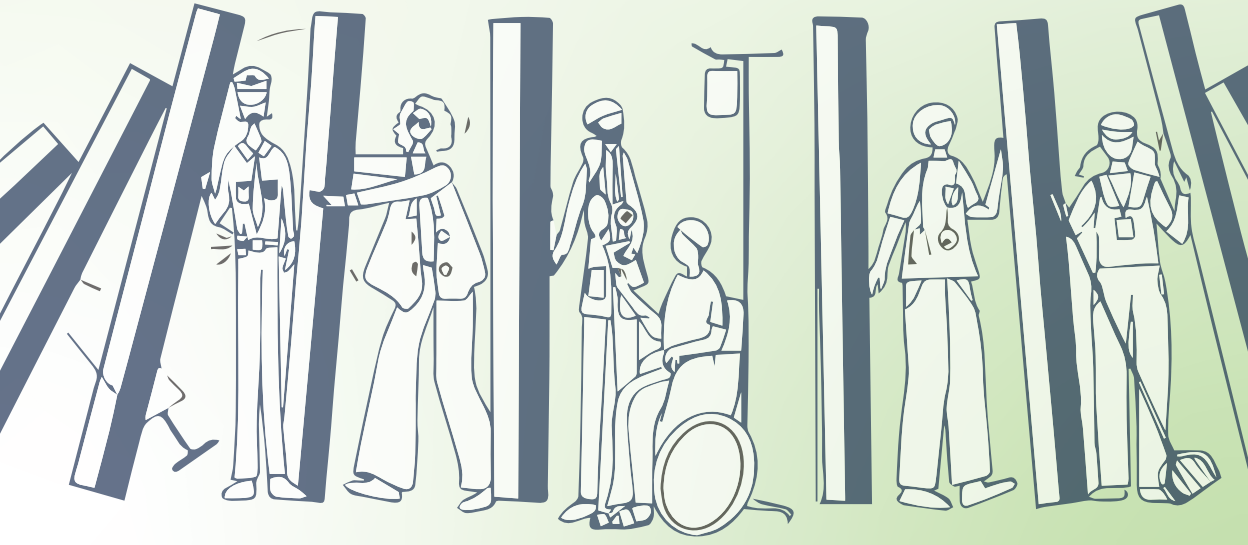
Risk Management Framework Manual for District Hospitals

2024



NATIONAL HEALTH SYSTEMS RESOURCE CENTRE

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ISBN : **978-93-82655-36-7**

Designed by : NHSRC-Publication Team

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INTRODUCTION

1.1 BACKGROUND OF RISK MANAGEMENT

Origin of Modern Risk Management in the world falls back to 1955-1964.

Healthcare setup can never eliminate risks related to patient care. With the advent of new technologies and complex treatment plans, the risks of adverse events and odds of a patient getting harmed have risen by multiple folds. Past studies on the patient safety have claimed medical errors to be "diseases of medical progress" and the price that we pay for modern diagnosis and therapy. One of the remarkable papers "Hazards of Hospitalization" by E M Schimmel says " **The classical charge to the physician has been Primum Non Nocera. Modern medicine, however, has introduced potent procedures that can not always be used harmlessly"(1).**

A revolutionary change was observed in November 1999 in the history of patient safety and risk management following the release of a report " To Err is Human: Building a Safer Health System" which claimed that preventable medical errors alone caused about 44-98,000 annual deaths in the US. It forced the Government to set a minimum goal of 50% reduction in errors over the next 5 years. ISO 9001 Quality Management System advocates mitigation of risks and implicitly addresses the preventive actions to avoid risks. JCI also has recently launched " A Guide to Risk Assessment".

In India, though activities related to Risk management have been taking place for decades, the term " Risk Management" as a separate entity has been recently coined in the healthcare setup. Until the 1970s, Risk management in a hospital setting was confined to incident reporting and was more prevalent in hospitals where the core patient care was acute or emergency care. National Quality Assurance Standards (NQAS) have dedicated standards. Risk management enforces the establishment of a framework for quality improvement.

1. Schimmel EM. The hazards of hospitalization. Ann Intern Med 1964;60:100-10

1.2 RATIONALE AND SCOPE OF RISK MANAGEMENT FRAMEWORK

National Health Policy (2017) and National Health Mission envisage the achievement of universal access to **equitable, affordable, & quality** healthcare services that are accountable and responsive to people's needs.

The launch of the NQAS along with "Operational Guidelines for Improving Quality in Public Health Facilities" strengthened the vision of NHM by facilitating it with guidelines, standards, and means to assess the quality of care delivered at public health care facilities. Subsequently, National Quality Assurance Standards and assessment guidelines are developed for DH, CHC, AAM-PHC, AAM-UPHC and AAM-SC.

As an extension to "Swachch Bharat Mission", an initiative to improve and promote cleanliness and hygiene, waste management, and infection control practices - "Kayakalp Incentive Scheme " was launched. The scheme provides incentives to exemplary performing health facilities. Subsequently, flagship programs 'LaQshya' and 'MusQan' were launched with specific focus on improving Quality of Care among mothers & newborn and children (up to 12 years of age).

Though, all of these initiatives aimed for excellence in different zones or areas of healthcare but at the core, they were all woven with a strong thread of Quality and safe services to the patients. As Patient safety is fundamental to a healthcare organization, National Patient Safety Implementation Framework and Patient Safety Standards were launched. It was soon realized that safety at any healthcare facility can not be restricted to just patient safety but extends to much beyond such as service providers, buildings, support services etc. So, the identification of risks, their assessment, evaluation, and mitigation are vital for the normal functioning of any healthcare setup, and to address each of these issues, it is essential to have a risk management framework in place.

The NQAS Framework has dedicated standards for risk management at DH and CHC under Area of Concern G 'Quality Management' that advocates the establishment of a framework of Risk Management and its execution. This manual is in congruence with Standard G8 and G9 for DH and provides a framework to meet the requirements. The manual will provide its users with tools and guidance to implement these standards,

though facilities will be required to list risks at individual departmental and facility levels. Currently, the manual is facilitating users at district hospitals but tools provided in this manual can be replicated and utilized at the other level of healthcare facilities as well. This manual also provides an organizational structure that will elaborate on the roles and responsibilities of staff for the execution of the Risk Management Framework. For a better understanding, the requirements of Standard G8 and G9 for DH are revisited in the next section.

STANDARD G8

FACILITY HAS DEFINED, APPROVED AND COMMUNICATED RISK MANAGEMENT FRAMEWORK FOR EXISTING AND POTENTIAL RISKS.

Healthcare facilities at all levels are exposed to risks from internal and external sources, which may put the attainment of quality objectives at risk. In public hospitals, these risks may be patient's safety issues, shortage of supplies, fail in the allocation of resources, man-made or natural disasters, failure to comply with statuary and legal requirements, violence towards service providers, risk of getting outdated or becoming obsolete. Hospitals are complex organizations and just reacting to the occurrence of threats may not be enough alone. There is a need to be proactively vigilant towards these risks.

This standard requires healthcare facilities to develop, implement and continuously improve a risk management framework considering both internal and external threats. The Risk Management framework should not be an isolated exercise. It should be integrated with the facility's objectives and intended quality management system (QMS).

In this direction, the initial step is to define the scope of risk management and objectives of the framework keeping in mind the context and environment. The management should prepare a comprehensive list of current and perceived risks. It is also important to define the responsibility and process of reporting and managing risks. Facilities should also have the provision for training of staff on risk management framework.

1.3 REVIEW OF RELEVANT STANDARDS OF NQAS

STANDARD G9

THE FACILITY HAS ESTABLISHED PROCEDURES FOR ASSESSING, REPORTING, EVALUATING AND MANAGING RISKS AS PER RISK MANAGEMENT PLAN.

To implement risk management framework, a facility needs to have a risk management plan. The plan will delineate responsibilities and timelines for risk management activities such as assessment and risk treatment. All staff and external stakeholders should be made aware of the plan in general and their roles and responsibilities in particular. The facility should also define the criteria for identifying the risks and finalize the assessment tools. These tools may be simple checklists, reporting formats or work instructions for identifying the risks. Few such examples are checklists for fire safety preparedness, infections control audits, electrical safety auditor, open-ended questionnaire, etc for the staff on what potential threats they feel to their security at the workplace. Once risks are analyzed they should be evaluated for their impact. Based on their impact the risk should be graded – Severe, moderate or low. Accordingly, actions are taken to eliminate the risks, if complete elimination is not possible, then there should be a plan to minimize the risk. Actions may need to be prioritized in terms of the potential impact risk may have. The facility should also establish a risk register. The register will record the identified or reported risks, their severity and actions to be taken.

The risk registers needs to be maintained and updated timely based on identified risks. The hospital administration and staff require to be trained and findings of the risk register to be disseminated to all the stakeholders for leaning and improvement.

1.4 PURPOSE AND OBJECTIVE OF THE MANUAL

Risks and uncertainties form an integral part of any hospital or healthcare setup. The provision of intricate and multifaceted care, complexities of interdepartmental processes, the requirement of optimum coordination between healthcare providers, and many more such factors expose hospitals to a great amount of vulnerability. Activities related to risk management have been in place for decades, though without a specific name "Risk Management ". The approach to risk management in healthcare setups until very recently has been a reactive one, which worked only after an event has already taken place. A reactive approach exposes the institution not just to financial liabilities but disrupts the normal functioning of the organization and lowers the reputation of a hospital. It is imperative to shift to an approach that is proactive in nature and minimizes the odds of the occurrence of any adverse events.

This manual shall act as a reference document for all district hospitals and a training resource for public health facilities. The manual will enable service providers to render quality health services in a safe environment by treating and controlling the residual risks.

Key objectives of the manual :

- To acquaint hospital management, NQAS assessors, program officers, implementors and public health professionals with key concepts of risk and risk management.
- To facilitate healthcare professionals to transit from a reactive approach in risk management to a proactive approach.
- To enable the service providers to identify and assess risks and enforce ways to mitigate them
- To encourage a culture of incident reporting across all the departments of the hospital in order to achieve maximum monitoring of adverse events.
- To accustom all the stakeholders with the framework of risk management.

1.5 HOSPITAL RISK MANAGEMENT – "A MORAL IMPERATIVE"

Millions of patients lose their lives because of unsafe environment and poor-quality healthcare services. Out of an enormous no. of reasons, the following reasons form a major chunk of the list:

MEDICATION ERRORS :

This is the leading cause of harm to patients. Medication errors are preventable in nature, yet the cost per year associated with medication errors is about 42 Billion US dollar.

HEALTHCARE ASSOCIATED INFECTIONS :

Out of every 100 hospitalized patients, 10 patients contract nosocomial infections in low and middle income countries. It just does not risk a patient's health but also puts an added burden on the hospital and its staff. This can also be prevented.

UNSAFE SURGICAL CARE PROCEDURES :

Every year, about 7 million patients suffer complications and 1 million patients die during or post surgical interventions. This makes about 25% of the patients undergoing surgical interventions. This too is largely preventable.

UNSAFE INJECTIONS PRACTICES :

DALY (Disability-adjusted life years) account for about 9.2 million years of life lost to disability because of unsafe Injection practices. This also comes under the umbrella of preventable errors.

DIAGNOSTICS ERRORS :

Most people will suffer diagnostic errors once in their lifetimes.

1.5 HOSPITAL RISK MANAGEMENT – "A MORAL IMPERATIVE"

A Harvard study published in 2013 mentions(2) –
5.2 million injuries (Not Deaths) take place in India due to medical negligence .

Another Hopkins study suggests that(3)
3rd leading cause of deaths in US is Medical Errors.

Another study mentions that Each year, (4)
134 million adverse events occur in hospitals in low and middle-income countries (LMICs), due to unsafe care, resulting in 2.6 million deaths

– And Globally, as many as
4 in 10 patients are harmed in primary and outpatient health care(4)

Up to 80% of harms are preventable. The most detrimental errors are related to diagnosis, prescription and the use of medicines, these reports suggest that patient safety comes before patient treatment as the first principle of Health care service is "First to do no harm" – "Primum non-nocere" . It is essential for all hospitals to inculcate a culture that is free of ABC – Accuse, Blame and Criticize and encourage a safety culture that emphasizes on an impartial assessment of safety levels in the hospital and blame-free reporting by establishing an open, fair and non-punitive environment .

2. Ashish Jha, BMJ Quality & Safety, Sept 2013
3. Martin A Makary,BMJ 2016 Medical error—the third leading cause of death in the US
4. WHO/details/fact sheet/ patient safety,Sept 2019

2

APPROACH TO RISK MANAGEMENT

2.1 HAZARDS & UNCERTAINITIES IN HEALTHCARE

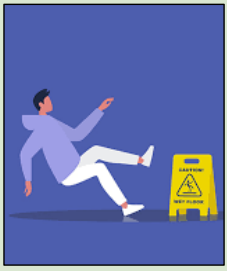
Hazard

"Anything that has a potential for harm".

Hazards in Healthcare can be infrastructural, physical, chemical, psychological etc. Certain examples of these categories of hazard are as follows:

Infrastructural Hazard

Physical Hazard



Chemical Hazard

Psychological Hazard

Uncertainties

Uncertainties could be Scientific, Practical or Personal/Patient oriented in nature. Outcome of the uncertainty will vary due to "Unknown probabilities, ambiguities and complexities" on underlying illness and patient's health. The following diagram represents how uncertainty can range from arriving at a diagnosis to treatment modalities and its impact on patient. Below figure 1 shows a man contemplating heart surgery for newly-diagnosed Myocardial Infarction may experience uncertainty about numerous issues.

2.1 HAZARDS & UNCERTAINITIES IN HEALTHCARE

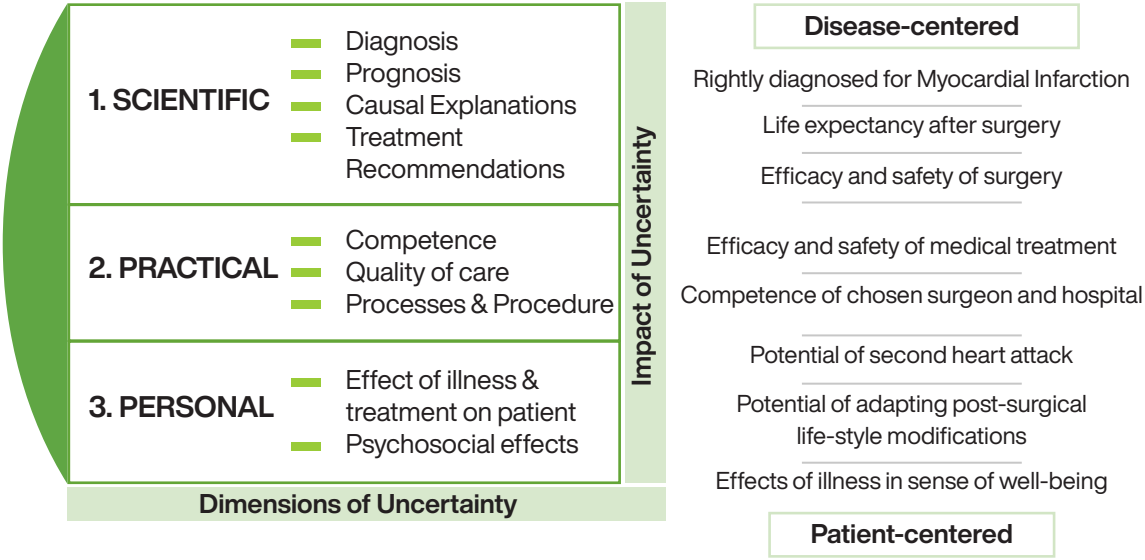


Figure 1: Range of uncertainty and its impact on patient

2.2 RISK IN HEALTHCARE

What is Risk?

Risk is the uncertainty that negatively impacts objectives of an organization. It is essential to differentiate between risk from its causes and effect, as many a times either cause or effect is misunderstood as risk.

Example

"Risk of fire "- In this case, Fire is the effect and not the risk.
"Risk of harm due to fire" - In this case, fire is the cause and again, not the risk.
"Risk of harm to the infrastructure and lives because of short circuit of wires that can lead to fire"
In this case, Short circuit of wire is the cause , fire is the effect and Risk is – "harm to lives and infrastructure"

What is Risk Management in Healthcare?

Risks are everywhere, hence risk management should be an integral part of any organization, more so, in healthcare settings as it can mean the difference between life and death, which makes the stakes significantly higher. It is important to understand that one cannot reduce risks in a hospital to zero. An efficient Risk Management process ensures the prevention of adverse events and /or mitigation of their consequences. Risk Management in Healthcare is a challenging task, as sometimes, one deliberately takes the risks as it outweighs cost in comparison to the benefit. Risk management in healthcare comprises the clinical and administrative systems, processes, and reports which detect, monitor, assess, mitigate, and prevent risks. By employing risk management processes, healthcare organizations proactively and systematically safeguard patient safety as well as the hospital's assets, lives, processes and community standing. (Under given list is not an exhaustive list but a few examples of risks in healthcare.

2.2 RISK IN HEALTHCARE

Few examples of risks in a hospital are:

Facility and infrastructure risks

- Risk of fall due to uneven surface
- Risk of interruption to important surgery due to loss of power supply

Occupational Health risk

- Risk of exposure to radiation
- Risk of HIV infection because of a needle stick injury

Communication risk

- Risk of falling sick due to incorrect dispensing of prescribed medication
- Risk of wrong site surgery due to failure in communication

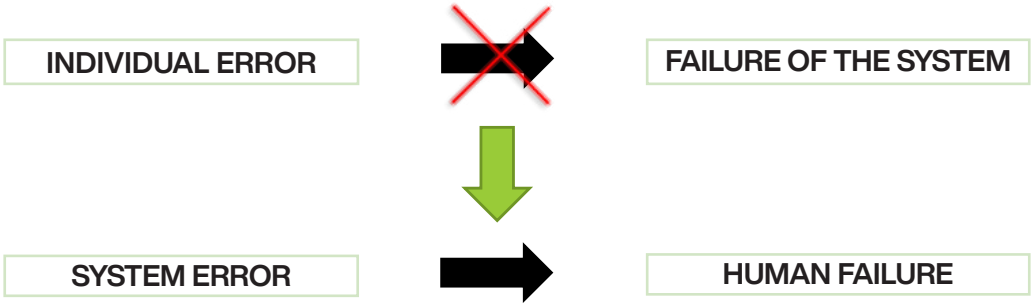
Operational risk

- Risk of patient dissatisfaction due to employee attitudinal issues
- Risk of delay of supplies due to logistics mismanagement

Security risk

- Risk of a staff getting harmed due to a security breach
- Risk of infant abduction due to non- functional alarm system

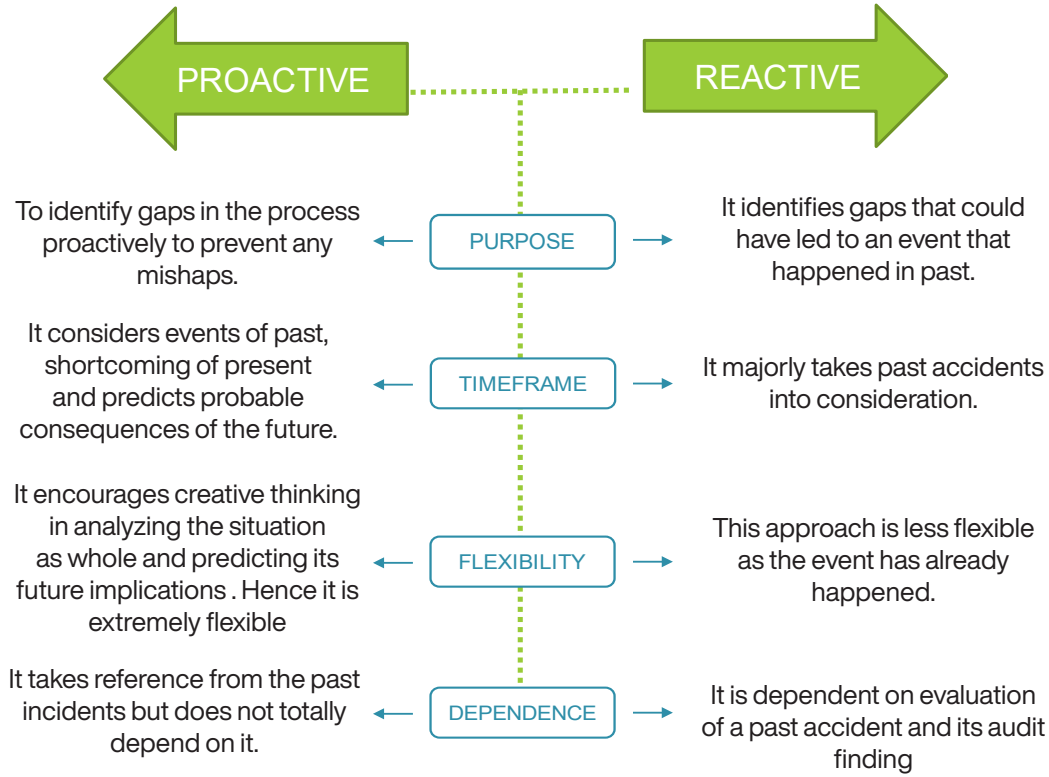
APPROACH TO A HAZARD



Generally, an individual is blamed for the failure of a process, but the right approach is to identify errors in the system that led to human failure. Risks that occur due to the rotation of shifts are quite frequent. Imagine, a staff nurse in the department of medicine/ endocrinology On the morning shift mistakenly adds one ahead of 6 units of short-acting insulin and makes it 16 units in writing. Due to work overload and staff shortage, she does not give a proper handover to the staff nurse of the evening shift. The staff nurse of the evening shift injects 16 units of short-acting insulin instead of 6-unit insulin, and the patient suddenly shows signs of hypoglycemia. Such operational risks can be fatal. But we must question if this was a system or a human failure or mistake of that staff nurse or a system failure wherein her efficiency was compromised because of the overload she served.

2.4 PROACTIVE VS. REACTIVE APPROACH IN HEALTHCARE

Namely, there are two approaches to Risk management in a hospital – Reactive and proactive. Until the recent past, the approach to Risk Management was largely reactive in nature. Solutions were realized only when there was an alarming situation. Since this approach failed to prevent risks and caused substantial losses to the hospital, gradually a new approach came to the picture – Proactive Risk Management.



2.4 PROACTIVE VS. REACTIVE APPROACH IN HEALTHCARE

Advantage of Proactive Risk Management Approach

- Proactive risk management approach provides more control over risk management
- It Prevents potential risks from becoming adverse events.
- Mitigates disruption of the normal functioning of the hospital.
- It helps in prioritizing the risks basis severity.
- It involves and facilitates continuous monitoring of risk management systems and processes.

Disadvantage of Reactive Risk Management Approach

- It catalogs mishaps and errors of the past that led to adverse event. Hence, does not consider fresh or potential unidentified sources of accidents
- Since there is the unpreparedness for the adverse event, it can disrupt the normal functioning of the hospital.
- Resolving issues according to this approach becomes a tedious and complex task as the cause is greatly unknown and the majority of the focus diverts towards reverting to the normal functioning of the hospital.
- It may involve a great loss of finances and can lead to damage to the reputation of the hospital.

2.5 EXAMPLES : PROACTIVE APPROACH TO MITIGATE RISK

Avedis Donabedian in his paper “Evaluating the Quality of Medical Care” provides 3 major criteria for assessing the quality of care: Structure, Process and Outcome.

Structure- Structure refers to the environment and organization healthcare setting wherein process take place. This includes infrastructure, drug supplies and skills & competence of the staff.

Process- This includes the steps performed by health care providers, within the structure, to achieve the desired outcome. Process is also described as what was done. Examples of this include staff compliance rate with handwashing and adherence to interventions as defined in policies & guidelines.

Outcome- It reflects the impact of the health care service or intervention on the health status of patients (ex. Healthcare-associated infections, morbidity rate, medication errors, etc.). Simply stated, outcome is described as what happened to the patient.

Risks pertaining to healthcare can be categorized in the similar fashion under these broad categories: Risks due to deficient structure, Risks due to inefficient processes and Risks due to unattained outcomes. Following table represents risks under these categories could be avoided or prevented the impact by using proactive approaches.

RISKS DUE TO DEFFICIENT STRUCTURE

1. Risks due to lack or irregular inspection and non-maintenance of equipment

Proactive Approach

- Regularly ensuring that all equipment are covered under AMC including preventive maintenance and it is being followed
- Regularly ensuring that there is system of timely corrective break down maintenance of equipment
- Regularly ensuring that operating instructions for critical equipment are available

2.5 EXAMPLES : PROACTIVE APPROACH TO MITIGATE RISK

2. Risks due to non establishment of program for fire safety

Proactive Approach

- Ensuring on regular interval that facility has sufficient fire exits to permit safe escape to its occupants at time of fire
- Ensuring on regular interval that facility has installed fire extinguishers that is class A , class B ,class C types or ABC types
- Regularly checking for staff competencies for operating fire extinguishers and what to do in case of fire

3. Risks due to lack of drugs and consumables required for assured lists of services

Proactive Approach

- Regular ensuring availability of analgesics, antipyretics, anti inflammatory, antibiotics, IV Fluids
- Regularly ensuring availability of vaccines as per national immunization programs
- Regularly ensuring availability of HIV testing kits 1,2 and 3 at ICTC

4. Risks due to lack of 24*7 water and power back up

Proactive Approach

- Ensuring at regular intervals that the facility has availability of 24*7 running and potable water
- Ensuring at regular intervals that there is the availability of power backup, UPS and emergency lights in the facility
- Regularly ensuring the availability of hot water in the maternity ward

5. Risks due to lack of availability of adequate specialist doctors as per service provision

Proactive Approach

- Ensuring availability of Ob & G specialist on duty
- Ensuring the availability of a paediatrician
- Ensuring the availability of an anaesthetist

2.5 EXAMPLES : PROACTIVE APPROACH TO MITIGATE RISK

RISKS DUE TO INEFFICIENT PROCESSES

1. Risks due to lack of incomplete or non updated medical records

Proactive Approach

- Regular clinical audit of admitted patients for complete patient records
- Ensuring availability of updated forms and formats on a regular basis
- Ensuring safe, adequate storage and timely retrieval of medical records

2. Risks due to lack of procedures for safe drug administration

Proactive Approach

- Regular internal audit of pharmacy to check segregation of expiry drugs
- Regular internal audit to check if the patient is advised by pharmacist about dosages and timings
- Regular review of adverse drug reaction records

3. Risks due to non established procedures for blood bank/storage management & transfusion

Proactive Approach

- Regular random audit to ensure that consent is taken before transfusion
- Proactively ensuring that the blood transfusion is monitored and regulated by a qualified person
- Review of records on a regular basis to assess that any minor or major transfusion reactions are recorded and reported to the assigned officials

4. Risks due to non establishment of procedures for antenatal care as per guidelines

Proactive Approach

- Ensuring on regular basis that high risk pregnant women are referred to specialists
- Regularly auditing internally if pregnant women are educated for nutritional requirements, breast feeding etc.
- Regular internal audits of prescription slips in the ANC clinics to check if diagnostic tests under ANC checks ups are being prescribed and undertaken

2.5 EXAMPLES : PROACTIVE APPROACH TO MITIGATE RISK

5. Risks due to non execution of procedures for ensuring hand hygiene practices and antisepsis

Proactive Approach

- Ensuring availability of hand washing facility and running water at all the points of use
- Regular audit of staff for knowledge and adherence to six steps of hand washing
- Ensuring display of 6 steps of hand washing near hand washing facility

RISKS DUE TO NON-ATTAINMENT OF OUTCOMES

1. Risks due to non- attainment of productivity indicators

Proactive Approach

- Ensuring on regular basis the availability of records on the
- number of trauma, poisoning, cardiac and obstetric cases
- Regular review of the percentage of deliveries conducted atnight
- Regular review of records for bed occupancy and LAMA rates

2. Risks due to non-attainment of efficiency indicators

Proactive Approach

- Regular review of records for referral and discharge rates
- Regular review of data to assess OPD's (medicine, surgery, pediatric etc.) per doctor
- Regular review of the records for downtime of critical equipment

3. Risks due to non- attainment of clinical care and safety indicators

Proactive Approach

- Regular review of records for case fatality rate
- Regular review of internal data for average length of stay
- Regular review of data for percentage of deliveries conducted using safe birth checklist

2.5 EXAMPLES : PROACTIVE APPROACH TO MITIGATE RISK

4. Risks due to non- attainment of service quality indicators

Proactive Approach

- Random internal audit to assess time gap between issuing and requisition of blood in emergency conditions
- Record review of number of stock out incidences of reagents
- Regular review of record for operation cancellation rate

5. Risks due to non- attainment of patient satisfaction

Proactive Approach

- Interview of patients on quality of food , cleanliness of linen etc
- Interviewing patients on behavior of staff
- Interview of patients on availability of services

3

RISK MANAGEMENT PROCESS

3.1 RISK MANAGEMENT FRAMEWORK

A **risk management framework (RMF)** as summarised in figure 2, is the structured process used to identify potential threats to an organisation and to define the strategy for eliminating or minimising the impact of these **risks**, as well as the mechanisms to effectively monitor and evaluate this strategy.

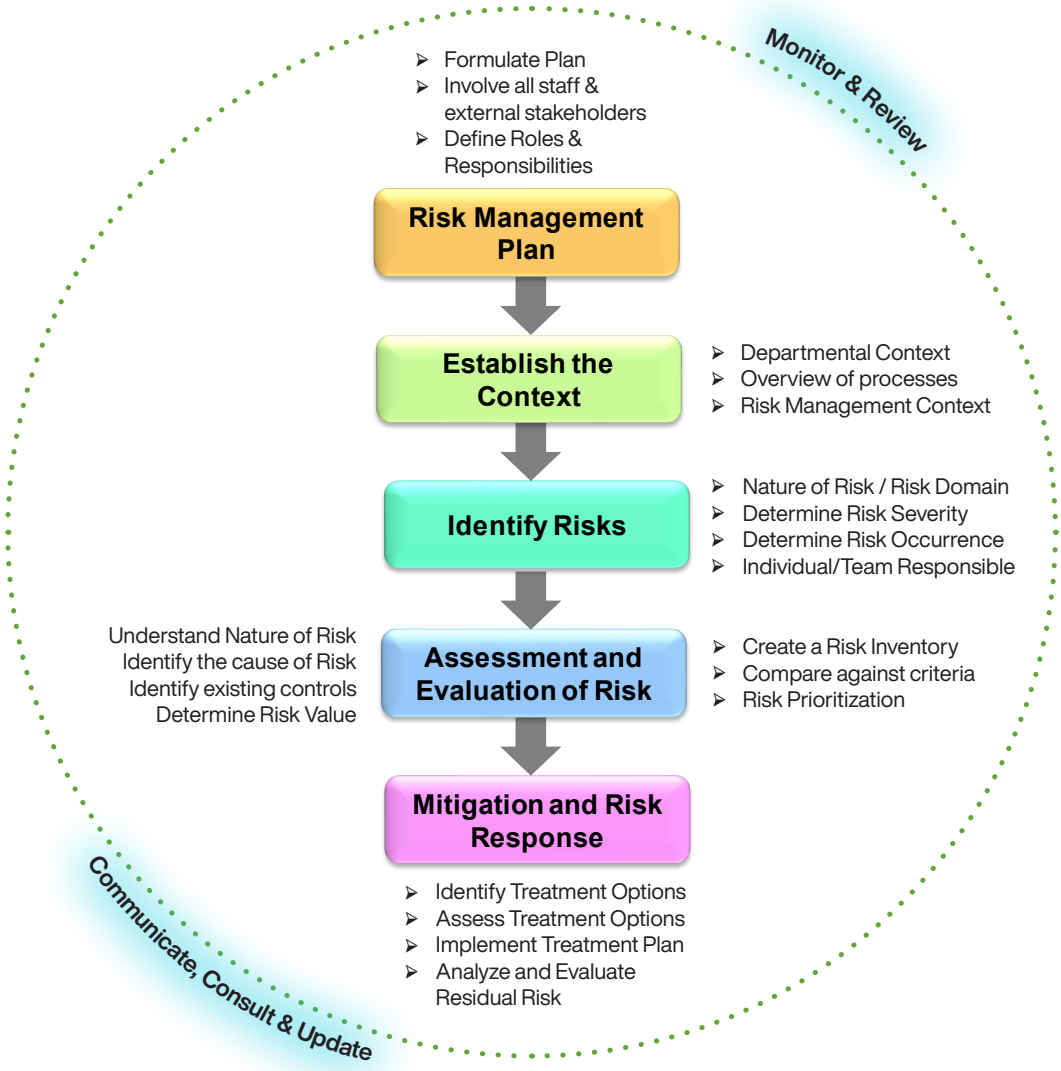


Figure 2 : Risk Management Framework

3.2 RISK MANAGEMENT PROCESS

1. Risk Management Plan (RMP)

Facilities must have an established risk management plan in place. The Risk Management Plan should be documented, and it should be referred to as the guiding document for how a facility defines the context of risks, strategically identifies the risks, manages and mitigates potential and current risks. The Risk Management plan should clearly define roles and responsibilities at each level of function. RMP should include process of reporting and documenting the incident. There should be a detailed structure to explain – how to assess, evaluate and prioritize each risk. In charge of the facilities, department heads and all the relevant stakeholders should be well versed with it. Fundamental components of a Risk Management Plan in a healthcare setting is shown in fig 3.

Fundamental components in a healthcare risk management plans

Detail employee training requirements should include new employee orientation, ongoing and in-service training, annual review and event-specific training.

Quick and easy-to-use, system for documenting, classifying and tracking possible risks and adverse events. These systems must include protocols for mandatory reporting.

Patient satisfaction reduces the likelihood of litigation, procedures for documenting and responding to patient and family complaints.

Define the purpose and benefits of the risk management plan. Specific goals should be made to reduce liability claims, sentinel events and near misses.

Contingency preparation for adverse facility-wide failures and catastrophic situations such as electricity cuts and depletion of oxygen cylinders, disease outbreaks and terror attacks.

Response & Mitigation
Include collaborative systems for responding to reported risks and events including acute response, follow-up, reporting, and repeat failure prevention.

Promote open and spontaneous dialogue, information about how to communicate about risk, and with whom should be provided in the healthcare risk management plan. Next steps and follow-up activities should be documented.

Figure 3: Components of Risk Management Plan

2. Establish the Context

This broadly involves identifying the location where the risk happened, such as

- ICU (Intensive care unit),
- OT (Operation theatre),
- Other areas.

It is recommended that the facility develops detailed blueprint and process map of the facility and each department and staff of that particular department should be well versed with them so that potential or current risks can be easily located and corrected.

Example 1

If there is a fire in the hospital because of a short circuit of wires, Establishing the context will mean- To locate the department where the short circuit of wires took place.

Example 2

If there is an adverse event reporting of needle stick injury, Establishing the context will mean – To locate the department where needle stick injury happened.

3. Identifying Risks

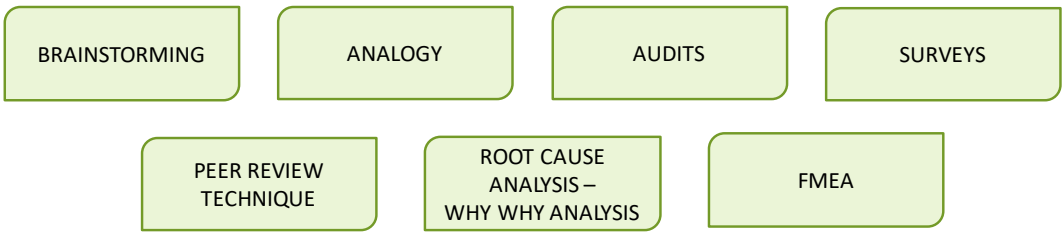
Risks can be identified before and after the event has taken place, though it is always beneficial to identify risks in advance so as to avoid any harm happening– small or big. Risk identification methods should be systematic, comprehensive, and reproducible.

Sources of Risk Identification

- Discussions with Department Heads, Senior Doctors, managers and staff
- Patient Tracer Activity (Tracing the journey of a patient from admission till discharge)
- Retrospective screening of patient records
- Reports of accreditation bodies/ Certification agencies (In case the facility is certified/accredited)
- Incident reporting system & Sentinel events
- Healthcare associated infections (HAI) reports

- Executive committee reports
- Facility management & safety committee report
- Patient complaints and satisfaction survey results
- Specialized committee reports (such as Morbidity and mortality committee, medication management and use, Infection control, blood utilization, facility management and safety committee).

Following are few of the recommended* tools to identify the risk



A. BRAINSTORMING

This is a group/team exercise, and it helps in the identification of not one but many risks at one point of time. Brainstorming should be done at the departmental level at a time when all the team members are present. Within the team, a facilitator should be identified who should define the scope of the process and consolidate all the responses. Identified risks should be listed and worked upon. There are high chances of getting carried away during the discussion, therefore, the rules mentioned below must be exercised during discussions-

Rules

1. Defer judgment
2. Encourage “out of the box” or new ideas.
3. One conversation at a time.

4. Build on ideas of others.
5. Encourage members for listing of as many risks as possible
6. Stay relevant and focused on the topic

Example : Brainstorming done by the members of the quality circle to identify the various risks that may happen in a Labour Room.

B. ANALOGY

Literal meaning of Analogy is "A comparison between 2 things that shows a way in which they are similar". It is an inferential way to derive risks from similar past events. Analogy in risk management means having a reference from the past in order to avoid certain risks and also to predict potential risks. To perform an Analogy, knowledge and recording of past events are a must. Though, one must keep in mind that the available information of the past events must be adjusted to the current scenario.

Example : A review of past records reflects that the number of patients increases by two folds on every Monday OPD resulting in chaos. Problem identified can be used as a reference point to avoid any risk due to overcrowding by undertaking relevant measures on Mondays.

*** Few other risk identification tools are mentioned under Annexure-II**

C. AUDITS

It is an independent, systemic, and documented procedure to gather information about an event. It can be inter-departmental, intradepartmental, or can be facility audit. There are audit criteria laid by an internal and external agency and it serves to determine if those criteria have been met by the hospital.

Example : Prescription audits are conducted to identify the risks that may happen during medication prescription like writing the strength, dose etc.

D. SURVEYS

They are the systematic feedback from the patients, staff, and visitors with the objective of not only achieving patient satisfaction but to optimizing the procedures and increasing patient safety.

Example : Patient satisfaction survey

E. PEER REVIEW TECHNIQUE

Peer review procedure is mostly executed for risks caused under the ambit of "Patient and Clinical safety". Peers are people belonging to the same profession and having a similar set of education and practicing in a similar environment. The main purpose of the peer review is to ensure the quality of care through the safe dissemination of evidence-based care and practice. Also, the review is based on patient and treatment outcomes delivered by a team of professionals rather than focusing on an individual professional.

Steps for the peer Review are as follows:

Step 1	Step 2	Step 3	Step 4	Step 5
Identify Case Case referred and reviewed by appropriate review committee	Identify opportunity for improvement. If provider issue is identified referred to Dept Chair for action plan	System issue is identified and Reviewed action plan is created to improve process or system	Review of action plans monthly until resolution achieved	Action plan or resolution is communicated to core team

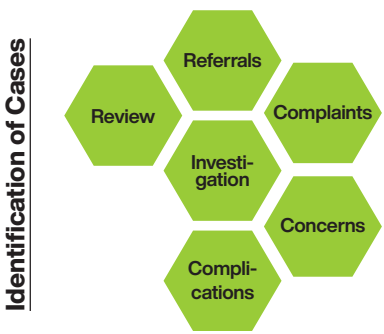


Figure 4: Peer Review Process

If a potential opportunity for improvement is identified from another service, the case is referred to their PEER (ETC, surgery, medicine, nursing, quality) for review and feedback to the referring committee. Action plans that result from this peer review are communicated back to the core team.

F. ROOT CAUSE ANALYSIS (WHY - WHY ANALYSIS)

This identification tool helps the team to reach beyond the obvious reason or cause of the hazard. The staff member performing the hazard should continue asking the question "Why" until he/she reaches the most logical and explanatory cause of the hazard. One must ensure that only relevant reasons should be kept in the process and ones with less probability of causing the hazard should be discarded.

Example : A diabetic patient shows up in an emergency with chest pain, difficulty in breathing, and on investigations, he is found to have a silent Myocardial infarction. This patient has been on insulin for several years and has been injecting insulin himself and his recent HbA1C levels were 7.8% depicting poor condition. In this situation after performing a series of "Why" analyses, the team could finally reach the conclusion that it happened because of the prescription error.

Q #	WHY?	RESPONSE
1	Why did the patient have MI attack?	The team looked into recent investigations and vitals of the patient. The results did not respond to the question as most of his results showed progress in his health.
2	Going one level deeper, Team assessed other areas and found out that he had been seen in the medicine department. His prescription was assessed.	There was a difference of 10 units of insulin in his latest and earlier prescription.
3	Why was there an increase of 10 units from the last time?	It was found out that it was a prescription error, wherein, 16, got written in place of 6, which might have caused hypoglycemia to the patient.
4	Why was there a prescription error?	Because the treating Medical officer asked an intern to repeat the drugs in the prescription and the intern wrote 16 units instead of 6.
One can stop the analysis at this point but it is advised to look for latent failure, instead of, active failures. As corrections happening at the systemic level ensure better outcomes.		
5	Why did the doctor not write the prescription himself and give it to his intern?	His fellow physician had gone on leave and he had to manage double the load of patients.

G. FMEA

FMEA requires formation of a team and evaluation of each step in the process to identify hazards. It lays down a systemic approach wherein the SOPs are revisited, and certain changes are undertaken to mitigate the risks and a surveillance plan is laid down to ensure that control measures are being executed. Brief process of FMEA is mentioned below in figure 5.

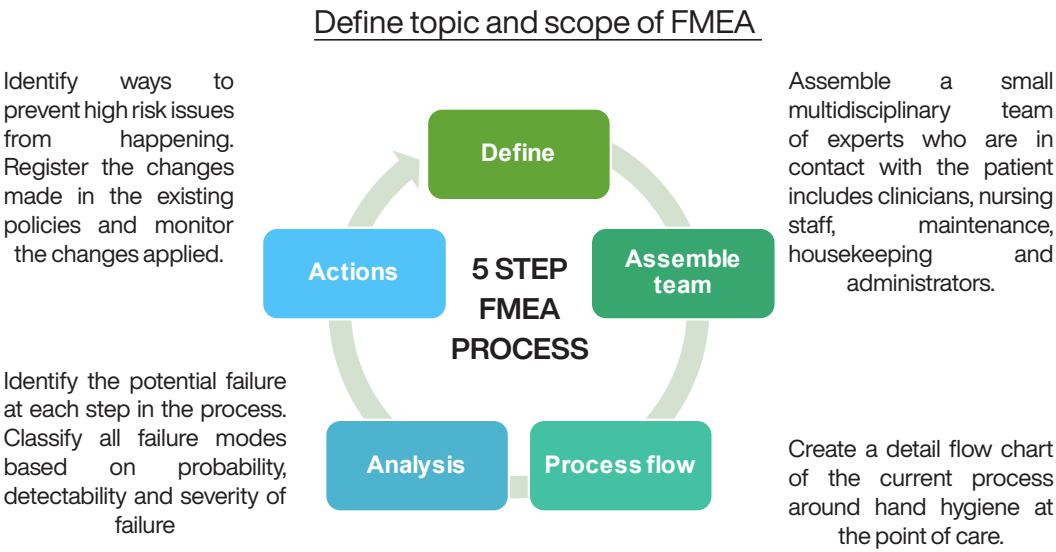


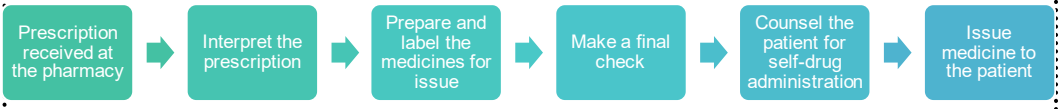
Figure 5: Steps of conducting Failure Mode Effect Analysis

Let's understand the methodology with an example

1. Define: Medication dispensing process

2. Assemble Team: All personnel in the pharmacy

3. Process Flow:



4. Analysis: List anything that could go wrong for each process followed by reasons and its probable consequences as per below given format

Steps in the process	Failure Mode	Failure Cause	Failure Effects	Likelihood of consequence (1-10)	Likelihood of detection (1-10)	Severity (1-10)	Risk Profile Number (RPN)	Actions to reduce occurrence of failure
Interpret the prescription	Wrong interpretation	Illegible handwriting	Wrong medicine dispensed	7	7	10	490	Prescription are written in capital letter only

5. Action: Failure modes with high RPNs are probably the most important parts of the process to plan improvement efforts.

4. Assessment and Evaluation of Risk

The objective of risk evaluation using a risk rating matrix (figure 6) is to understand the nature and magnitude of the risks. All risks can be assessed qualitatively and quantitatively. Not every risk has the same impact or can disrupt the functioning of the facility to the same extent. Therefore, it is essential to list the risks on the basis of their impact on the functioning of an organization.

An Impact factor is derived considering two major parameters:

Likelihood

How likely or often can a risk happen? If a risk is experienced five times in two months, Risks due to that hazard have a higher likelihood than risks due to hazard occurring once in two months.

Severity

How much damage a risk can cause to the objective of an organization? Risks arising due to less space in OPD have lower severity than risks due to fire in the hospital.

These two parameters are used to deduce a Total Impact Factor.

Total Impact Factor : *An impact score of the risks. This score combines the "likelihood of its occurrence" and "severity" that it can cause. The higher likelihood and higher severity can cause a greater impact.*

Risk Rating Matrix

Likelihood		Severity 1 Negligible	2 Minor	3 Moderate	4 Major	5 Catastrophic
5	Almost Certain	5	10	15	20	25
4	Likely	4	8	12	16	20
3	Possible	3	6	9	12	15
2	Unlikely	2	4	6	8	10
1	Rare	1	2	3	4	5

Figure 6: Risk Rating Matrix

Example 1 : Incidence of needle stick injury was reported three times in two months. Wherein, all the emergency measures were taken such as washing with soap and running water, reporting to immediate supervisor, PEP protocols were followed immediately after AEB, etc. But in 1 case – staff was found to be exposed to a blood sample of an HIV patient.

Likelihood – 4 Points
Likelihood of getting a needle stick injury is high, therefore a score of 4 is attributed.

Severity – 5 Points
Severity of this incidence is high as it can expose the patient to diseases like HIV, HBV and HCV therefore, a score of 5 is attributed.

Total Impact factor : 4 x 5 = 20 (refer figure 7 to calculate the impact factor)
This falls in the red zone and should be looked into immediately and CAPA should be performed to ensure that this incidence has minimal chance of repetition. This incidence should be escalated and should be discussed in Quality team meetings and if required be, changes in the SOP's should be made with immediate effects.

Figure 7: Risk Rating Matrix for needle stick injury

Example 2 : Incidence of injury by a sharp object was reported in the psychiatry IPD. On investigation, it was found that a patient, suffering from Schizophrenia and Acute depression, cut himself with a knife that was brought by the attendant for cutting fruits. This incident was reported to Supervisor in the psychiatry IPD and all immediate steps were taken to revive the patient.

Likelihood – 2 Points
Likelihood of getting impacted by a sharp object is moderate, therefore, a score of 2 is attributed to this case.

Severity – 5 Points
Severity of getting harmed by a sharp object is high, therefore, a score of 5 is attributed

Total Impact factor : 2 x 5 = 10 (refer figure 8 to calculate the impact factor)
This falls in the yellow zone, should be looked on an urgent basis and steps should be taken by QC, security staff should be involved in the process and strict measures should be taken at the departmental level to prevent this from occurring in the future. This risk should be mentioned in the risk register and should be discussed in the quality circle committee meeting.

Risk Rating Matrix

Likelihood	Severity 1 Negligible	2 Minor	3 Moderate	4 Major	5 Catastrophic
5 Almost Certain					--
4 Likely					--
3 Possible					--
2 Unlikely					10
1 Rare					-

Figure 8: Risk Rating Matrix for injury due to sharp object in the psychiatry OPD

Knowledge of past events and their impact on the functioning of the hospital can help in the calculation of likelihood and severity values faster. Thus, it is desirable that these values should be calculated by staff members with maximum experience and deep knowledge of their individual departments.

Also, there is a great risk of subjectivity attached to the calculation of risk value, therefore any risk that is bound to have a risk value of more than 15, should be assessed by more than two staff members.

5. Mitigation & Risk response

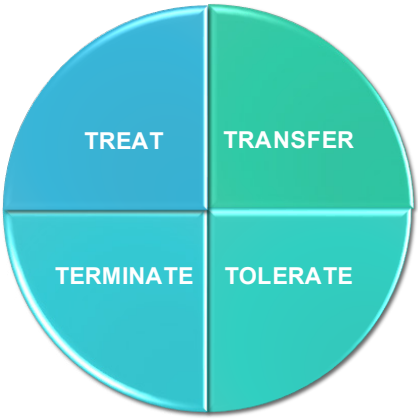


Figure 9: Risk Mitigation/Termination Strategies

TREAT

Risks that fall under this category can be treated or reduced to a level where the impact or likelihood of its occurrence or severity diminishes to minimal levels. Once the risk is treated, changes in SOPs should be documented and relevant alterations should be made in policies and communicate to each staff member. For example: if there is recurrent incident reporting of trips and falls in the OPD waiting area, certain immediate measures should be taken to prevent its occurrence such as:

- Cleaning all spills immediately
- Marking spills and wet areas
- Mopping or sweeping debris from floors
- Removing obstacles from walkways and always keeping walkways free of clutter
- Securing (tacking, taping, etc.) Mats, rugs and carpets that do not lay flat
- Always closing file cabinet or storage drawers

TREAT	▪ Covering cables that cross walkways ▪ Keeping working areas and walkways well lit ▪ Replacing used light bulbs and faulty switches
TRANSFER	In this method, the liability of the risk is transferred to a third party, or the risk is pooled among multiple parties. Liabilities in such cases generally are pre-assigned or delegated. One of the key examples belonging to this category is insurance coverage for family planning surgeries, AMC/CMC of equipment.

5. Mitigation & Risk response (Continued)

RISK MITIGATION/TERMINATION STRATEGIES

TOLERATE	When risk benefits outweigh the risk cost, the risk should be tolerated. This action does not require an immediate change in policies, procedures and SOPs. Most of the clinical risks and interventional treatments form the major constituent of this category. For example- Even though endoscopy is considered a safe procedure, still there are certain risks involved with the procedure like perforation, reaction to sedation, infection, bleeding etc. Even though the surgeon is aware of these risks, she/he decides to proceed with this intervention as it provides a confirmed diagnosis and treatment plan, thereby including likelihood of survival. Tolerating the risk involves maintenance of the risk at its current level(any failure to maintain the risk may lead to increased risk exposure).

TERMINATE	If any procedure or activity gives rise to significant risk – Risk that bears capacity to alter or disrupt normal functioning of the hospital or can cause loss of life and major loss of credibility of the hospital, that activity should either be performed in a different manner or should be permanently stopped. For eg, terminating the practice of use of single-use needle.

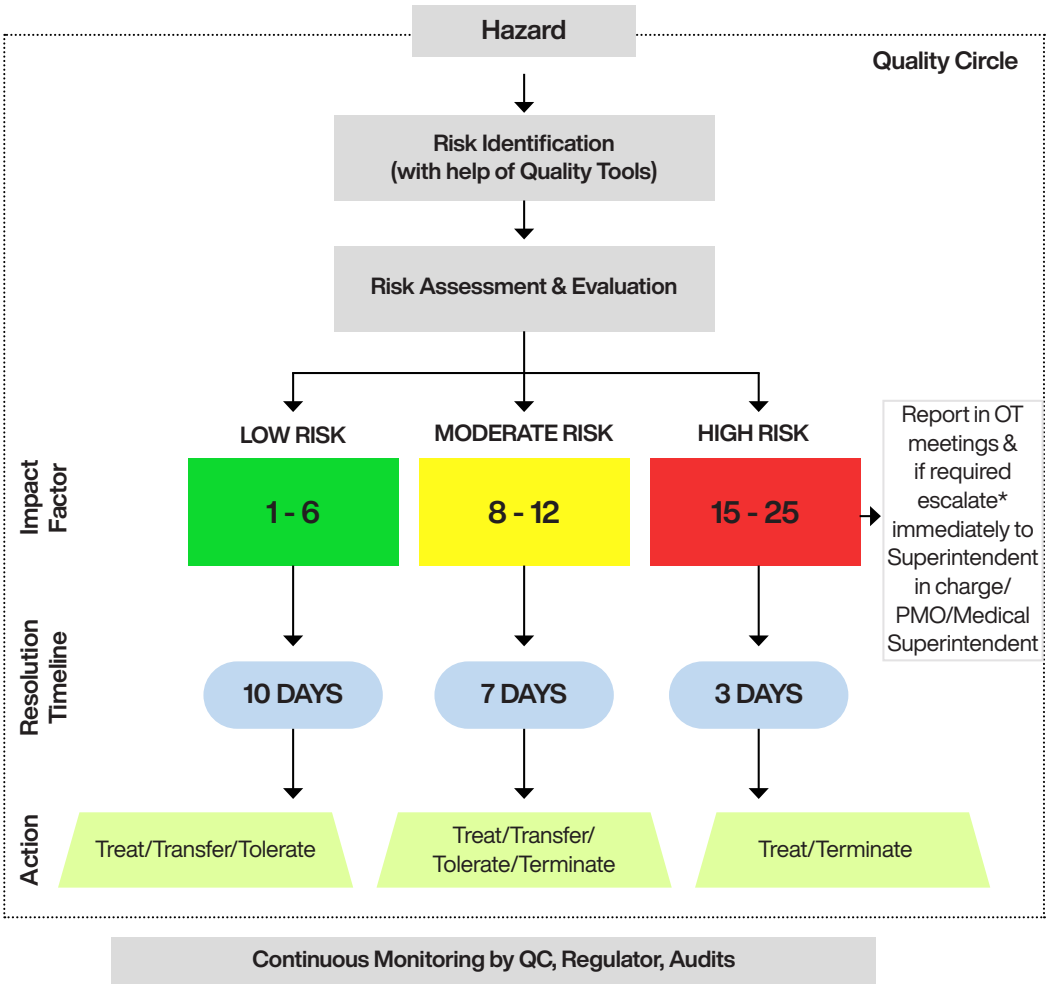
Every Mitigation strategy should be SMART – Specific, measurable, attainable , relevant and time bound. Mitigation strategies must be documented in the risk registers and residual risks must be calculated and documented in the risks register following the execution of these strategies.

6. Risk Monitoring and Review

This is a continuous process and undoubtedly the most effective in ensuring the achievement of safer work practices. Quality circles in association with Hospital/ Risk manager work in collaboration to monitor risks at the departmental level.
Following are a few steps required to ensure control of already identified risks and monitoring of potential risks:

1. Ensuring employment and execution of Risk Management Framework in all the departments.
2. Review of risk registers periodically to ensure enlisting of all the current and potential risks with their assessment scores and employed mitigation strategies. This should be done internally by Quality circles and externally by Hospital managers once in a month's time.
3. Evaluations of mitigation strategies applied for each risk and ensuring their capacity to contain the risk. Mitigation strategies should be updated if they fall short to contain the risk.
4. Enlisting potential risks from time to time and proactively taking measures to prevent them from happening or minimize their impact.

5. Ensuring staff and hospital capacity in case of disasters, pandemics, and mass contingencies.
6. Regular process remapping, risk audits, and re-assessment of risks.



(Yearly meeting to review Risk Register & Closure of Risks)

Figure 10: Risk Management Process

***Detailed risk escalation responsibility and action plan is described in Annexure-I**

3.3 CHALLENGES AND WAYS TO STRENGTHEN RISK MANAGEMENT

Challenges of Risk management

- Lack of Leadership commitment to ensuring risk management.
- Risks are not proactively identified and prioritized
- Sometimes risks are ignored
- Lack of Proactive involvement of the risk management team with the employees and processes
- Non-availability of expertise in the team
- Resources for risk treatment/mitigation are not adequate
- Changes in the process/system are not accepted when indicated
- Monitoring and control systems are not in place

Ways to Strengthen Risk Management

- Continuing education of staff and responsible key persons.
- Monitoring and evaluation of the integrated programs.
- Communication with peers at local, regional, state, and national organizations in order to
- Improve the program at the hospital.
- Discovering situations that present potential for accidents.
- Availability of sophisticated data on past occurrences.
- Identifying areas of high risk in the hospital
- Elimination of needlessly dangerous procedures and prescribed medicines even though safer substitutes may be found.
- Staff training
- Bio-medical technology training needs (e.g. Inadvertent unplugging of an intravenous pump by untrained staff can result in shut-off due to battery depletion, which at times can go unrecognized. This can cause potentially serious patient care ramifications)
- Staffs should be informed about various laws & enactments.
- No Blame Culture

3.4 RISK MANAGEMENT IN PRIMARY CARE

Primary healthcare plays a pivotal role in delivering comprehensive set of services. In addition to the basic curative services at the Primary Health Centres (Rural/Urban), Ayushman Arogya Mandir - Sub Centre (AAM-SC) have an important role in the prevention of several disease conditions, including both communicable and non-communicable diseases. The provision of health services includes, early identification, primary management, counselling, ensuring treatment adherence, follow-up care, ensuring continuity of care by appropriate referrals, followed by optimal home and community follow-up.

Risk management in primary care appears as a potentially nebulous concept although the relevant risk factors involved can be attributed to patients, doctors and healthcare systems. The risk factors incorporate a range of processes or events and can include, serious adverse events following immunisation, medical errors (e.g. in diagnosis or prescription), technical problems (e.g. failure to adhere with infection prevention practices) and issues in patients with multimorbidity in relation to care continuity, care transitions and polypharmacy.

Hence, it is essential to identify the risk, risk categorization attributed to service seekers and service providers followed by risk assessment and risk analysis. Appropriate mitigation strategies could be planned based on score obtained to minimise the occurrence of inherent risk. The basic layout of risk management framework in primary healthcare settings will remain the same, as picturised below in figure 11:

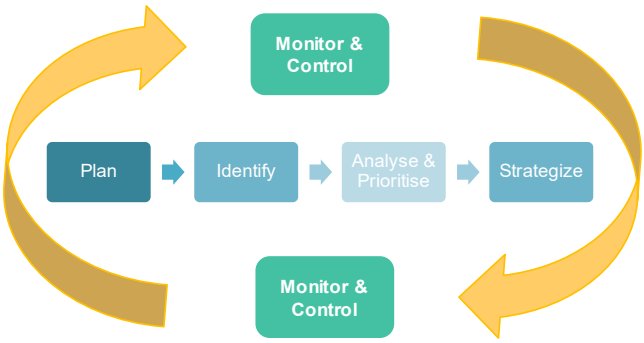


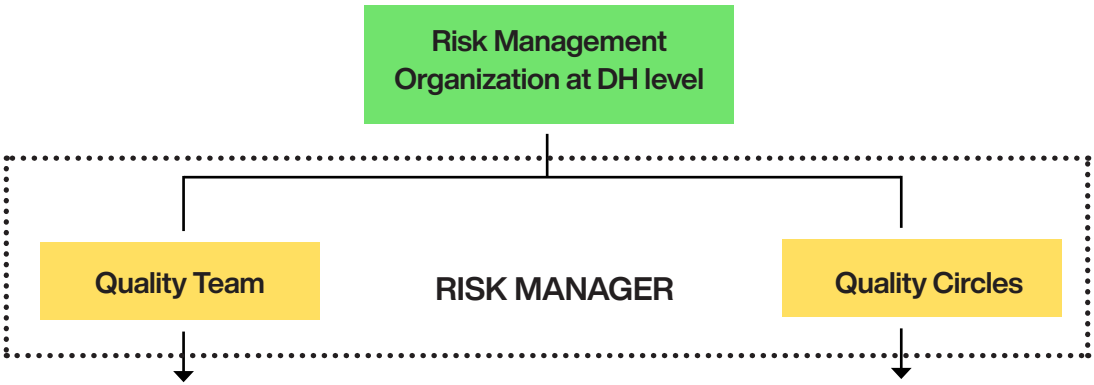
Figure 11: Risk Management Framework in Primary Care

4

RISK MANAGEMENT ORGANIZATIONAL STRUCTURE

4.1 RISK MANAGEMENT ORGANIZATION STRUCTURE

Management of risks need to be an integral part of existing Quality Assurance Structure at each level including quality circles formed at the departmental level. The facility should assign responsibilities related to risk management either to the hospital manager or infection control nurse. The assigned person is referred to as **Risk Manager** in this manual.



Quality Team includes in charges of all the departments, including head or medical superintendent, all medical specialists of the facility

Composition of QT

Refer operational guidelines for improving quality in public healthcare facilities 2021

Quality Circles are informal groups of the staff in each department. For example, the Quality circle in medicine will include all the MO's / In charge of the medicine department, nursing staff, matrons, and support staff. The Quality circle will work in coordination with Quality teams at the facility level.

Composition of QT

Refer operational guidelines for improving quality in public healthcare facilities 2021

Periodicity

As per existing norms, District Quality Team (DQT) meetings will happen on a monthly basis, and it should integrate Risk Management as a regular discussion topic.

Periodicity

Quality circle meetings must take place once every month or earlier as per any urgent requirement. **It should be ensured that the Quality circle's team should be kept a week prior to the DQT meeting so as to give Quality Circle enough time to collate and assess risks at the departmental level.**

There should be a separate yearly Risk Management meeting and it should be attended by all the members of DQT. DQT should go through all the risks documented in risk registers for that particular financial year.

It should re-ensure that all the risks have been closed and applied mitigation strategies are in place so as to avoid recurrence of any risk.

4.2 ROLES & RESPONSIBILITY

	QUALITY CIRCLE	QUALITY TEAM	RISK MANAGER
ROLE	**DEPARTMENTAL LEVEL**	**FACILITY LEVEL**	**INTERLINK BETWEEN THE DEPARTMENTS AND FACILITY**
Development & update of risk management plan	Execution of risk management plan at the departmental level	Execution of risk management plan at the facility level, review the risk management plan & establish the objectives	Develops risk management plan ,establishment of document related to risk management framework
Training and education	Selected members trained by risk manager further train the rest of their Quality Circle team members pertaining to Risk Management Framework, its documentation and implementation	QT organizes training and education on risk management for all staff (priority may be given to QCs) QT assesses staff from different QC on their knowledge of Risk management framework from time to time	Risk manager provides on job training to 1 or 2 members from each department selected by Head of the department pertaining to Risk Management Framework , its documentation and its implementation
Establishing the context & Identification	QC identifies all the risks within the department and registers them in the departmental register.	Approve the SOPs/ framework of risk management. Share it with all concerned for QT reviews all the risks above an impact factor of more than equal to 15 or risks belonging to "high" category. Disseminate the mitigation plan to all concerned	Risk Manager collates and maintains a record of all the risks from all the QC's and present the high category risks in the QT meetings and all the risks in Yearly Risk Management Meeting
Evaluation & Prioritisation	QC should assess, evaluate and prioritize all the risks on the basis of their impact factor. Since deduction of impact factor can be impacted by a subjective bias, it is recommended to have a 2/3 consensus of QC for all the risks	QT should reassess the cause and severity of risks with an impact factor of more than equal to 15 and should formulate a plan that enable the facility to avoid its re-occurrence.	Risk Manager must ensure that all the risks are closed at the end of monthly QT meetings and strategies planned to avoid recurrence of high category risks are well executed at the departmental level
Timelines for Mitigation	It is QC's responsibility to execute mitigation plan for all the categories of risks – High, Moderate and low. Timelines for mitigating all the three category risks should be followed ,i.e., High category Risks – within 3 days Moderate category risks – Within 7 days Low category risks – within 10 days	QT should ensure that all the timelines are adhered by QC, especially for high category risks	Support departments in resolving the risks within a set timeframe
Recognition	Recognise the efforts of team members who identify and resolve maximum risks within the department	Recognises efforts of departments that identifies and mitigates the risks in timebound manner	Analyses performance of all the QC's and inform the QT about best performing Quality circle in respect to timebound resolve of risks

4.3 DOCUMENTATION

Facilities must have the supporting documents to enforce and sustain an efficient Risk management Framework In their organization. Templates have been attached per the required document in the annexures as examples, Hospitals may amend them as per their utility.

Key documents required for smooth functioning of the hospitals

1. RISK MANAGEMENT POLICY

Risk Management policy is a set of documents explaining existing risk management practices, SOP's pertaining to risk management on all the functional levels, existing organizational framework/committee's or teams and periodicity of their meeting, defining roles and responsibilities of its members, explicating relevant existing documentation. DQT and members of the Quality circle should be well versed with Risk management policy. The policy should be strictly adhered to and should be kept flexible to include changes to match local needs at a later stage. Also, Risk Management Policy should be updated periodically as per the policies defined in the Quality manual.

The risk management policy should identify:

- **Who:** is required to report, communicate, act
- **What:** is required to be reported by staffs, managers, committees, etc.
- **When:** risks are to be reported
- **Where:** information to be stored, communicated
- **How:** tools & processes are to be used

2. RISK REGISTER

- Risk register has to be filled and maintained by all the departments and all the risks should be recorded in the risk register irrelevant of their magnitude and impact.
- Risk register must contain Date of identification, risk title, risk description, Possible cause of risk, likelihood rating, severity rating, Impact factor before and after assessment, name of the risk owner, date of assessment, date of resolve, impact factor of residual risk, date of surveillance, Risk avoidance/mitigation plan. Risk owner is the team member who is either assigned or voluntarily agrees to manage

that particular risk.

» Risk register should be reviewed in every Quality circle meeting every month and risks that have been closed or already managed should be documented with the residual impact score (Residual impact score is the impact score obtained after mitigation measures have been taken. It should always be less than the initial derived Impact score.)

» Risk register of every department is to be produced in the DQT meetings.

Risk Register Snapshot (Details are covered in Annexure-IV)

RISK REGISTER

								A	B	A x B						
S #	Department	Risk Reported by	Date of Identification	Risk Title	Risk Domain	Risk Description / Statement	Possible Reason	Likelihood Rating	Severity Rating	Impact Factor (Risk Profile)	Risk Owner	Date of Assesment	Date of Resolve	Residual Risk	Date of Surviellance	Risk Avoidance/Mitigation Plan

3. RISK MANAGEMENT REPORT

Risk Management report acts as a dashboard where one can look and compare risks prevailing in all the departments at once. All the risks are categorized into – high, medium and low categories on the basis of their impact factors. Each category will reflect a cumulative effect of all the risks present in that department. Risks displayed in the risk report are the ones filled by each Quality circle in its monthly meeting. The Risk Management report will be created by the Risk Manager and shall be updated on the monthly basis.

Example : As depicted in figure 12, five out of 18 departments have risks belonging to the high-risk category, four departments have risks from the medium-risk category and five have risks from the low-risk category. Every department could have risks from all three categories, or one may have risks from one category or there may be chances that some departments do not have any risk identified. Each department is supposed to prepare a risk management report every month. All 12 reports for a year should be compiled and presented in the yearly risk review

meeting. Based on the departmental score, an average risk score should be calculated for the hospital under all three risk categories, as shown below in figure 12.

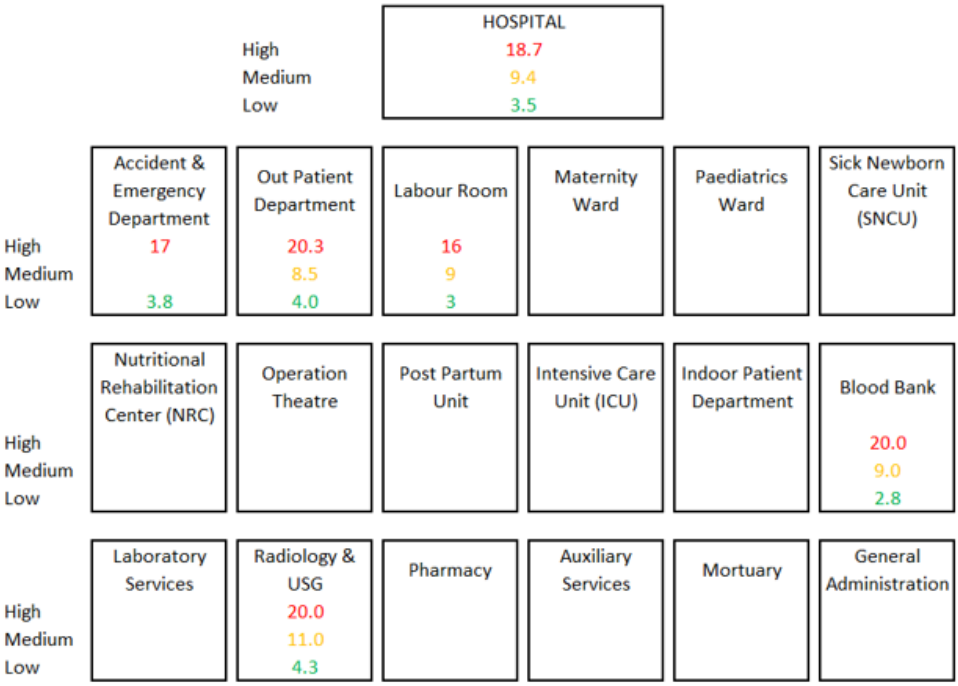


Figure 12: Risk Management Report of a District Hospital

5

ANNEXURE

RISK ESCALATION AND RESPONSIBILITY (Annexure-I)

Risk Score	Risk Response	Action	By Whom	Escalation
High Risk	**Treat/Transfer/ Terminate**			
15-25	Risks deemed as high require a systems approach to identify the root causes of the risk and thereby help choose an appropriate risk response. There should be a change in the existing structure so as to reduce the impact factor	• Risk register reviewed by DQT and make changes in policy framework of the organization • DQT makes changes in the SOP's of the activities where immediate termination of the risk is required . • DQT makes random audits to ensure that changes made in SOP's are executed	QC & QT	
Moderate Risk	**Treat**			
8-12	Risks deemed as moderate to high will require a treatment plan. Those risks where it is deemed that no further treatment can reduce the risk ,it should be continuously monitored to see impact on the organization	• Risk register discussed with departmental heads • Risks identified as red reported to the DQT • Amber and red risks and associated treatment plans reviewed by departmental heads and reported to DQT in annual meeting • Review of the similar category of risks	QC	

RISK ESCALATION AND RESPONSIBILITY (Annexure-I)

Risk Score	Risk Response	Action	By Whom	Escalation
Moderate Risk	Treat			
8-12		that have taken place in the past and strategies applied to mitigate them are discussed within QC	QC	
Low Risk	Tolerate			
1-6	Risks graded as 1-6 either require no action or can be managed through local action or by an appropriate person or department.	▪ Risk is identified ▪ Risk added to team risk register ▪ Action to reduce risk where necessary is considered ▪ Risk register discussed at DRMC meetings ▪ Departmental risks discussed with specific departments	All Staff	

RISK IDENTIFICATION TOOLS : POKA YOKE (Annexure-II)

Poka yoke is a Japanese term that means mistake-proofing (pronounced Poh-kah YOH-kay). It's a means of thinking about a process so that you can prevent defects from occurring in the first place. Poka Yoke stems out of lean six sigma implementation.

CONTROL APPROACH	WARNING APPROACH
The process stops until the correction takes place	Process produces a signal whenever there is a defect so that the end user takes corrective action.

» Poka Yoke is an integrated feature of multiple healthcare products already. Few of them are mentioned below:

» **CPOE – Computerized physician order entry** system can reduce errors by 55%. CPOE is used by clinicians to issue and record patients orders for diagnostics and treatment. CPOE can be installed on computer on wheels that can be availed by the physician from any location. It informs providers of common dosages as per the weight and age of the patient and also warns the clinicians of the overdosages. This system can eliminate issues of legible handwriting of physicians. It also can assist in providing support in formulating clinical decisions. It also can help with the aid of pop ups for drug interactions and allergies which otherwise had chances of getting missed up.

» **Transport monitors with trigger flashing and alarms –** Transport monitor units use alarms and flashlights to indicate any deviation in Vital signs like heart rate or breathing rates. This is a type of warning approach that is sent to the healthcare provides to ensure if the warning stemmed out of incorrect positioning of the equipment or patient requires critical attention.

» **TLD badges** used in Radiation department - Radiation badges aim to identify the amount of radiation that a staff working in radiation department is exposed to. Radiation badges contain radiation –sensitive lithium fluoride crystal that produces light when exposed to radiation and measures the amount of radiation at the same time.

» Use of **different colour tube** racks to match vacutainer tops and tests so that they do not get mixed up.

RISK IDENTIFICATION TOOLS : LONDON PROTOCOL

London protocol refers to a comprehensive investigation and analysis of an incident. It identifies multiple or chain of events and almost negates the single source responsibility theories. London protocol finds Root cause Analysis grossly oversimplified as it almost does not give significance to contributing factors leading to an adverse event. London protocol is based on James Reason's model of organizational accidents.

London Protocol identifies problems that may have occurred during the Care Delivery Process (CDP), and any Contributory Factors present at the time of the incident. Care delivery problems are problems that arise in the process of care, usually actions or omissions by staff. Contributory factors include factors such as high workload, inadequate instruction, lack of skills, lack of knowledge, inadequate maintenance of building and equipment. These are the precipitating factors that can affect staff performance and patient's outcomes.

Some examples of **Care Delivery Process** include:

» Failure to monitor patient adequately, observe or act upon some test results

» Incorrect decision such as the wrong drug prescribed for a particular situation

» Not seeking help when a patient's condition is deteriorating.

Many **Contributory Factors** may cause to a single CDP. The factors are listed below with examples:

» Patient factors e.g., the patient was very distressed or unable to understand instructions.

» Task and technology factors e.g., poor equipment design or the absence of protocols

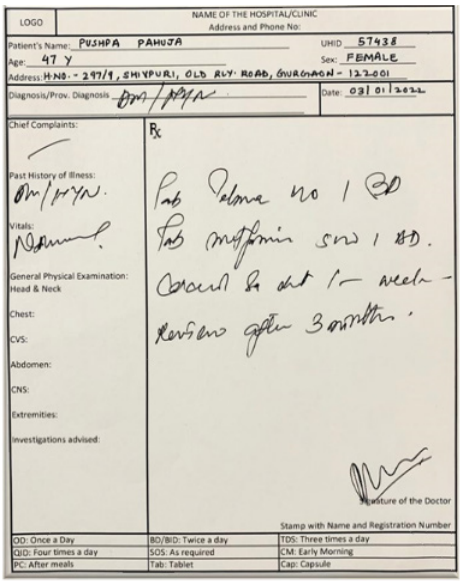
» Individual factors e.g., lack of knowledge or experience of particular staff

» Team factors e.g., poor communication between staff

» Work environment factors e.g., an unusually high workload or inadequate staffing.

1. Example

A 47-year-old female presents in the emergency with **hypotension** and other clinical manifestation of decreased tissue perfusion.
On Investigation it was found that she is a patient of **hypertension and diabetes** type II for the past 3 years and has been regularly visiting the department of medicine ever since.
Current complaints had started 3 days ago, after her visit to medicine department. When her prescription was checked it was found that her dose of B-Blocker was increased from OD to BD in the latest prescription she was carrying but there were no apparent reasons found for the change as her BP XXXXXXXXXXX.
A requisition was sent to the consulting doctor to enquire if her dose was doubled and if yes, reason were requested for the change. It was later found that doctor had not changed dose but apparently it looked like OD dose as "BD" dose.


LOGO
NAME OF THE HOSPITAL/CLINIC
Address and Phone No:
Patient's Name: PUSHPA PAHUJA UHID 57438
Age: 47 Y Sex: FEMALE
Address: H.NO.-297/1, SHIVPURI, OLD RLY. ROAD, GURGAON - 122001
Diagnosis/Prov. Diagnosis DM/HTN Date: 03/01/2022
Chief Complaints:
Past History of Illness: DM/HTN.
Vitals:
General Physical Examination:
Head & Neck
Chest:
CVS:
Abdomen:
CNS:
Extremities:
Investigations advised:
Rx
Tab Telma 40 1 BD
Tab Metformin SR 1 BD.
Consult Dr at 1 week
Review after 3 months.
Signature of the Doctor
Stamp with Name and Registration Number
OD: Once a Day | BD/BID: Twice a day | TDS: Three times a day
QID: Four times a day | SOS: As required | CM: Early Morning
PC: After meals | Tab: Tablet | Cap: Capsule

List of reasons	Applicable
○ Incorrect Diagnosis	✗
○ Prescribing Error	✓
○ Dose miscalculation	✗
○ Poor drug distribution practice	✓
○ Incorrect drug administration	✗
○ Failed communication	✓
○ Lack of pt. education	✓

Causes In this incident

- ○ Prescribing Error ✓
- ○ Poor drug distribution practice ✓
- ○ Failed communication ✓
- ○ Lack of pt. education ✓

Existing Controls

- ○ Verbal Communication with patient in OPD and Pharmacy
- ○ Rechecking of earlier prescription (Pharmacist & Doctor).

Failed due to overload of patients

RISK EXAMPLES

1

Hazard

Medication Error

Establish the context

Medicine OPD & Pharmacy

Identifying Risks

Prescription error & Drug Dispensing error

- Due to heavy workload and miscommunication between Patient-Doctor-Pharmacist

Assessment & Evaluation of Risk

Assessment of Risk

Pharmacy dispensing errors due to following reasons.

- ❖ Overload of patients
- ❖ Appalling handwriting
- ❖ Poor drug distribution practice
- ❖ Failed communication

Evaluation

Likelihood of dispensing errors is High : **Rating 4**
Severity of how damaging is the risk to lives, property and processes is High : **Rating 5**
Impact Factor: Likelihood Rating (4) x Severity Rating (5) = **20 High**

Mitigation

- ❖ Patient information and their medical history
- ❖ Drug information
- ❖ Communication of drug orders and other information
- ❖ Drug labelling, packaging, nomenclature
- ❖ Legible handwriting
- ❖ Medication device acquisition, use, monitoring
- ❖ Workflow, staffing pattern
- ❖ Staff competency and education
- ❖ Patient education
- ❖ Quality process

Risk Monitoring and Review

- ❖ Regular check of maintenance charts

2. Example

A 61-year-old male is admitted in the ward with complaints of pain in abdomen. Upon investigation, he is found to have acute cholelithiasis. He is operated for cholecystectomy after 2 days and is kept in Surgery IPD post surgery. He is given antibiotics and pain killers post surgery. 2 days after surgery, he is admitted to ICU as the patient was nonresponsive with unstable vitals. It was found that the patient fell from the bed at around 2 in the night.

List of reasons

Altered Physical status	Altered Mental status	Medications	Physical infrastructure
Seizure disorder	Inability to follow instructions	Narcotics	Slippery or wet floor
Impaired mobility	Confusion	Sedatives	Area under construction
Fatigue/ weakness	Disorientation to time, place or person	Psychotropics	Less lights
Dizziness	Lack of familiarity with immediate surroundings	Hypnotics	Cords/wire in the way
		Tranquilisers	Transfer of patient from bed to wheelchair to stretcher
			Absence of bed rails
			Absence of beds at low levels
			Absence of calling bell esp. for geriatric patient beside bed side and in bathroom
			Absence of grab bars

Causes
In this incident

- ✓ Absence of Bed Rails,
- ✓ Absence of Calling Bell,
- ✓ Absence of Bed at Low Levels ,
- ✓ Non-Education of patient's attendant of medication effects and side effects,
- ✓ Lack of supervision of Nurses on duty

Existing Controls

- Anti skid floor ,
- Presence of caution signages

Failed due to nonadherence to guidelines and unavailability of infrastructure

2

Hazard	Patient's fall
Establish the context	Surgery IPD
Identifying Risks	Injury on head due to Bed fall of a 61 year old patient post cholecystectomy
Assessment & Evaluation of Risk	**Assessment of Risk** ❖ Absence of Bed Rails, ❖ Absence of Calling Bell, ❖ Absence of Bed at low levels, ❖ Non-Education of patient's attendant of medication effects and side effects, ❖ Lack of supervision of nurses on duty **Evaluation** **Likelihood** of this incident- older patients may have an impaired mental status post surgery due to intake of painkillers is Medium : **Rating 3** **Severity** of this incident may have serious implications esp. for geriatric patient therefore is High : **Rating 5** **Impact Factor** : Likelihood Rating (3) x Severity Rating (5) = **15 High**
Mitigation	❖ Screening of patients d for intrinsic and extrinsic risk factors ❖ Patient and family education and regarding medication effects and side effects ❖ Bed side and trolley's rails up ❖ Strict implementation of nursing daily day and night assessment ❖ Presence of maintenance of emergency lights
Risk Monitoring and Review	❖ Review of all the fall cases ❖ Review of bed fall cases ❖ Identification of reasons of falls ❖ Review of execution of mitigation strategies ❖ Timely comparing of data of fall pre and post application of mitigation strategies

3. Example

An emergency officer complaint of verbal abuse and threats by family of the sick child admitted in emergency last night. The boy was brought to emergency preceded by 15 episodes of loose stools. His vitals were consistently deteriorating even after administration of IV fluids. Emergency officer at duty referred him to nearest medical college and ambulance was called at 11:30 at night on a central ambulance call center. Ambulance did not arrive until 02:00 am even after continuous reminders at call center. By then, patient's family and relatives gathered and started verbally abusing and blaming emergency officer for delay in ambulance and failed system. Officer somehow managed to escape the premises then but suffered anxiety for a long time and could not join hospital for a week's time after this event.

List of reasons

Patient and Setting related risk factors	Organisational Risk Factors
1. Working with patients with history of violence, drugs or alcohol, gang members, and relatives of such patients. 2. Communicating with parents or relatives who are already stressed and anxious because of illness of their loved ones. 3. Poor environmental design of workplace with less exits, poorly lit corridors and lack of emergency communication 4. Working in neighborhood with high crime rates 5. Breach in security system failing to detect knives and weapons with families and relatives of patients.	1. Lack of policies and staff training to recognize and manage hostile and assaultive behavior from patient's family and relatives 2. Working in understaffed situation 3. Inadequate security 4. Overcrowded premises and long waiting for patients 5. Unrestricted movement of public in hospitals 6. Inefficient referral system

Causes
In this incident

✓ Inefficient referral system,
✓ Lack of hospital policy and staff training
✓ Inadequate security
✓ Unrestricted movement of public in hospital

Existing Controls

- Calling facility available ,
- One security guard available but he was absent at the time of event

Failed due to unavailability at the time of the event

3

Hazard

Delay in Arrival of Ambulance

Establish the context

Emergency

Identifying Risks

Risk of physical abuse by patient's family and relatives because of failure in system.

Assessment & Evaluation of Risk

Assessment of Risk

- Inefficient referral system,
- Lack of hospital policy and staff training
- Inadequate security
- Unrestricted movement of public in hospital

Evaluation

Likelihood of this incident- Family and relatives of patient's brought in emergency are usually anxious and can be easily agitated is High: **Rating 4**

Severity of this incident may turn into an extremely critical situation in very less time therefore is High : **Rating 5**

Impact Factor: Likelihood Rating (4) x Severity Rating (5) = **20 High**

Mitigation

- Developing Workplace Violence prevention program and training staff on it.
- Maintaining a system of accountability for involved staff, supervisors and security personnel.
- Allocating sufficient resources to support violence prevention program
- Upgrading system and processes as per inputs from the staff on the ground level
- Ensuring a robust referral system and randomly checking its efficiency from time to time.

Risk Monitoring and Review

- Mock trainings on workplace violence prevention program
- Interviewing staff on knowledge on combating similar situations
- Ensuring availability of security staff especially in areas with more public engagement
- Random audits to ensure limited public movement

RISK REGISTER (Annexure-IV)

S #	Department	Date of Identification	Risk Title	Risk Description	Possible Cause	Likelihood Rating	Severity Rating	Impact Factor (Risk Profile)	Risk category	Risk Owner	Date of Assessment	Date of Resolve	Residual Risk	Date of surveillance	Risk Avoidance/Mitigation
1	Laboratory Services	6-Nov-21	Needle Stick Injury	Incidence of needle stick injury was reported three times in two months. Wherein, all the emergency measures were taken such as washing with soap and running water, reporting to immediate supervisor, PEP protocols were followed immediately after AEB, etc. But in 1 case – staff was found to be exposed to a blood sample of an HIV patient.		4	5	20	High	Dr ABC		10-Dec-21			
2	Indoor Patient Department	10-Dec-21	Injury by a sharp object	Incidence of injury by a sharp object was reported in the psychiatry IPD. On investigation, it was found that a patient, suffering from Schizophrenia and Acute depression, cut himself with a knife that was brought by the attendant for cutting fruits. This incident was reported to Supervisor in the psychiatry IPD and all immediate steps were taken to revive the patient.		2	5	10	Medium	Nurse XYZ					

DETAIL OF SECTIONS IN RISK REGISTER

1	Department	Name of the department where the risk has happened or is likely to happen
2	Date of Identification	When the risk was first identified in DD-MM-YYYY format
3	Risk Title	Broad category of the risk. Few examples have been added in the attached excel for reference.
4	Risk Description	Detail of the risk including description of incident , activity or hazard leading to risk or a sentinel event
5	Possible Cause	The most relevant and logical reason of occurrence of the risk
6	Likelihood Rating	How often can that risk happen or how higher are the chances of the risk getting repeated
7	Severity Rating	How damaging is the risk to lives, property and processes
8	Impact Factor (Risk Profile)	A result of multiplication of severity and likelihood factors . This factor describes the overall impact that particular risk can cause on the hospital
9	Risk category	Risk with an impact factor of more than equal to 15 have been termed as high category. Risk with an impact factor of more than equal to 8 until 15 have been termed as moderate category. Risks below 8 are termed as low category risks.
10	Risk Owner	Any person who takes the responsibility to mitigate or resolve the risk . Risk owner is not necessarily someone from that particular department only
11	Date of Assessment	When the risk was first assessed/evaluated in DD-MM-YYYY format
12	Date of Resolve	When the risk was mitigated to most achievable level and its non- recurrence was ensured in DD-MM-YYYY format
13	Residual Risk	Reduced impact factor after the mitigation strategies have been executed
14	Date of surveillance	When the risk was monitored or observed to identify if it has been mitigated to most achievable levels in DD-MM-YYYYY format
15	Risk Avoidance/Mitigation	Details of strategies applied to mitigate or resolve the risk including actions taken to avoid its recurrence in future

GLOSSARY: COMMON TERMS USED IN RISK MANAGEMENT

ACTIVE FAILURE	**Failures that are apparent and are relatively easily identifiable**
CONTROL	An intervention used to manage and treat risks
EXPOSURE	Extent to which an organization is subjected to an event
INCIDENT	Event in which a loss has occurred or could have occurred regardless of severity
INHERENT RISK	The intrinsic or a specific risk prior to considering any controls in place
LATENT FAILURE	Failures that hidden in nature and are identified only after critical analysis of the processes or a systemic overview
LEVEL OF RISK	Overall magnitude of a risk .It can be significant, high , moderate , low or very low .
NEAR MISS	Operational failure that did not result in a loss or give rise to an inadvertent gain
RESIDUAL RISK	Current risk. The risk remaining after risk treatment.
RISK ACCEPTANCE	Informed decision to take a particular risk
RISK ANALYSIS	Process to comprehend the nature of risk and to determine the level of risk
RISK APPETITE	Amount and type of risk that is desirable and the hospital is prepared to seek , accept or tolerate
RISK ASSESSMENT	Overall process of risk identification , risk analysis and risk evaluation
RISK AVOIDANCE	Decision to not to be involved in, or to withdraw from ,an activity that is based on the level of the risk
RISK MANAGEMENT	Coordinated activities to ensure patient and anyone involved in day to day's hospital functioning's safety.
RISK OWNER	Person or entity with the specific accountability and authority for managing the risks and any associated risk treatments.
RISK REGISTER	A record of information about identified risk
SENTINEL EVENT	Any unanticipated event in a healthcare setting that results in a death or a serious physical or psychological injury to a patient or patient's known, that is not related to natural course of patient's illness

LIST OF ABBREVIATION

AMC	Annual maintenance contract
ANC	Antenatal Care
CAPA	Corrective and Preventive Action
CHC	Community Health Centre
DALY	Disability-adjusted life years
DH	District Hospital
DQT	District Quality Team
EMO	Emergency Medical Officer
FMEA	Failure modes and effects analysis
GERD	Gastroesophageal reflux disease
HAI	Healthcare Associated Infection
HCW	Healthcare workers
HIV	Human Immunodeficincy Virus
ICTC	Integrated Counseling & Testing Center
ICU	Intensive Care Unit
IPD	In Patient Department
ISO	International Organization for Standards
IV	Intra Venous
JCI	Joint Commission International
LAMA	Left Against Medical Advice
LMICs	Low and middle income countries
MO	Medical Officer
MOHFW	Ministry of Health and Family Welfare
NQAS	National Quality Assuranec Standards
Ob&G	obstetrician-gynecologist
OPD	Out Patient Department
OT	Operation Theatre
PEP	Post exposure prophylaxis
PHC	Primary Health Centre
QC	Quality Circle
QMS	Quality Management System

QT	Quality Teams
RMF	Risk management Framework
RMP	Risk management Plan
SOP	Standard Operating Procedure
TLD	Thermoluminescent Dosimeter
UPS	Uninterruptible power supply
WHO	World Health Organization

BIBLIOGRAPHY

1. Assessor's Guidebook for National Quality Assurance Standards in District Hospitals, 2020 Volume I.
2. Assessor's Guidebook for National Quality Assurance Standards in District Hospitals, 2020 Volume II
3. Assessor's Guidebook for National Quality Assurance Standards in District Hospitals, 2020 Volume III.
4. Australian/New Zealand Standard. AS/NZS ISO 31000:2009, Risk management-Principles and guidelines; 2009.
5. Health Service Executive. Risk assessment tool and guidance; 2008.
6. ICH Guideline Q9 on quality risk management, European Medicines Agency, 2015
7. IEC 31010, Risk management — Risk assessment techniques.
8. International Organization for Standardization, ISO 31000:2018. Risk management-guidelines; 2018.
9. International Organization for Standardization, ISO 9001:2015 Quality Management System.
10. National Quality Assurance Standards for Public Health Facilities, 2020.
11. Quality risk management principles and industry case studies (December 2008) sponsored by the Product Quality Research Institute Manufacturing Technology Committee (PQRI-MTC).
12. Risk Analysis in Healthcare Organizations: Methodological Framework and Critical Variables.
13. WHO Technical Report Series No. 1025, 2020.
14. WHO Technical Report Series No. 981, 2013.

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