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GUIDELINES:

Patient safety has become a major policy for the healthcare organizations. A new perception of risks has been developed due to the adverse events in patient care, the accidents occurring in the medical field and the consequent results, the requirements of transparency towards the users, the excessive rates of insurances schemes relative to the Healthcare Organizations (HCO) and medical responsibilities and the litigation of the medical risk.

The previous accreditation survey highlighted the risk management process through various approaches divided based on vigilance themes, committees and for some services. The new iteration evokes a systematic strategy of patient safety.

The promotion of the safety of care requires a management commitment and leadership, a collaboration and cooperation of all the professionals who are well trained not only on risk management but also on the hospital and medical practice change.

This chapter is about the transparency, the reporting of adverse events and accidents, the evaluation and analysis of risks especially medical, the training, the disseminating of corrective actions, the communication and stimulation of professionals representing the principle areas of the safety of care and risk management.

Also, this chapter introduces requirements related to the leadership in the application of the risk management. It encourages the change of the organization systems and the change of attitude and culture of safety.

The priority is given to the patient safety, which includes the leadership role, the sensitization via the training and communication, the alignment of the objectives focusing on safety, the patient setting, the teamwork, the open environment which allows for example the rise and rigorous analysis of adverse events without fear of sanction or blame.

As well this processes touches, in general, on the external and internal environments, ecological, epidemic, financial, and professional risks

A specialized multidisciplinary committee and a coordinator trained in patient safety and risk management shall ensure the proper implementation of the strategic objectives of the organization. Also, they shall follow up on its implementation by service, committees, high risk areas (infections, medications, interventional sectors, emergency, radiotherapy) and risky clinical practices (prevention of the DVT, Pressure Ulcer).

The patient safety program sets up a preventive and corrective action plan in case of a crisis. It develops a system of reporting (nominative or anonymous) for professionals and

users. Also, it performs a multidisciplinary analysis of the various events, their sources, the causes, and the corrective actions. Scientific methods of analysis are recommended to be used such as FMEA (Failure Mode and Effects Analysis) and the RCA (Root Cause Analysis).

The committee shall develop a plan to:

- Eliminate all surgical error (site, person, procedure)
- Decrease the nosocomial infection rate
- Decrease the harm risks caused by falls
- Improve the circuit of medications throughout the patient care
- Reduce the risk related to the pandemic influenza and pneumococcal diseases
- Improve patient safety by encouraging the patient in participating in his/her care
- Identify Pressure Ulcers related to care

Patient safety actions are based on evidence and guided by a better understanding of the impact of practices on the results whether it consists of clinical practices (acute myocardial infraction for example), organizational practices (the reduction of bacteraemia on vascular central catheters in the resuscitation units) or practices influencing the culture of the healthcare staff (reporting of events).

The new accreditation procedure includes the improvement of the patient identification process upon hospitalization and when undergoing surgery (having the right patient, with the right side, and the right procedure).

In order to build continuity in the process, the committee should invest regularly in indicators. The indicators can be classified into measures applicable to the Hospital or by themes. For instance, some indicators can be pertaining to the culture of safety including the reporting levels, fight against infections of the surgical site. Another example can be Hemorrhages and haematomas rate in post-operation, hygiene of hands measured by the consumption of alcoholic products, medication errors rate as well as obstetric problems and patients' falls measures.

The HCO shall have a management and communication plan in case of disaster.

The committee shall schedule an annual audit for the process of patient safety and risk management. It prepares an annual report of the organization activities whereby it states the annual objectives (these should be quantified, measurable and approved by the management), evaluates the strategic progress and fulfilled actions, and summarizes the events and accidents reported by the professionals (by service, job, committee, ...). It analyses the report, presents a plan of preventive and corrective actions, monitors disaster plans, coordinates various activities, ensures proper communication and dissemination of feedbacks, as well as presenting indicators. It demonstrates and presents the audit results and the measures and sets up the new improvement axis for the coming year.

The above and below information is not intended to be all inclusive. Thus, individual hospitals and each department have the responsibility to research and source information that allows them to comply with the accreditation standards below.

PS1	The HCO identification and management of risks of:
1.1	▪ The external environment of the HCO (massif influx, victims, natural disasters, pandemics ...)
1.2	▪ The internal environment related to the safety of professionals and patients (structures, care provisions, clinical practices, internal communication...)

PS2	The HCO coordinates its preventive actions, corrective and disasters with the available processes of :
2.1	▪ External plans to manage and face natural disasters, epidemics, ecological problems
2.2	▪ Plans of action developed by the committees and internal vigilances (alert) teams already operational

PS3	A multidisciplinary committee for patient safety and risk management (however named) is operational as evidenced by the following:
3.1	▪ Regular meetings are held and clearly defined
3.2	▪ There is a list of members of the committee
3.3	▪ The term of references of the committee is available
3.4	▪ Outcomes from issues discussed at all meetings can be tracked through documentation
3.5	▪ Evidence is available that members of the committee are adequately trained with respect to the principles of patient safety and risk management
3.6	▪ Evidence is available that members of the committee know the operation of the action plan of patient safety and risk management

PS4	A trained member of the personnel for this mission is designated as the patient safety and risk management coordinator (however named) with an allocated number of working hours. These responsibilities are mentioned in the job description
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PS5	A mechanism of adverse events alert system is established and operational for:
5.1	▪ The patients
5.2	▪ The personnel
5.3	▪ The visitors/others
	▪ Policies and procedures exist for at least the following:
5.4	▪ Standardized forms for identifying, reporting, analyzing and feedback are available across the hospital
5.5	▪ All filled forms are submitted to the coordinator of the patient safety and risk management committee

5.6	• Evidences of analysis, evaluation of the event and feedback are present
5.7	• Training on the reporting system of events is included in the orientation program of all the newly recruited staff

PS6	There is evidence of accident and incident reporting and a resolution system that includes:
6.1	• Origin of the reporting
6.2	• Type of accident/incident/event
6.3	• Causes and sources of accident/incident/event
6.4	• Date and hour of accident/incident/event
6.5	• Name of the department/service where the accident/incident/event took place
6.6	• Analysis of all points mentioned above
6.7	• Action provided for accident/incident
6.8	• Evidence of planned intervention to prevent reoccurrence
6.9	• Responsible staff for the corrective actions

PS7	A policy and procedure manual exists which describes the patient safety and risk management system in the hospital
7.1	• Policies are clearly identified as per the established policy and procedure hospital framework
7.2	• Policies and procedures are presented in a hospital wide, uniform manner
7.3	• The index for the policy and procedure manual is accurate

PS8	Policies and procedures exist for at least the following:
8.1	• Procedure for preventive management for the hospital external risk
8.2	• Procedure for preventive management for the hospital internal risk
8.3	• Documented process of communication of incidents/adverse events in the hospital, its analysis, evaluation and corrective actions
8.4	• Tools of evaluation, prioritization and analysis of risks including the FMEA(Failure Mode and Effects Analysis) and the RCA(Root Cause Analysis)
8.5	• Management of disasters and communication of disasters related to a serious accidents
8.6	• Management of given indicators relative to the management of risk and patient safety
8.7	• Communication of risks and corrective actions between committees and services of the HCO
8.8	• Identification of patients by at least two methods
8.9	• Identification of right patient, right side, and right procedure in surgery
8.10	• Proofreading of the verbal orders and tests results or critical diagnosis
8.11	• The annual review of the list of drugs “look-alike, sound alike”
8.12	• The control of concentrated electrolytes solutions

PS9	The HCO coordinates its preventive actions, corrective and disasters with the available processes:
9.1	• Evidence exists that all the new members of personnel shall be trained on the risk management and patient safety system including the reporting of incidents

	and adverse events. This is done during the general orientation process and during the orientation processes specific to the department/unit or committee
9.2	• Evidence exists that all members of personnel and committees have been trained on patients safety and risk management

PS10	The HCO coordinates its preventive actions, corrective and disasters with the available mechanisms:
10.1	• Evidence of annual audit is conducted across all the hospital for risk management and patient safety
10.2	• The audit report is presented to the administration and to the committee of patient safety and risk management
10.3	• Evidence is present of an action plan for solving identified problems
10.4	• Evidence is present that the committee has communicated and distributed the reports to the concerned services

PS11	An annual plan of action across the hospital for the patient safety and risk management is established and contains sections for:
11.1	• The Management
11.2	• The Finance
11.3	• The Medical Services
11.4	• The Nursing Services
11.5	• The General Services
11.6	• It shall contain specific, measurable, attainable, realistic performance indicators with time timelines
11.7	• Evidence that the plan is continuously controlled is available

PS12	
12.1	• Each department and each committee shall evaluate on annual basis the training needs of the personnel and present a report to the training service (if available) or to the coordinator of the patient safety and risk management
12.2	• The patient safety and risk management committee has a copy of the training program of each service/department and committee