"Most of the evil in this world is done by people with good intentions." – T.S. Eliot

"RISK MANAGEMENT"

.....risk identification

analysis and

mitigation

The concept of risk is not new

Gamblers and investors
Finance
Manufacturing
Service industry
Transportation
Airlines
Insurance

They all try to mitigate

The concept of risk is not new

Gamblers and investors
Finance
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It is new to us

Healthcare (1970s)

Patient safety programs (2000)

Medical laboratories (2003)

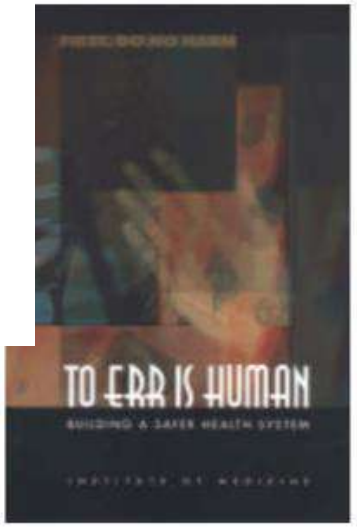
November 1999

INSTITUTE OF MEDICINE

Health care is a decade or more behind many other high-risk industries in its attention to ensuring basic safety.

ure for Health

TO ERR IS HUMAN
BUILDING A SAFER HEALT



Health care in the United States is not as safe as it should be--and can be. At least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented, according to estimates from two major studies. Even using the lower estimate, preventable medical errors in hospitals exceed attributable

Risk: Chance of something happening that will impact the objectives

Riscare: to dare (latin)

Risk is the effect of uncertainty on objectives (ISO 31000:2009 Risk management – Principles and guidelines)

ISO 14971: Medical Devices – Application of Risk Management to Medical Devices

CLSI EP18-A2 Risk management techniques to identify and control error sources

CLSI EP23-A (2011) Laboratory QC based on risk management

Harm: Physical injury or damage to health of people

Hazard: Potential source of harm

Mitigate, mitigate and mitigate…

Sten Westgard (2005)

- Put simple, risk is the possibility of suffering harm
- Risk is omnipresent in healthcare

more so in diagnostic services

- *Risk management is the art* of
    - figuring out the possible outcomes
    - planning for these outcomes

Risk mitigation is science

If **quality** asks

"How do we do the right things right?",

Risk management asks

"What can go wrong and what can we do about it?"

…….Mitigate and mitigate……

The AB perspective (ISO 15189:2012)

4.10 (FRACAS), 4.11 (FMEA)

4.12: Improvement activities are to be directed at areas of highest priority based on risk assessment

4.13 n) – Risk management records

The NABL perspective (ISO 15189:2012)

The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken

(4.14.6 Risk management)

The AB perspective (ISO 15189:2012)

4.15.2 Review input

The input to management review shall include information from the results of evaluations of at least the following:

a) the periodic review of requests, and suitability of procedures and sample requirements (see 4.14.2);

b) assessment of user feedback (see 4.14.3);

c) staff suggestions (see 4.14.4);

d) internal audits (see 4.14.5);

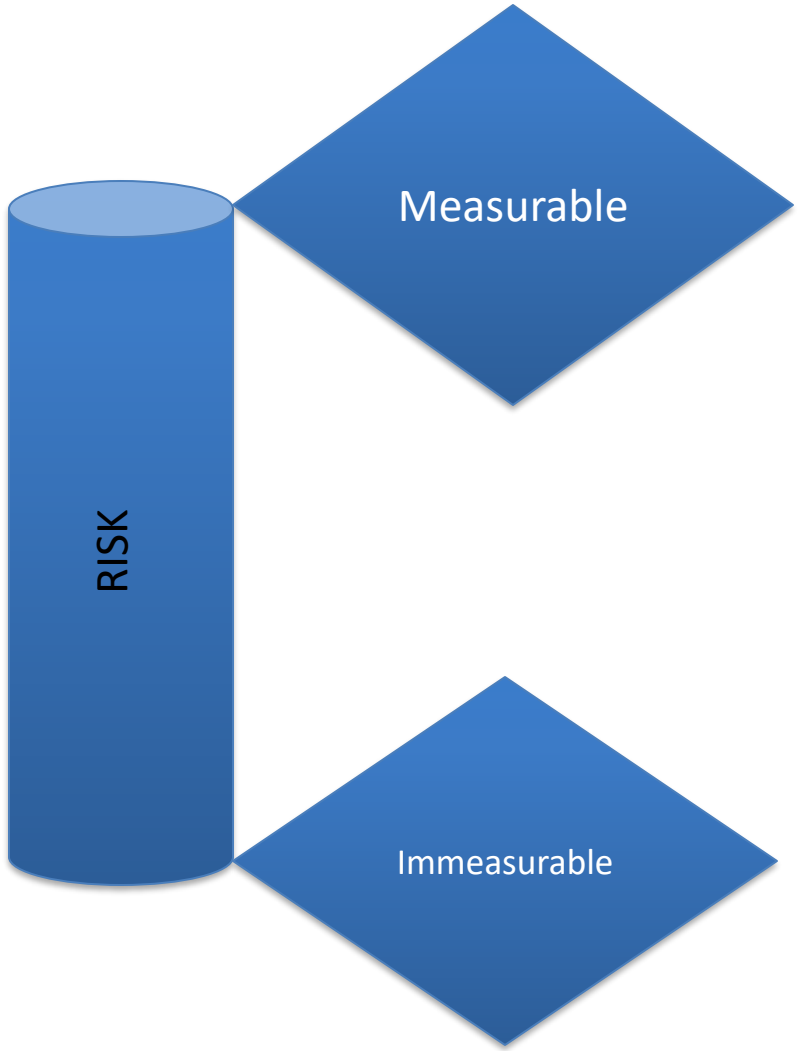
e) risk management (see 4.14.6)

f) use of quality indicators (see 4.14.7);

g) reviews by external organizations (see 4.14.8);

h) results of participation in interlaboratory comparison programmes (PT/EQA) (see 5.6.3);

- One can never completely predict a cause or outcome
- Risk is not a fixed measurement. Small causes may have big effects (down streaming)
- Greater the interval between cause and effect, the less likely the relationship is recognized
- Reduce element of surprise by increasing information



Risk and the Medical Laboratory

- Clinical decisions are made on the results of analysis
- Poor information leads to adverse outcomes
- Variables are many – some controllable, others difficult to control and still others that we cannot foresee
- Laboratory is often seen as the source of the problem regardless of contributing events

Risk footprint of Medical Laboratory

Medical Laboratory Standards on Quality and Risk

Deming cycle

- Plan for Risk
- Identify Risk
- Examine for Impact
- **Mitigation strategies**
- Monitor & Control outcome

Decision making

- High risk does not necessarily mean “avoid”
- Low risk does not necessarily mean “forget about it”

Risk level sets the responsibility matrix for RISK DECISION MAKING

What impacts RISK DECISION making?

Source of information to identify risk / hazard

- From manufacturer
- From patient satisfaction surveys
- From technical records (QC, Calibration, Maintenance)
- From process mapping and brainstorming
- From other lab records
- From gap analysis using standards

Risk mitigation involves **taking action to reduce an organization's exposure to potential risks and reduce the likelihood that those risks will happen again**. ... Risk mitigation is one of the steps in risk management, which includes identifying the risk, analyzing the risk, and mitigating the risk.

Identification------analysis-------**mitigation**

RISK MITIGATION

Risk mitigation is the process of **planning** for **PREVENTING WRONGS HAPPENING IN THE DIAGNOSTIC CENTERS** and having a way to lessen negative impacts **IN THE DIAGNOSTIS AND TERATMENT PROTOCOL**.

There are five general steps in the design process of a risk mitigation plan:

Identify all possible events in which risk is presented. A risk mitigation strategy takes into account not only the priorities and protection of mission-critical data of each organization, but any risks that might arise due to the nature of the field or geographic location. A risk mitigation strategy must also consider organization's employees and their needs.

After identifying perform

Perform a risk assessment, which involves quantifying the level of risk in the events identified. Risk assessments involve measures, processes and controls to reduce the impact of risk.

Prioritize, prioritize, prioritize…….

Prioritize risks, which involves ranking quantified risk in terms of severity. One aspect of risk mitigation is prioritization -- accepting an amount of risk in one part of the organization to **better protect another**. By establishing an acceptable level of risk for different areas, an organization can better prepare the resources needed.

Risk is dynamic

Track risks, which involves monitoring risks as they change in severity or relevance to the organization. It's important to have strong metrics for tracking risk as it evolves, and for tracking the plan's ability to meet compliance requirements.

What is implemented need to be monitored

Implement and monitor progress, which involves reevaluating the plan's effectiveness in identifying risk and improving as needed. In medical laboratory, testing a plan is vital. **Risk mitigation is no different**. Once a plan is in place, regular testing and analysis should occur to make sure the plan is up to date and functioning well. Risks facing data centres are constantly evolving, so risk mitigation plans should reflect any changes in risk or shifting priorities.

Types of risk mitigation strategies

The four types of risk mitigating strategies include **risk avoidance, acceptance, transference and Risk Monitoring/limitation**.

•**Risk avoidance** is used when the consequences are deemed too high to justify the cost of mitigating the problem. For example, an organization can choose not to undertake certain testing activities or advisery practices to avoid any exposure to the threat they might pose. Risk avoidance is a common diagnostic strategy and can range from something as simple as limiting acceptance to something as severe as not offering services.

•**Risk acceptance** is accepting a risk for a given period of time to prioritize mitigation effort on other risks.

•**Risk transfer** allocates risks between different parties, consistent with their capacity to protect against or mitigate the risk. One example of this would be a wrong result generated with some amount of third-party material. The producer of the producer of the result may transfer responsibility for a certain fraction of the risk because of this.

•**Risk monitoring** is the act of watching projects and the associated risks for changes in the impact of the associated risks.

Risk mitigation best practices

- **Make sure stakeholders are involved at each step.** Stakeholders may be employees, managers, management, clinicians and patients. All perspectives are important for developing a comprehensive, holistic risk mitigation strategy.
- **Create a strong culture around risk management.** This means communicating the values, attitudes and beliefs surrounding risk and compliance from the top down. It's important for every employee to have risk awareness, but the probability of a strong culture is greatly improved when management sets the tone.
- **Communicate risks as they arise.** Risk awareness must be strong throughout the entire organization, so facilitating communication of new, high-impact risks is important to keep everyone up to speed.
- **Ensure risk management policy is clear** so employees are able to follow it. Roles and responsibilities should be clearly defined, and each defined risk needs a clear process for dealing with it.
- **Continuously monitor possible risks.** Risk monitoring practices should also be clearly defined and implemented to continuously improve the risk mitigation plan.

Risk mitigation tools

Some other commonly used risk mitigation tools are:

A probability and impact matrix.

A SWOT (strengths, weaknesses, opportunities, threats) analysis.

A root cause analysis.

Source of information to identify risk / hazard

The following five strategies can be used in risk mitigation **planning and monitoring. Assume and accept risk. Avoidance of risk.**

...

Watch and monitor risk.

1. Assume and accept risk. ...
2. Avoidance of risk. ...
3. Controlling risk. ...
4. Transference of risk. ...
5. Watch and monitor risk.

Mitigation strategies in MDL

Examples of mitigation strategies include: **hazard specific control activities in vital areas of MDL such as resource management (5.1,5.2 & 5.3), process control (5.4, 5.5, & 5.7) and information management** (rest of the Technical Clauses of ISO 15189 :2012

Source of information to identify risk / hazard for mitigation

- From manufacturer
- From patient satisfaction surveys
- From technical records (QC, Calibration, Maintenance)
- From process mapping and brainstorming
- From other lab records
- From gap analysis using standards

Documentation and recording …. to

- Demonstrate that process is correctly managed
- Provide evidence of a systematic approach to identification and analysis
- Complete knowledge database
- Provide decision makers with plan for approval
- Provide an accountablity mechanism and tool
- Facilitate monitoring and review
- Provide an audit trail
- Share and communicate information

“Risky” management situations

- Loses sight of patient and focuses solely on revenue and cost reduction
- Does not understand the needs of the laboratory
- Has not defined a goal / objective for the organization and the laboratory

RISK MITIGATION

....IS

POSSIBLE

THE ONLY
LIMITS IN
LIFE ARE
THE ONES
YOU
MAKE