King Faisal Specialist Hospital and Research Centre (Gen. Org.)
Patient Safety and Risk Management (PS&RM) Plan

PURPOSE

The purpose of the Patient Safety and Risk Management (PS&RM) Plan is to maximize patient safety and ensure a safe, secure environment for the patients, employees and visitors at King Faisal Specialist Hospital & Research Centre (KFSH&RC) (Gen. Org.) Patient Safety and Risk Management Plan is complementary to the Quality and Safety Management Plan (QSMP) that provides an elaboration on the Patient Safety and Risk Management activities of the Hospital.

INTRODUCTION

The PS&RM Plan at KFSH&RC (Gen. Org.) is an integrated, comprehensive plan designed proactively to anticipate and therefore, prevent harm/risk to all patients, employees and visitors. It outlines all aspects of Patient Safety and Risk Management activities in coordination with KFSH&RC (Gen. Org.) different Departments.

The Patient Safety and risk management program/plan addresses patient safety issues and makes use of the information developed from the investigation of the following:

- Adverse incidents including near misses and sentinel events.
- Patient complaints, this can be accomplished by the involvement of Patient Relation through the reporting and analysis of all patients' complaints.
- Cases of premature discharges, this can be accomplished through mortality and morbidity cases reviews.
- Data and performance scorecard metrics related to clinical processes and patient safety.
- Mortality and significant morbidity cases reviews.
- Risks related to the organizational Strategic and Operational Goals.
- Compliance reports with laws and regulations and accreditation standards.
- Media and public reports about hospital performance or individual quality and safety incidents.
- Common cause analysis of serious safety events
- Trending patient safety issues
- Precursor events review

GOAL

The goal of this plan is to maximize patient, staff, and visitors' safety in order to deliver safe and effective healthcare as an element to become a High Reliability Organization (HRO).

OBJECTIVES

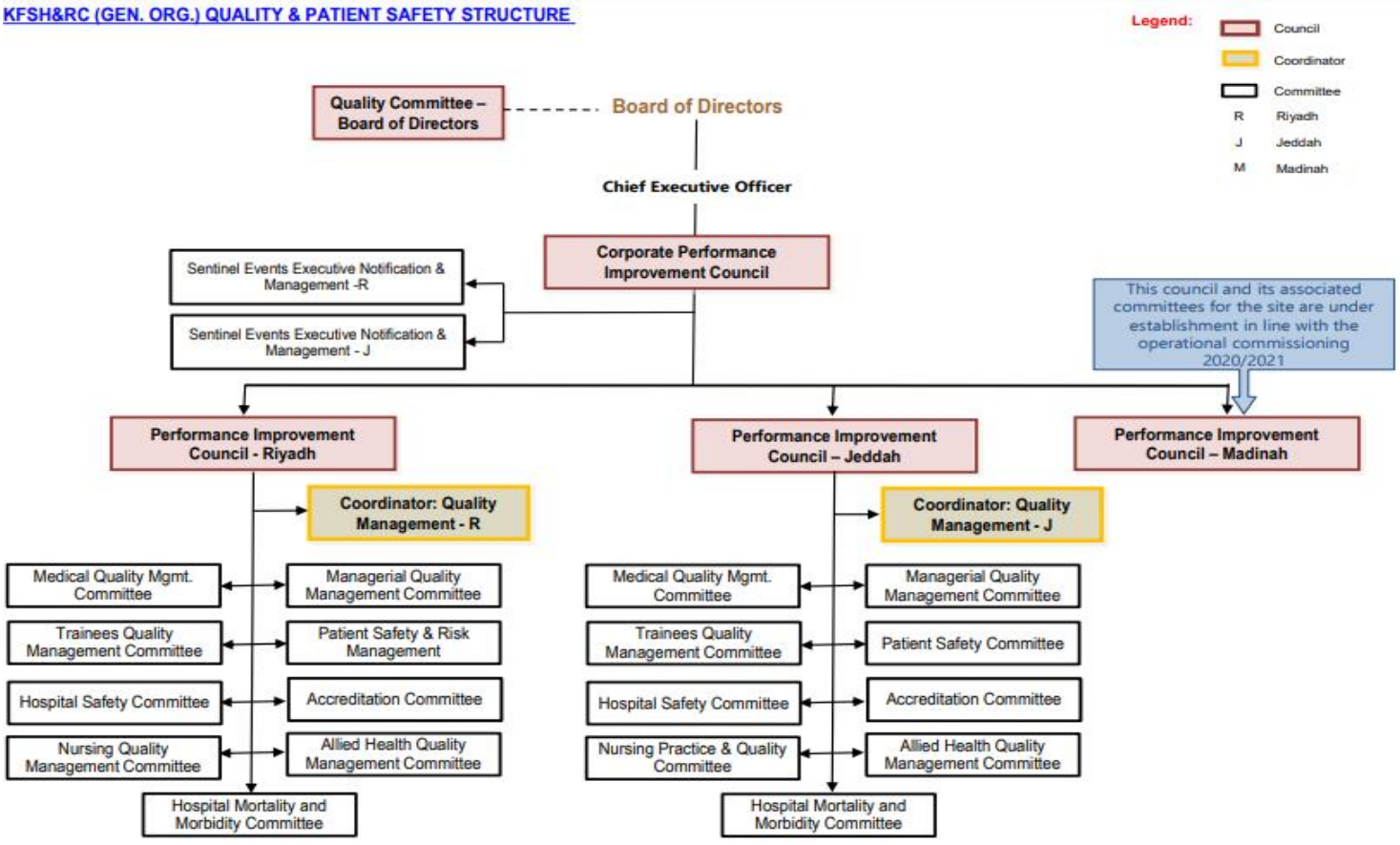
- Proactively identify risks that could cause harm to patients, staff, visitors or organization through various risk assessment tools such as FMEA, quality rounds and analysis of incidents.
- Identify and analyze potential and actual risks according to severity and likelihood of occurrence
- Design and constantly review processes and systems to minimize the risk of errors and harm.
- Facilitate Just Culture implementation to promote the culture of safety
- Foster a culture of safety among all employees through regular assessment and identification of improvement opportunities.
- Identify factors that cause or could cause harm or injury by critically analyzing reported incidents or trends and high-risk processes utilizing Apparent Cause Analysis or Root Cause Analysis to prevent recurrence.
- Evaluate and document the effectiveness of implemented patient safety and risk reduction strategies.

- Facilitate ongoing education and communication of patient safety initiatives to patients & families in addition to the importance of their role to "Speak-up" to facilitate the safe delivery of healthcare.
- Facilitate ongoing education to all KFSH&RC (Gen. Org.) staff as well as external entities staff on the principles of patient safety and risk management related activities.
- Apply national and international patient safety standards and monitor compliance with a focus on International Patient Safety Goals (IPSGs) and National Essential Safety Requirement (ESR).
- Adopt high reliability and safe practices that have been proven to improve patient safety and reduce harm to patients.
- Encourage innovation in the field of patient safety and risk management through research and publication.

RESPONSIBILITY

The Board of Directors Chairman approves the Hospital Quality and Safety Plan and oversees its implementation through the Hospital Quality and Safety structure. QMD is responsible for coordinating the implementation of the plan with each senior manager throughout the Organization. The Hospital Quality & Patient Safety structure is outlined in Figure 1:

Figure 1



CORPORATE PERFORMANCE IMPROVEMENT COUNCIL (CPIC) (CFO 1337)

The organization CEO chairs the CPIC and provides oversight for KFSH&RC (Gen.Org) Performance Improvement (PI), Patient Safety, Risk Management, Accreditation and Hospital Safety activities. The CPIC focuses on resolving the issues that require awareness, alignment or coordination across Riyadh, Jeddah and Madinah branches. The council receives an update of the corrective actions implemented to prevent recurrence of sentinel events.

PERFORMANCE IMPROVEMENT COUNCIL (PIC) (CFO-R: 755 & CFO-J: 021)

The Deputy Chief Executive Officer of Health Care delivery, or the General Manger of the site, chairs the PIC that is composed of members from the senior managers. The Council provides executive oversight and direction for performance improvement, patient safety, risk management, safety, and accreditation activities. The Director of Quality Management coordinates the PIC meetings every two (2) months. The Chairs of the following committees: Patient Safety and Risk Management; Hospital Safety; Accreditation; Hospital Mortality and Morbidity; Nursing Quality Management; Managerial Quality Management and Allied Health Quality Management attend the PIC and their updates are part of the council agenda. The PIC chairman forwards the issues raised from the quality and safety committees to the applicable senior manager or committee for review and appropriate action(s). QMD coordinates the process until actions are completed.

SENTINEL EVENT EXECUTIVE NOTIFICATION AND MANAGEMENT COMMITTEE (SEENMC) (CFO-R: 1262 & CFO-J: 096)

The Deputy Chief Executive Officer of Health Care delivery or the General Manger of the site chairs the SEENMC that is composed of members from the senior managers. SEENMC is responsible for assuring that a timely reporting and thorough investigation and intervention occurs for all potential and actual sentinel events at King Faisal Specialist Hospital and Research Centre (Gen. Org.). It ensures immediate corrections of the system to minimize any further harm and prevent a recurrence. The SEENMC expedite any immediate morbidity and mortality review whenever specialized peer review is needed, and ensure that patients/families involved in the sentinel events receive a timely, accurate and empathetic disclosure about the event. The committee also monitors executive interventions and corrective plans and submits a sentinel events report to the Corporate Performance Improvement Council.

PATIENT SAFETY AND RISK MANAGEMENT COMMITTEE (PSRMC) (CFO-R: 795&CFO-J: 020)

The Deputy Chief Executive Officer of Health Care delivery or the General Manger of the site appoints the Chairman of the PSRMC. The PSRMC chairman approves the members assigned by concerned departments. Membership is multidisciplinary with representatives from clinical and non-clinical departments and assigned by the departments' Chairmen/Director/Head. The committee provides oversight for Patient Safety and Risk Management activities. PSRMC meetings are held once per month and are coordinated by QMD. The committee main functions are:

- Monitors and analyses of aggregated and trended data as well as individual case reports related to patient safety as submitted by the Quality Management and /or other departments.
- Ensures that patient safety issues and /or initiatives are referred to the appropriate committee(s), department(s), and individual(s) for follow-up and action.
- Follows up on the implementation of the corrective action plans generated from the meeting discussions.
- Directs and oversees proactive patient safety activities.

- Review and oversees clinical risks
- Support risk management mitigation plans post failure mode and effect analysis (FMEA)
- Ensures regular assessment of the patient safety culture "at least once annually" and supports implementation of corrective actions.
- Supports development of policies and procedures related to patient safety as requested.
- Ensures that unresolved issues are referred to the PI Council for action.
- Submits quarterly reports to the PI Council.

QUALITY MANAGEMENT DEPARTMENT (QMD) – RIYADH, JEDDAH & MADINAH

- Develops, coordinates, evaluate, update and improve the PS&RM Plan regularly
- Appoints qualified individual to provide coordination and supervision of the organization-wide patient safety and risk management program
- Identifies and facilitates process for incident reporting as per policy, APP-105: Reporting and Management of Incidents
- Identifies risk for repeated harm utilizing the quality rounds, hazard analysis, daily leadership safety huddles and other risk identification tools.
- Classifies reported incidents based on the actual and potential risk utilizing the SAC matrix framework as per policy, APP-105: Reporting and Management of Incidents
- Notifies Deputy Chief Executive Officer Health Care delivery or the General Manger of the site, Executive Directors, Chiefs and Chairman of PS&RM Committee for sentinel/serious events.
- Initiate Patient Safety Alerts and coordinate other safety alert types (e.g. Medical/Device alerts requiring immediate action to prevent recurrence using the Safety Alert Module in the QIS.
- Initiates an immediate review, and conduct Root Cause Analysis on sentinel/serious events. Also, data is aggregated and analyzed for indicating trends & near miss incidents in collaboration with relevant parties. Report the findings to PS&RM Committee, as per policy, APP-105: Reporting and Management of Incidents.
- Communicates with the involved Department(s) concerning incidents and follows-up on the implementation of corrective actions and Shares sentinel or serious events in departmental meetings
- Aggregates, analyzes and reports quarterly to Executive Management, relevant departments, committees, and Performance Improvement Council (PIC) areas where risk reduction is required.
- Conducts the Patient Safety Culture Survey annually and facilitate the development and implementation of improvement strategies
- In collaboration with other quality management sections monitors the effectiveness of implemented corrective action plans, and ensure changes are sustained.
- Facilitates annual Failure Mode and Effect Analysis as per recommendation of PS&RMC.
- Facilitates education to all Hospital staff on PS and RM Plan, lessons learned from reported incidents, risk assessment, universal skills for error prevention, basic patient safety topics and risk management concepts in addition to their roles and responsibilities related to the activities of the risk management program.
- Communicate and collaborate with PS&RM related Committees including Medication Safety & Utilization Subcommittee, Cardio Pulmonary Resuscitation (CPR) Committee, Blood Transfusion Committee, Medication Process Taskforce, Laser Safety Committee and Infection Control Committee.
- Maintains appropriate documentation of the risk management and patient safety activities.

- Integrates the relevant information developed from the risk management and patient safety with the quality improvement activities and projects.

HOSPITAL MORTALITY & MORBIDITY COMMITTEE (HM&MC) (CFO-R: 177 & CFO-J: 118)

- Accepts referrals of serious events from PSRMC & SEENMC for further review.
- Oversees the review of all mortalities and identified morbidities in one of the three (3) Sub-committees or main Hospital Committee.
- Discusses selected mortalities and morbidities in detail to identify lack of care and develop recommendations to improve patient care.
- Refers identified system issues of HM&M reviews to the PS&RM Committee for further review if no recommendations have been developed in the HM&MC.
- HM&MC member participates in sentinel event and Root Cause Analysis reviews as required.

HOSPITAL SAFETY COMMITTEE (HSC) (CFO-R: 110 &CFO-J: 040)

Deputy Chief Executive Officer of Health Care delivery or the General Manger of the site appoints the Chairman of the HSC. The HSC oversees all safety activities related to the management of the environment of care contained within the seven functional areas of safety, security, fire/life safety, emergency preparedness, hazardous materials and waste, medical equipment, and utility management. Including the preparation, implementation, evaluation and revision of the Hospital emergency (disaster) management program. Meetings are held on a monthly basis and as required and coordinated by the Disaster Clinical Specialist or his designee on the site. HSC provides oversight of the Hospital Safety Management Plans. Committee Chairmen of Hazardous Materials Management and Emergency Preparedness Management report to the chairman of the HSC. Other Hospital Safety Plans will be monitored through regular reports to the HSC from concerned departments or committees.

The Hospital Safety Plans are integrated into the PS&RM plan through frequent interaction between responsible personnel and participation on appropriate oversight committees. Appropriate referral of issues takes place between the HSC and PS&RM Committee as required.

HOSPITAL STAFF

Hospital staff including trainees, part time and locum employees are expected to provide timely and accurate reporting of safety incidents and near misses through the Quality Information System (QIS). Hospital staff assigned to investigate or handle incidents are expected to provide feedback, validate the information, and assist in incident management as per the **APP-105 (REPORTING AND MANAGEMENT OF INCIDENTS)**.

Hospital staff shall also actively participate in the assessment, elimination, minimization and prevention of risks in the workplace as far as reasonably practical, and with consultation of Quality Management staff whenever required.

BUILDING CULTURE OF PATIENT SAFETY

- KFSH&RC employees' perception on patient safety culture is measured annually, data is analyzed and communicated at the unit's and the organizational level, actions are proposed by stakeholders, and changes are implemented and sustained.
- Health Care Providers (HCP) involved in reported incidents are dealt with according to the Just Culture Framework.
- Communication on reported incidents to increase awareness and understanding of the nature of adverse events at KFSH&RC is conducted periodically and as needed.
- Lessons' learned from reported incidents that resulted in system improvement are shared and communicated with all stakeholders.

RISK IDENTIFICATION AND PREVENTION

Figure 2 describes the basic risk management framework to be utilized Organization wide to evaluate risks associated with processes, systems and the work environments. It is an ongoing process that will be adopted by Hospital staff to identify risk proactively to reduce unanticipated adverse events and other potentially harmful impact of known or possible risks to patients and staff and develop risk mitigation strategies. Proactive risk – reduction exercise is conducted on one of the priority risk processes at least annually, and high risk process are redesigned based on the analysis of the test results. Risk Management Framework (Figure 2) will be considered while managing risk in the Hospital, the essential components of the risk management program include:

- Risk identification.
- Risk analysis, evaluation and prioritization
- Risk mitigation
- Risk reporting and monitoring
- Risk structure and governance

Figure 2: Risk Management Framework

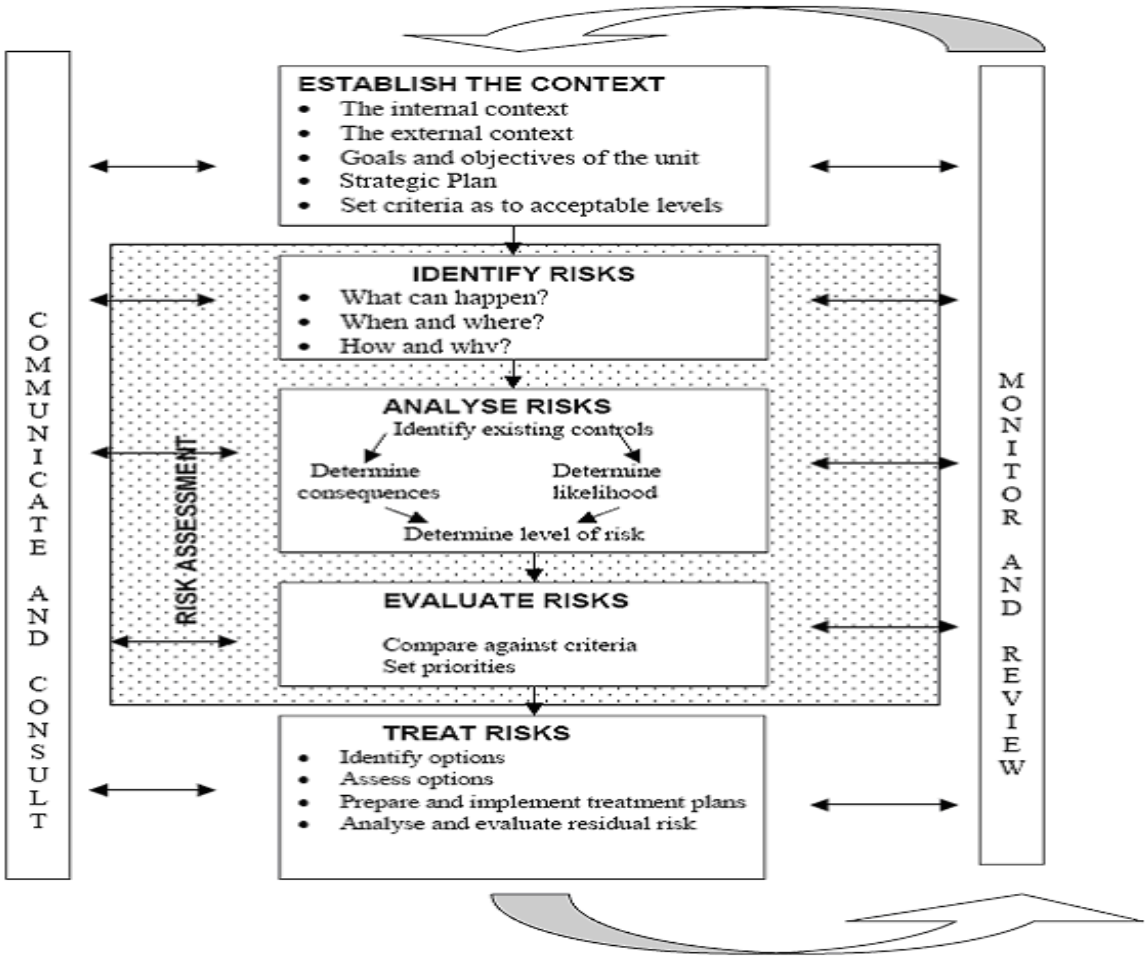


Figure 1: Risk Management Framework (from AS/NZS 4360:2004 Risk Management Standard)

INTERNATIONAL PATIENT SAFETY GOALS (IPSG's)

QMD in collaboration with relevant hospital departments will ensure the ongoing monitoring of IPSGs. The monitoring strategies will include IPSGs Scorecard indicators and incidents reports. In addition, documentation and observation reviews are conducted regularly and as deemed necessary. IPSG's reports will be presented periodically to the PSRMC. Identified issues referred to the appropriate committee(s), department(s), or individuals for improvement actions.

HEALTH CARE PROVIDERS SUPPORT

Staff involved in a serious event shall be offered appropriate support, which may involve first aid, psychological or other form of support as applicable.

DISCLOSURE OF INFORMATION AND PATIENT AND FAMILY SUPPORT:

The attending physician, in collaboration with Patient Relations and other identified Hospital staff, shall be responsible for disclosing the information about the incident to the involved patient and/or legal guardian as deemed appropriate as per policy APP-5302 (Disclosure of Medical Adverse Events)

SAFETY ALERT COMMUNICATION SYSTEM

QMD in collaboration with key stakeholders has developed a mechanism for developing, receiving, evaluating and disseminating of safety alerts throughout the Organization. Safety alerts are generated from the QIS based upon a known incident, pertaining to medical devices, medications and other items related to healthcare or patient safety which is easily recognized by all the staff. A process of acknowledging receipt of a safety alert and providing feedback on the implementation of necessary actions or recommendations by end users is part of the process as per departmental specific policies and procedure and as per policy APP-1437-06 (Handling Safety Alert Utilizing Quality Information System). In addition, Safety alerts may be received from external agencies such as the Food and Drug Administration (FDA) & Centers for Disease Control and Preventions (CDC).

DATA MANAGEMENT PROCESS

Quarterly reports will be submitted by QMD to senior managers and relevant committees to communicate related data on the following:

- Sentinel Events corrective actions.
- Near miss incidents with potential high level of harm.
- Trended reported incidents.
- Risk identification data highlighting trends.
- Action plans and areas requiring improvement.

CONFIDENTIALITY

Quality data and information are confidentially maintained in accordance with the guidelines in the Employee Relation Manual (ERM), Effective 10 Shawwal 1441 (02 June 2020). The ERM states in page #2 of "employee conduct, responsibilities, and disciplinary procedures - Chapter V-2" item 2.11: "Refrain from disclosure or dissemination of information in any manner, concerning job related matters and/or Hospital operations, without prior authorization." and APP- 42 "Confidentiality Policy", effective 24 Dhu Al Qada 1438 (16 August 2017).

Quality staff may get a photo for some evidences/ documents using their personnel devices for the purpose of incident investigation, this will be discarded right after the fact gathering. Staff are responsible that such data are not accessible and not shared with others

PATIENT SAFETY AND RISK MANAGEMENT PLAN (PS&RMP) EVALUATION AND REVISION

Quality Management Department will evaluate the PS&RMP and revise the plan annually or earlier when deemed necessary.

SEVERITY ASSESSMENT CODE (SAC)

Adapted from Department of veterans Affairs, Veterans Affairs National Center for Patient Safety, Ann Arbor, Michigan, USA

Figure 1 Consequences Table Attachment **A** page 1

		Serious	Major	Moderate	Minor	Near miss
Clinical consequences	Patient	▪ Cardiac and/or respiratory arrest/ Failure as result of occurrence ▪ Ventilation required or prolonged ▪ Patient with **Death** unrelated to the nature course of the illness and differing from the immediate expected outcome of the patient management ▪ Procedures involving the wrong patient or body part ▪ Possible suicide ▪ Retained instruments/material requiring intervention ▪ Intravascular gas embolism resulting in death or neurological damage ▪ Hemolytic blood transfusion ▪ Medication error leading to death ▪ Maternal death or serious morbidity associated with labor or delivery ▪ Infant abduction or discharge to wrong family	▪ Cardiac changes requiring intervention as a result of occurrence ▪ Hospital-acquired fractures ▪ Bleeding requiring immediate intervention ▪ Transfer to higher level of care (ICU) as result of occurrence ▪ Change of laboratory values to critical levels ▪ Surgical intervention required as a result of occurrence ▪ Increased length of stay ▪ Hospital admission is Required as result of occurrence	▪ Vital Signs changed as result of occurrence ▪ Decreased level of consciousness ▪ Additional medication/ treatment required ▪ Invasive diagnostic procedures required	▪ **No harm** to the patient or person involved ▪ Patient **requiring Increase level of care including:** ▪ Review and evaluation ▪ Additional investigations ▪ Referral to another clinician	▪ Occurrence **did not reach** the patient, ▪ May have potentially led to harm, but did not actually occur (for example wrong medication prescribed but alerted before dispensed)
Corporate Consequences	Staff	Death of staff member related to work occurrence or suicide, or hospitalization of **3** or more staff	Permanent injury to staff member, hospitalization of **2** staff, or lost time or restricted duty or illness for **2** or more staff	Medical expenses, lost time or restricted duties or injury/illness for **1** or more staff	First aid treatment only with no lost time or restricted duties	No injury or review required
	Visitors	Death of visitor or hospitalization of **3** or more visitors	Hospitalization of up to **2** visitors related to the incident/injury	Medical expenses incurred or treatment of up to **2** visitors not requiring hospitalization	Evaluation and treatment with no expenses	No treatment required or refused treatment
	Services	Complete loss of service or output	Major loss of agency/service to users	Disruption to users due to agency problems	Reduce efficiency or disruption to agency working	No loss service
	Financial	**Loss of assets** replacement value due to damage, fire etc > SR 10 Million, **loss of cash/ investments/ assets** due to fraud, overpayment or theft > SR 100,000-300,000 or **claims** > SR 500,000	**Loss of assets** replacement value due to damage, fire etc SR 1-10 Million, **loss of cash/ investments/ assets** due to fraud, overpayment or theft or **claims** SR 50,000-100,000	**Loss of assets** replacement value due to damage, fire etc SR 500,000-1 million or **loss of cash/ investments/ assets** due to fraud, overpayment or theft to SR10, 000 – 50,000	**Loss of assets** replacement value due to damage, fire etc to SR > 500,000	No financial loss
	Environmental	Toxic release off-site with detrimental effect. Fire requiring evacuation	Off-site release with no detrimental effect or fire that grows larger than an incipient stage	Off-site release contained with outside assistance of fore incipient stage or less	Off-site release contained without outside assistance	Nuisance releases

Figure 2 Likelihood Table

PROBABILITY	DEFINITION
Frequent	Is expected to occur again either immediately or within a short period of time (likely to occur most weeks or months)
Likely	Will probably occur in most circumstances (several times a year)
Possible	Possibly will recur – might occur at some time (may happen every 1 to 2 years)
Unlikely	Possibly will recur – could occur at some time in 2 to 5 years
Rare	Unlikely to recur – may occur only in exceptional circumstances (may happen every 5 to 30 years)

Figure 4 Actions Required

	ACTION REQUIRED
1	Extreme risk – immediate action required – A Root Cause Analysis (RCA) investigation must be commenced. Reportable Incident to the CED, MCO, Patient Safety/Risk Management Committee
2	High risk – senior management attention needed and / or RCA investigation is to be undertaken at the discretion of management. If RCA not undertaken, aggregate then undertake a practice improvement project
3	Medium risk – management responsibility must be specified – Aggregate data then undertake a practice improvement project. Exception – all financial losses must be reported to senior management
4	Low risk – manage by routine procedures – Aggregate data then undertake a practice improvement project
NB	The department will manage an occurrence that rates a SAC of 3 or 4.

FIGURE 3 SAC MATRIX

		CONSEQUENCE				
		Serious	Major	Moderate	Minor	Near Miss
LIKELIHOOD	Frequent	1	1	2	3	3
	Likely	1	1	2	3	4
	Possible	1	2	2	3	4
	Unlikely	1	2	3	4	4
	Rare	2	3	3	4	4

Every incident assessed against the Severity Assessment Code Matrix should be scored for both their actual and potential outcome

Synopsis of the Changes (2019)
Updated the plan with the current structure
Updated the plan with the new hospital organization structures names of departments and senior managers titles
Included the Risk Management related activities as part of the plan.
Synopsis of the Changes (2020)
Update the plan with the current structure/ titles
Remove the Quality Information System Incident handler and risk owner details and kept the APP reference
Update the Risk Management Framework

PATIENT SAFETY AND RISK MANAGEMENT PLAN APPROVAL

Reviewed by: **Date:** 7 January 2021

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Date: 7 January 2021

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Recommended by: **Date:** 20 January 2021

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Dr. Nezar Khalifah
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Date: 21 January 2021

Dr. Eyad Althenayan
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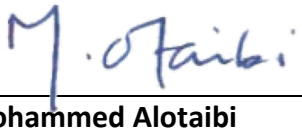
PATIENT SAFETY AND RISK MANAGEMENT PLAN APPROVAL

Recommended by:  **Date:** 24 January 2021

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Approved by:  **Date:** 24 January 2021

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