Alexandria Patient Safety Alliance

For Safer Hospitals and Practice

Introductory Booklet

Clinical Risk Management

Including FMEA

2011

APSA

CONTENTS

Risk management

Definitions

Risk management is the identification, assessment, and prioritization of risk followed by corrective action to minimize or control the probability of its occurrence in the future.

In risk management the term "risk" is used to mean simply the probability of something, usually harmful, happening while the term hazard means the event, or source, or situation that caused the harm.

Why conduct risk management?

The benefits of integrating risk management into clinical practice are many such as:

1. Helps in creating a safety culture
2. Improves patient safety
3. Improves understanding and communication within healthcare team
4. Improves quality of care
5. Reduces complaints
6. Helps in accreditation and revalidation

How to guarantee a successful risk management program?

The following issues are vital to settle before attempting to introduce a risk management program:

1. Leadership commitment
2. Patient safety culture
3. Active incident reporting system
4. Adequate resources (human and financial) to support the program
5. Audit system to ensure that the program is delivering its intended output

When is risk management useful?

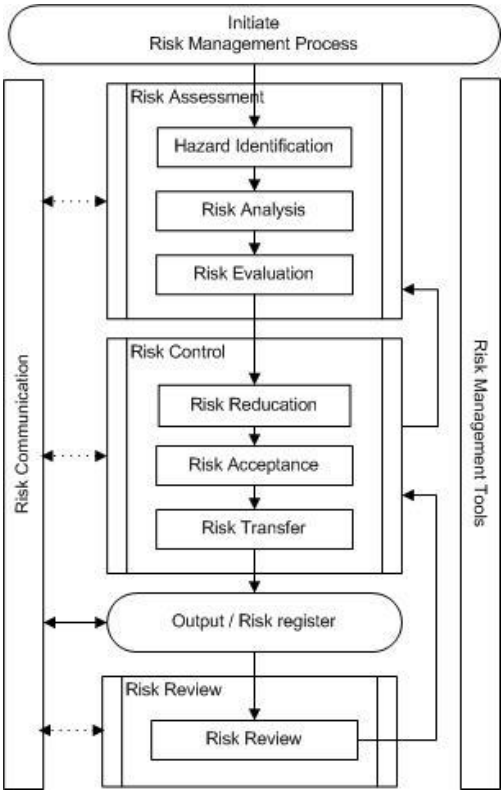
1. When introducing a new process
2. When redesigning an already ongoing process
3. Evaluating the safety of an ongoing process

Approaches to risk management

Risk is part of everyone’s daily life. Clinical practice is no different and is full of risks to both patients and their carers. Traditionally risk management was reactive in its approach; waiting for the harm to happen then seeing how to prevent it from happening again. Nowadays, a more proactive approach is required where hazards are identified and the risk of harm anticipated and measures taken to prevent it or lesson its effects.

Framework for risk management

Basically risk management is composed of two consecutive steps; **risk assessment** followed by **risk control**. The following figure illustrates the various components of risk management.



Integral to the framework is risk documentation, communication and review. The output of risk assessment and recommended controls are usually documented in a **risk register**. **Risk communication** is the sharing of information about risk between those involved in the program and all parties involved in patient care. Parties are expected to communicate at all stages of the program but essential is the communication of the risk management output as shown by the solid arrow in the framework which is facilitated by the risk register..

To ensure that the risk management program output is leading to an equivalent or acceptable increase in patient safety level a **risk review** process (re-risk assessment) of related adverse events is necessary which is then documented in the risk register for better monitoring.

If such audit finds that the risk is still high a reconsideration of the risk control measures becomes essential and if that does not lead to risk reduction the risk assessment process might need to be re-initiated.

Risk Assessment

Risk assessment is formed of three steps. The first step is to identify the hazards (what may go wrong?). Second, to know what are the consequences of this risk and how often could this risk happen. Third, involves a decision regarding the need for further action to be taken against the specific risk based on quantitative or a qualitative description.

1. Hazard Identification (What may go wrong?)

There are several methods that can be used in identifying hazardous clinical processes that carry high risk to patient safety (see table below). Once a process is identified, it is mapped and broken down into its component steps. In doing so, the events that may lead to patient harm (hazards) can be further identified and related to each step.

Hazard identification

Adverse event reporting
Complaints and law suits
Medical records review
Observation of practice (work space and procedures performed)
Mortality and morbidity meetings
Patient and health care staff interviews
Patient safety organizations

2. Risk analysis (How serious and how often?)

Risk analysis is the estimation of the risk associated with the identified hazard. Each step of the chosen process is analyzed by answering the following three questions. First, what are the consequences of the event if it happens and second how often is it expected to recur and third how easily can it be detected?

In answering the first question the next consequence table can be used.

Consequence Rating

Descriptor	**Impact**
5 – Catastrophic	Death Continued ongoing long-term effects at time of discharge Many > 50: Vaccination error
4 – Major	Permanent injury Increase in length of hospital stay by > 15 days Moderate 16 – 50: Lost specimens
3 – Moderate	Semi-permanent injury Increase in length of hospital stay by 4-15 days Small 3 – 15
2 – Minor	Short term injury Increase in length of hospital stay by 1-3 days 1 – 2
1 – Insignificant	No injury No increase in hospital stay N/A

Other factors can be taken into account and integrated into the consequence table such as cost of the risk, impact on the service, impact on the organization, etc.

In answering the second question the following likelihood table can be used.

Likelihood Rating

Descriptor	**Description**
5 – Certain	Will undoubtedly happen/recur possibly frequently Expected to occur at least daily >50 percent
4 – Likely	Will probably happen/recur but it is not a persisting issue Expected to occur at least weekly 10-50 percent
3 – Possible	Might happen or recur occasionally Expected to occur at least monthly 1-10 percent
2 – Unlikely	Do not expect it to happen/recur but it is possible it may do so Expected to occur at least annually 0.1-1 percent
1 – Rare	This will probably never happen/recur Not expected to occur for years <0.1 percent

In answering the third question the following detection table can be used.

Detectability Rating

Descriptor	**Description**
5 – Remote	Detection not possible at any point in the system 0-5 percent
4 – Low	Error rarely detected before reaching patient 6-39 percent
3 – Moderate	Error infrequently detected before reaching patient 40-74 percent
2 – High	Error frequently detected before reaching patient 75-94 percent
1 - Very high	Error will almost always be detected 95-100 percent

3. Risk evaluation (Do we need to do something?)

Risk evaluation considers the evidence presented through the previous step (risk analysis) and a decision is taken either to take action to control the risk if considered high enough or no action if the risk is considered low. In addition, risk evaluation can help safety teams prioritize a set of risks that have been identified thus facilitating the

selection of the most significant ones for their treatment (risk control). There are two methods that can be used for risk evaluation

Risk Matrix

A risk matrix will plot risk consequence against risk likelihood to reach an estimate or grade for the risk. Each institution should decide on the level (grade) at which the risk is considered unacceptable and that necessary measures are needed. Furthermore, such a matrix can aid in deciding what management level should be involved in the risk control and how rapid should the response be.

The following risk table can be used to help reach a decision:

	Consequence				
Likelihood	1 Insignificant	2 Minor	3 Moderate	4 Major	5 Catastrophic
5 - 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

Risk	Low	Moderate	High	Extreme
	1-3	4-6	8-12	15-25

Criticality Index

The Criticality Index (CI) also known as the Risk Priority Number (RPN) is a numerical grading of the risk and can be used in prioritizing risks prior to the selection of the most significant ones for control. The CI can be calculated using the following formula:

CI = L X C X D

Where L: likelihood

C: Consequence

D: Detectability

Risk Control

Ideally all risk should be eliminated but in reality this is not possible. However, certain steps can be taken to minimize the likelihood of its occurrence, lessen its consequences and increase its detection. This can be done through the following:

1. Risk reduction

This is the main line of dealing with any risk in clinical practice. Risk reduction aims at preventing the risk from happening and either minimizing its harmful effects or preventing it from reaching the patient in case its occurrence could not be prevented.

2. Risk acceptance

If the risk cannot be totally eliminated and the consequences are minimum then it can accepted as part of practice, however, all involved should be made aware of such risk and trained to deal with such risk effectively in order to minimize any harm resulting from it.

3. Risk transfer

If the facilities and expertise available are limited then by transferring the service to another unit that is more equipped and trained the risk is minimized. This also applies to the involvement of insurance companies in the management of highly complex and costly treatments.

The following table is a summary of methods of risk control:

Risk Control

Avoidance	Identifying and implementing alternative procedures or activities to eliminate risk.
Contingency	Having a pre-arranged plan of action that will come into force as and when the risk occurs.
Prevention	Putting in place measures to stop a problem from occurring or having impact on a work area or organization.
Reduction	Taking action to minimize either the likelihood of the risk developing or its effects
Transference	Transferring the risk to a third party.
Acceptance	Tolerating the risk when its likelihood and impact are relatively minor, or when it would be too expensive to mitigate it.

Risk register

A risk register can be described as a log or repository of the various risk assessments and control performed within an organization. It is a dynamic document which enables the organization to understand its comprehensive risk profile. It provides a structure for collecting information about risks that will assist both in the analysis of risks and in decisions about whether or how these risks should be controlled, managed and monitored.

Risk Management Tools

There are many tools that can be used for effective risk management as shown in the table.

Risk Management Tools
Risk management facilitation methods (flow charts, check sheets, etc)
Failure Mode Effects Analysis
Healthcare Failure Mode effects Analysis
Failure Mode Effects and Critically Analysis
Hazard Analysis and Critical Control Points
Hazard Operability Analysis
Preliminary Hazard Analysis
Barrier analysis and risk controls
Supporting statistical tools

Failure Mode Effect Analysis (FMEA)

FMEA is the analysis of a process to identify the possible ways it might fail (failure mode), the effects of these failures, possible causes of these failures and to identify control measures that will prevent or minimize such failures in the future.

FMEA steps

1. Form of a multidisciplinary team
2. Select a high risk process for analysis
3. Describe and map the process
4. Identify ways in which the process could fail (fail to perform its desired function)
5. Identify the possible effects of each failure
6. Identity any controls already in place for failure detection
7. Prioritize the various failures identified
8. Determine causes of failures identified
9. Redesign the process to minimize the risk of failures and their effects on patients
10. Pilot, implement, and audit the redesigned process

Step 1

Multidisciplinary Team

To guarantee a successful outcome from FMEA the formation of a multidisciplinary team is essential. Keep the number small around 5 – 7 individuals. Teams usually include physicians, nurses, risk managers or patient safety managers in addition to any other specialty related to the process to be analyzed. Pharmacists when dealing with medication safety, surgeons when dealing with surgical safety, blood bank technicians when dealing with blood transfusion safety, etc.

Step 2

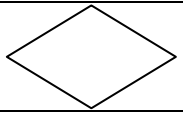
Selecting the process

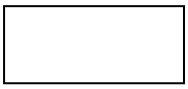
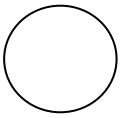
The process is usually chosen from hospital information on adverse or sentinel events or from recommendations produced by patient safety organizations (see risk identification).

Step 3

Map the process

It is essential for the success of FMEA that all members of the team understand the process to be analyzed. In doing so, the process is traced from its point of initiation until its completion. It is also advisable to break down the process into its components parts. Skills related to drawing flow charts are most helpful in this step. Below are some basic shapes that are used in the construction of a flow chart.

Start / end 	Decision 

Process 	Connector 

Step 4

Failure Mode

Evaluate each component of the process and determine what could go wrong with the related process. This step can be done through a series of "What if" questions and brainstorming between team members in order to define the various potential failures in the process and how often do they occur (see risk analysis).

Step 5

Effect Analysis

The effects of each failure have to be determined and their impact on patients or the organization defined (see risk analysis).

Step 6

Controls

The same is performed for the identification of any controls or safeguards already in place that help in the detection of each failure mode identified (see risk analysis).

FMEA sheet I can be used with step 4 to step 6.

Step 7

Prioritization

Prioritize the failure modes identified using the criticality index (see risk evaluation and FMEA sheet II) to identify those that pose the greatest threat to patients or the organization. If a large number of failure modes are identified, it is more effective to address the highest rated failure modes initially. The rest of failure modes are addressed later in descending order. Solutions to the failure modes with the high ranking may be also solutions to less significant failure modes. Some organizations establish a "cut-off" criticality index to establish which failure modes will be addressed.

Step 8

Causes

Determine through open discussion possible causes and predisposing factors for the identified failures. The use of Reason's error diagram or a fish bone diagram may help in the analysis.

Step 9

Improvement

For each failure mode selected identify actions required to decrease the corresponding criticality index which should lead to one or more of the following:

1. Decrease the likelihood of the failure to occur
2. Minimize harm resulting from the failure
3. Increase probability of its detection before reaching the patient

Step 10

PDSA cycle

Once improvement steps have been identified an action plan is developed to implement the suggested improvements. Before full scale implementation it is advisable to pilot the new action plan. After full scale implementation data is recollected and analyzed to make sure that the improvements introduced have lead to an increase in the process safety (decrease in Criticality Index).

Failure Mode Effect Analysis Sheet I – Criticality Index

Process: **Date:** **Page:** **of**

Process step	Failure Mode	L	Effect of failure	C	Current controls	D	CI

L: likelihood, C: consequence, D: detectability, CI: Criticality Index

Failure Mode Effect Analysis Sheet II – Priority Ranking

Process

Rank	Process step	Failure Mode	Criticality Index

Failure Mode Effect Analysis Sheet III – Criticality Index

Process: **Date:** **Page:** **of**

Process step:

Failure Mode: **Current Criticality Index:**

Effect of failure: **Current Controls:**

Causes	Solutions	Verification	Officer	Target Date	Done Date	New CI			
						L	C	D	CI

L: likelihood, C: consequence, D: detectability, CI: Criticality Index