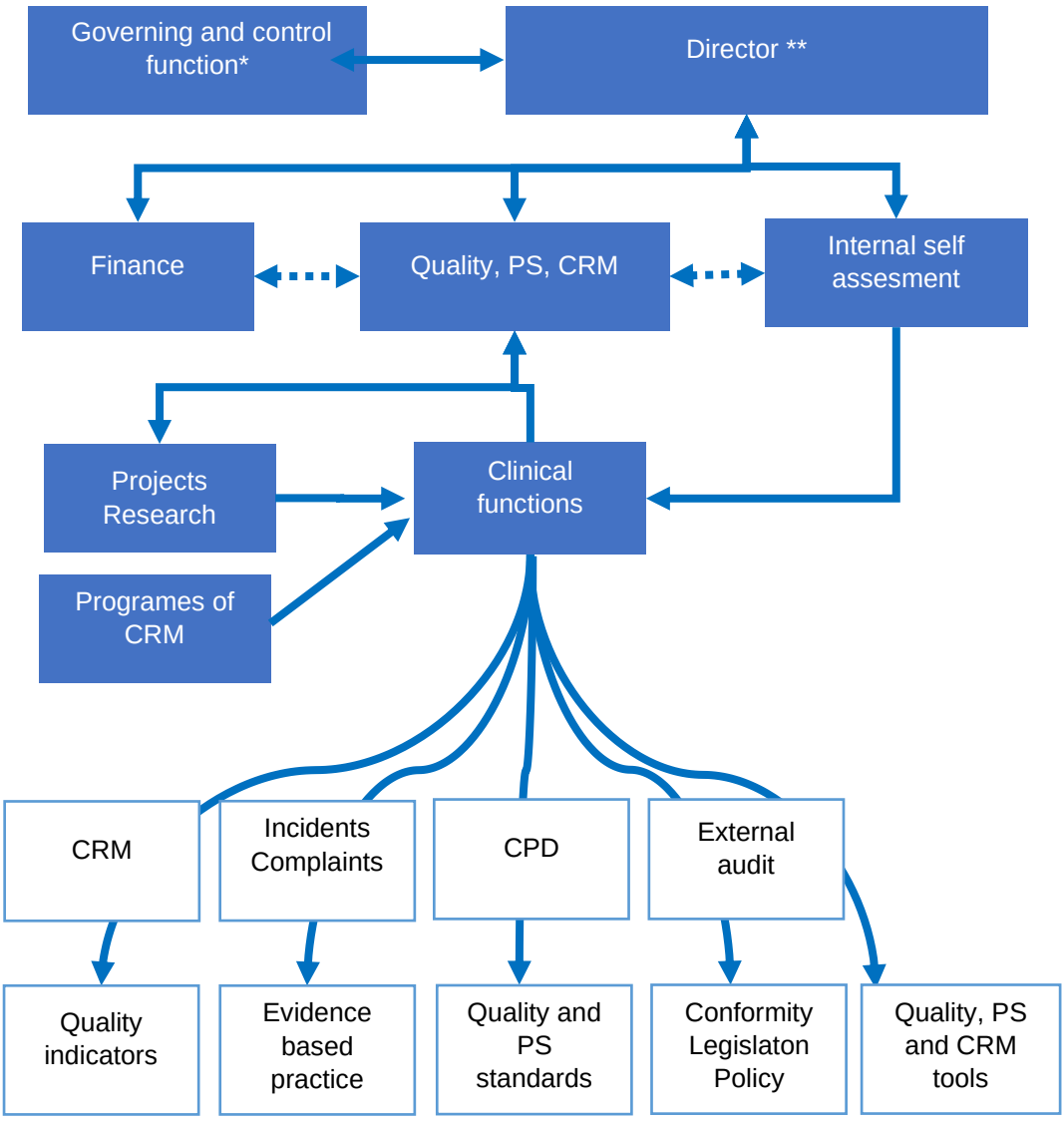

Figure 8. Proposal of organisational structure and process (II)

***** Governing and control function is the responsibility of the municipality council or MoH

** Director or another accountable leader

6.5. Appendix E - Study of foreign countries

Clinical Risk Management in 5 the studied countries

In terms of CRM, the five studied cases follow the ISO 31000 Risk Management Standards, which clearly define the CRM process.

Concerning risk mitigation, the studied cases are less specific in terms of the procedures applied to compensate for risks. Only Ireland provides information about the general framework for risk

mitigation. In Ireland, there is a National Risk Assessment which acts as a guide for risk. The Lead Government Department decides about prioritizing and resourcing appropriate mitigation measures and monitors and reports internally the progress on mitigation. They establish a five-stage procedure for risk assessment.

a) Tuscany (Italy)

The **CRM and PS Centre** is a clinical governance structure instituted in 2003 by the Tuscany regional council. Tuscany region invested one million euros to organize a center for CRM in this Italian region of 3.7 million inhabitants and 33 acute care hospitals.

Structure

Each of the *collaborators* of the CRM center has solid training in human factor/ergonomics and risk management. A *scientific committee* consisting of the best medical specialists and nurses had the function of supporting the CRM center clinically related aspects which would be encountered during significant events audit, mortality and morbidity meetings, and the promotion of safety practices. A *network of professionals* was designated by the general managers of each hospital for *CRM and PS* by differentiating these two functions after they had been trained.

The *clinical risk manager* is a professional who works on the clinical side and is entrusted with risk management in a department of a healthcare organisation , while the PS manager is a doctor, nurse, or non-healthcare professional who operates among the health management staff (7).

The law introduced in 2017 has protected reporting and learning systems from legal action since documents produced within these systems cannot be used for judicial purposes (8).

Clinical risk control consists on the implementation of prevention procedures and strategies that lead to the creation of a specific clinical risk prevention/mitigation.

CRM system in Tuscany follows the general requirements of risk management: **Identification of clinical risks**: done by using different sources such as public data, as the patients' claims and complaints, and the invisible data concerning near misses and accidents without damages for the patients and follows.

1. **Analysis of clinical risks and safety management:** methods used are CRM clinical audit as well as mortality and morbidity review. At the end of the analysis, an alert report is issued. It contains the analysis of the event and the related action plan for safety improvement. The alert report is then highlighted on the intranet and specifically sent to all those units that may draw advice. It is also sent to the CRM centre and added to the regional database.
2. **Promoting campaigns:** the campaigns focus on well-known risks for PS. Evidence shows that many incidents occur because of the same latent failures and that there are effective solutions for some kinds of adverse events. We only need to benchmark the solutions and push the system in the proper direction.

The training program is based on human factors/ergonomics for clinical risk managers, the CRM team, facilitators and healthcare workers have been designed to prepare the human resources for this effort.

b) Ireland

Clinical risk assessment and mitigation is a Framework for Major Emergency Management chaired by the National Steering Group. This Framework adopts an all-hazards approach to emergency management.

The process of CRM follows ISO 31000 standard. The principles regarding CRM are:

- Create value
- An integral part of organizational processes
- Part of decision making
- Explicitly addresses uncertainty
- Systematic, structured and timely
- Based on the best available information
- Tailored
- Takes human and cultural factors into account
- Transparent and inclusive
- Dynamic, iterative and responsive to change
- Facilitates continual improvement and enhancement of the organization

c) Catalonia (Spain)

The ISO 31000 Risk Management Standard helps manage risk through a Risk Management Plan.

The difference from other studied countries is that incidents and risks are classified according to gravity, probability, and type of clinical risk.

Low clinical risk: verification of possible presentation trends in the affected area/service; **moderate clinical risk:** assessment and monitoring of possible presentation trends in the affected area/service; **high clinical risk:** detailed analysis and adoption of measures to be disseminated in the affected area/service; **extreme clinical risk:** detailed analysis and adoption of immediate measures to be disseminated throughout the hospital.

d) Australia

The Australian/New Zealand Standard AS/NZS ISO 31000:2018 Risk Management is in use. The risk management process outlined is intended to be an integral part of any organization's practices and apply to all contexts. All organizations should record their clinical risks and management activities in a Risk Register.

Each of the treatment options should be evaluated based on the extent of clinical risk reduction, and the benefits or opportunities created. Following an evaluation process, health services may apply the alternative treatment options either individually or in combination. Selection of the most

appropriate treatment option will require health service providers to evaluate the cost of implementing each option against the benefits that may be derived from it.

Risk evaluation and prioritization involve comparing the level of risk found during the analysis step with previously established risk criteria and developing a prioritized list of risks for further action.

A decision is made for **treatment options** and it follows ISO 31000 standard: avoiding the activity/event associated with the unacceptable risk; reducing the risk by improving controls; transferring the clinical risks; retaining the clinical risks.

The **clinical quality registries** use clinical data to identify benchmarks and variations in clinical outcomes and feedback essential risk-adjusted clinical information. The clinical outcome feedback loop consists of:

1. Data recorded by clinicians
2. Data transferred to the registry
3. Data compiled and analysed
4. Regular reports that include benchmark and outliers
5. Feedback reports to clinicians, patients, management,
6. Stakeholders, and government
7. Improvement in clinical care

e) Denmark

Risk management is a cross-organizational process and involves many stakeholders with different tasks and areas of responsibility. Planning, coordination and communication are therefore always a backdrop in the risk management process, both before and after the implementation of the main activities. CRM is followed by ISO 31000 standard.

The risk assessment is the foundation of the risk management process. The risk assessment should always be carried out based on an established method. Choice of method can depend on the size and complexity of the organization. However, an assessment must always be made of the risk of loss of confidentiality, integrity and availability. How the risk assessment is carried out in practice must be stated in a process and method description, so that the risk assessment is systematic and the results comparable. Several of the activities will advantageously be carried out simultaneously. For example, many risks can be both identified and analysed by the same people.

The main conclusion from the studied countries that could help to develop or upgrade the system of CRM in Slovenia are:

- Creation of formal structure and capababilities for managenet of clinical risks
- Using standardized process of CRM
- Integrated CRM in generic healthcare risk management

There is a PDF with the complete comparative analysis (T.3.2) of the studied foreign countries.

6.6. Appendix F - Glossary

These definitions are predominantly based on the terms and definitions from the International Risk Management Standard ISO 31000.

Term	Definition
Action risk	Action risks relate to the day-to-day delivery of activities, operational business plans and objectives. Action risks typically have a short-term focus. Whilst they may impact a number of areas of the service, this does not necessarily make them a strategic risk. Action risks may have the ability to impact strategic and other action risks
Clinical risk management	Risks associated with the delivery of care to residents, patients and other healthcare customers. Clinical risks include failure to follow the evidence-based practice, errors, hospital-acquired conditions, serious safety events, and others
Controls	A mechanism, process, procedure, or action can be verified, which seeks to reduce the likelihood and/or consequence of a risk. Controls include any process, policy, device, practice, or other actions which modify risk. They can exist or be required as additional in order to mitigate the risk further
Establishing the context	Defining the external and internal parameters to be taken into account when managing risk and setting the scope and risk criteria for the risk management policy
Hazard	A potential source of harm or adverse health effect on a person or persons
Impact	The outcome or consequence of an event affecting objectives. It can be expressed either qualitatively or quantitatively, being a loss, disadvantage or gain. There may be a range of possible outcomes associated with an even
Likelihood	The chance of something happening (also described as the probability or frequency of an event occurring)
Middle manager	A person with responsibility for directly managing individual employees or teams. In turn, they report to a higher level of management on the performance and well-being of the employees or teams they manage
Monitor	To check, supervise, observe critically or record the progress of an activity, action or system on a regular basis in order to identify change
Patient safety[3] incident	Patient safety incident to includes near-misses, adverse events, and sentinel events, usually distinguished by the severity of the consequences. We do not differentiate between the terms “accident” and “incident,” where the former is generally used in high-risk industry referring to an event that affects quite a large number of victims, while the latter usually refers to individual harm
Policy	The policy is an explicit statement of intention and becomes the agreed “course of action”

[3] In SenSy project there was a new terminus ”safety deviation” and sometimes safety inciden was used. In the Slovenian patient safety literature the safety deviation was not used. Patient safety incident is mainly used in English references and also in Slovenia (among plethora of other euphemisms) and also in translated Conceptual Framework for the international Classification for Patient Safety the terminus safety deviation was not found.

Term	Definition
Residual risk rating	The remaining level of risk after all treatment plans have been implemented
Risk[4]	Risk is the effect of uncertainty on objectives. It is measured in terms of consequences and likelihood. In the context of healthcare and its services, it is any condition or circumstance which may impact on the achievement of objectives and/or have a significant impact on the day-to-day operations. This includes failing to maximize any opportunity that would help the healthcare service meet its objectives
Risk acceptance	Informed decision to take a particular risk
Risk analysis	Understanding the sources and causes of the identified risks; studying probabilities and consequences given the existing controls, to identify the level of residual risk
Risk criteria	Specifying the acceptable amount and type of risk and defining criteria to evaluate the significance of risk and to support decision-making
Risk appetite	Risk appetite is the amount and type of risk that an organisation is willing to pursue or retain
Risk evaluation	Comparing risk analysis results with risk criteria to determine whether the residual risk is tolerable

Table 8. Glossary

[4] In previous the previous project of the European Commission -The SenSys Project: “Establishment of a Management System for Safety deviations and Risks” the term risk is mentioned as patient risk, patient safety risks and also as risks to safety. We used the term “clinical riskmanagement” to distnguish it from patient risk to the indivividual patient that is explained ba a physician in the procees of informed consent.