Risk Management in the Medical Laboratory:
Reducing Risk through Application of Standards

Michael A Noble MD FRCPC
Chair, Program Office for Laboratory Quality Management
University of British Columbia - Vancouver BC Canada
Michaelanoble@gmail.com
Today’s Discussion on
Risk Reduction through Application of Standards

• Risky Scenarios
• Risk Books and Standards
• Risk Definitions
• Risk Management Tools
• Severity – Occurrence
• Summary
• Conclusions
Scenario 1

- A medical laboratory, acting in response to community demand, introduces a new molecular test, but without functional validation.
- It becomes apparent there are many false positives and false negative results that lead to wrong diagnosis and poor treatment decisions and poor patient outcomes including deaths.
- The community becomes engaged which results in an official public enquiry.
- Millions of dollars are spent.
- Reputations are damaged.

Commission of Inquiry on Hormone Receptor Testing
St. John’s, Newfoundland and Labrador, Canada
March 1, 2009.
Scenario 2

- A medical laboratory introduces a new test for sexually transmitted infection that is technically easier than the standard test.
- Despite the knowledge that the test has poor specificity, the test is used both for patient testing and patient screening.
- Many patients are incorrectly identified as having sexually transmitted infections. Unfortunately information is released and patient harm results.
- Patients seek redress through litigation.
- Community reputation is harmed.
What these scenarios have in common

Unhappy outcomes as a result of

unrecognized or unmanaged

RISK
Lots of Very Useful Books on Risk

- Peter L. Bernstein
  - Against the Gods: The Remarkable Story of Risk
  - 1998
- James Reason
  - Managing the Risks of Organizational Accidents
  - 2000
- J. Davidson Frame
  - Managing Risk in Organizations
  - 2003
- Dan Gardner
  - Risk: Why we fear the things we shouldn’t—and put ourselves in greater danger.
  - 2008
- Roberta Carroll
  - Risk Management Handbook for Healthcare Organizations
  - 2009
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Published International Standards on Risk Management

- **ISO 14971:2007**
  Medical devices -- Application of risk management to medical devices
- **ISO/TS 22367:2008**
  Medical laboratories -- Reduction of error through risk management and continual improvement
- **ISO 31000:2009**
  Risk management -- Principles and guidelines
- **ISO/IEC 31010:2009**
  Risk management – Risk assessment techniques
- **MIL–STD–882D:2000**
  Department of Defence – Standard Practice: System Safety
- **ISO Guide 73**
  Risk management — Vocabulary
- **(CLSI EP23-A)**
  Laboratory Quality Control Based on Risk Management (2011)
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The Study of Risk

The word RISK is a derivative from Latin *riscare* (to dare).
Risk Management became reality when humans realized that they could “dare the gods” and aspire to their own goals.

Peter L. Bernstein
Against the Gods: The Remarkable Story of Risk
1998
The concept of Risk is not NEW

- Gamblers and Investors
- Finance
- Manufacturing
- Service Sector
- Transportation
- Airlines
The concept of Risk is not NEW

- Gamblers and Investors
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- Service Sector
- Transportation
- Airlines

It’s just new to us!!

- Healthcare (1970s)
- Patient Safety Programs (2000)
- Medical Laboratories (2003)
What is Risk?

Risk is:

– the prospect of pain or the potential for gain
– the likelihood and impact of some potential outcome

– the effect of uncertainty on objectives

• ISO 31000:2009
• Risk Management – Principles and guidelines
  • an internationally recognised benchmark, providing sound principles for effective management and corporate governance.
Risk is a Management Nightmare

Uncertainty consists of two parts:
1 - Risk (which is measureable)
2 - Immeasurable Risk

Because we can only measure the “measureable risk” calculations are ALWAYS INCOMPLETE, and always in a way that we can never know how incomplete.

Knight, F. H. (1921)
Risk, Uncertainty, and Profit. Boston, Houghton Mifflin Company
Donald Rumsfeld said it better:
In 2002, when asked about the absence of evidence for terrorism, and WMDs

There are known knowns.
These are things we know that we know.
There are known unknowns.
That is to say, there are things that we know we don't know.
But there are also unknown unknowns.
There are things we don't know we don't know.
Modern Mathematics And Risk

- Game Theory and Chaos Theory

a. All events are cause and effect but often the cause is too obscure to be detected.
b. Cause and outcome may be non-linear or non-proportional. [small causes may have big effects]
c. The greater the interval between cause and effect, the less likely the relationship is recognized.
d. It is impossible to know every factor that can or will influence an outcome and
Downstreaming

A technologist sneezes

Another technologist turns to look
A key entry error is made

The sample is tested
The result is reported on the wrong patient
Impending renal failure is missed
Renal failure is missed
Patient dies

The fatal sneeze
What Game and Chaos Theory Teach about Addressing Risk

a. *You can never completely predict a cause or an outcome.*

b. *Risk is not a fixed measurement; it is mutable by events and susceptible to change.*

c. *Look to the best, but plan for the worst.*

d. *To the extent possible, reduce surprise by increasing information.*
Bad things happen...

- Organizational accidents are difficult events to understand and control. They occur very rarely and are hard to progress and foresee. To the people on the spot, they happen “out of the blue”.

- Difficult though they may be to model, we have to struggle to find some way of understanding their development to achieve gains in limiting their occurrence.

James Reason
Managing the Risks of Organizational Accidents
1997
Why Risk Management is important for medical laboratories

• We analyze many samples from which we derive information.
• The information impacts upon decision making and health of others.
• Poor information can lead to poor outcomes.
• Our samples have some variables that we can control, and others that are difficult to control, and others that we cannot either foresee or control.

• Regardless of contributing events, the laboratory is usually viewed as the source of the problem.
The Medical Laboratory Has a Wide Risk Footprint

- Patients
- Clinical Staff
- Laboratory Staff
- Institution
- Community
- Environment

Risks
Medical Laboratory Standards on Quality and Risk

- ISO 15189:2012
  Medical Laboratories: requirements for quality and competence

- ISO 22367: 2008
  Medical laboratories -- Reduction of error through risk management and continual improvement
Medical Laboratory Standards on Quality and Risk

Quality Management Framework

- ISO 15189:2012
  Medical Laboratories: requirements for quality and competence

Risk Management Framework

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Quality Management Framework
- Quality
- Competence
- Continual Improvement
- Prevention

Risk Management Framework
- Analysis and Calculation
- Risk Reduction
The Risk Management Framework

Plan
Do
Study
Act

Plan for Risk
Identify Risk
Examine for Risk Impact
Develop Risk Mitigation Strategies
Monitor and Control Risk Outcome

Deming Cycle
JUSE
1951

Managing Risk in Organizations
J. Davidson Frame
2003
Error – Risk Reduction Tools

• Quality Related
  Error Reduction through Monitoring, Detection, Remediation, Correction, Prevention, Internal Audit, Preventive Action Exercises, Internal Audit Checklist, External Assessment.

• Risk Specific
  Severity Outcome Grid
  Failure Mode studies
    Failure Mode Effects Analysis - (FMEA)
    Failure Mode Effects and Criticality Analysis - (FMECA)
  Hazard and operability study - (HAZOP)
  SWOT Analysis
  Computer Modelling - (Monte Carlo)
Error – Risk Reduction Tools

• Risk Specific

  - Severity Outcome Grid
  - Failure Mode studies
    - Failure Mode Effects Analysis - (FMEA)
    - Failure Mode Effects and Criticality Analysis - (FMECA)
    - Hazard and operability study - (HAZOP)
  - SWOT Analysis
  - Computer Modelling - (Monte Carlo)

Focus on Precision
Focus on Outcome
Failure Mode Effects Analysis

- Examine every step of the procedure or process.
- Consider every way in which it could fail.
- Develop an alternative strategies for each potential failure (new monitoring, new procedure).
- Reassemble the process with new safeguards in place.

*Thorough*
*Systematic*
*Lengthy*
*Detailed.*

*Useful in a setting where there is a lot of information and control*
Severity Outcome Grid

Consider only two major issues about potential negative outcomes

How terrible could the outcome be?
How frequent could it occur?

Less complete
Broad Brushstroke approach
Helpful to assist decision making

Useful in a setting where risk is a concern but circumstance and control is less rigid
Severity – Occurrence Analysis
Strategy Table

<table>
<thead>
<tr>
<th>SEVERITY</th>
<th>OCCURRENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW</td>
<td>LOW</td>
</tr>
<tr>
<td></td>
<td>HIGH</td>
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<tr>
<td>HIGH</td>
<td>LOW</td>
</tr>
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<td></td>
<td>HIGH</td>
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DEPARTMENT OF DEFENSE
STANDARD PRACTICE FOR
SYSTEM SAFETY

<table>
<thead>
<tr>
<th>Description</th>
<th>Level</th>
<th>Individual Item</th>
<th>Fleet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>A</td>
<td>Likely to occur often through the life of the item</td>
<td>Continuously experienced</td>
</tr>
<tr>
<td>Probable</td>
<td>B</td>
<td>Will occur several times in the life of an item</td>
<td>Will occur frequently</td>
</tr>
<tr>
<td>Occasional</td>
<td>C</td>
<td>Likely to occur some time in the life of an item</td>
<td>Will occur several times</td>
</tr>
<tr>
<td>Remote</td>
<td>D</td>
<td>Unlikely but possible to occur in the life of an item</td>
<td>Unlikely, but can reasonably be expected to occur</td>
</tr>
<tr>
<td>Improbable</td>
<td>E</td>
<td>So unlikely, it can be assumed occurrence may not be experienced</td>
<td>Unlikely to occur, but possible</td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
<td>Criteria</td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>-------------</td>
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<td></td>
</tr>
<tr>
<td>I</td>
<td>Catastrophic</td>
<td>Could result in death, permanent total disability, loss exceeding $1M, or irreversible severe environmental damage</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>Critical</td>
<td>Could result in permanent partial disability, injuries or occupational illness that may result in hospitalization of at least three personnel, loss exceeding $200K but less than $1M, or reversible environmental damage</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>Marginal</td>
<td>Could result in injury or occupational illness resulting in one or more lost work days(s), loss exceeding $10K but less than $200K, or mitigatable environmental damage.</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>Negligible</td>
<td>Could result in injury or illness without a lost work day, loss exceeding $2K but less than $10K, or minimal environmental damage that does not violate laws.</td>
<td></td>
</tr>
</tbody>
</table>
# Severity – Occurrence Analysis

**Strategy Table**


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- I: Catastrophic
- II: Critical
- III: Marginal
- IV: Negligible

A: Frequent
B: Probable
C: Occasional
D: Remote
E: Improbable
# Severity – Occurrence Analysis

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<td>?</td>
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<td>Negligible</td>
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### Legends
- **Severity**
  - I: Catastrophic
  - II: Critical
  - III: Marginal
  - IV: Negligible

- **Occurrence**
  - A: Frequent
  - B: Probable
  - C: Occasional
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---

**High**

**Serious**

**Medium**

**Low**
# Severity – Occurrence Analysis

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<td>Diagnostic false-negative ARO failure leading to missed nosocomial or community outbreak and laboratory closure. Environmental accident leading to laboratory closure.</td>
</tr>
<tr>
<td>II</td>
<td><strong>Critical</strong></td>
<td>Diagnostic false-positive special pathogen leading to reporting of pseudo-epidemic. Equipment/reagent failure leading to testing restrictions.</td>
</tr>
<tr>
<td>III</td>
<td><strong>Marginal</strong></td>
<td>PT failure requiring review of a test performance. Recurrent delay in release of STAT sample reports requiring RCA review.</td>
</tr>
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<td>IV</td>
<td><strong>Negligible</strong></td>
<td>Recurrent delay in release of routine samples reports requiring RCA review.</td>
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# Mishap Severity Categories (Proficiency Testing)

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<td>Catastrophic</td>
<td>Mass laboratory contamination leading to staff illness/death Unremitting contaminations resulting in program shutdown Closure/Damage suit costs greater than 3 X annual revenue</td>
</tr>
<tr>
<td>II</td>
<td>Critical</td>
<td>Sample selection leading to multi-laboratory epidemic TDG related environmental/community contamination Contamination costs greater than 15% annual revenue</td>
</tr>
<tr>
<td>III</td>
<td>Marginal</td>
<td>Sample errors leading to multi-laboratory formal complaints Biosafety hazard leading to 24 hour shut-down Contamination costs greater than 2% annual revenue</td>
</tr>
<tr>
<td>IV</td>
<td>Negligible</td>
<td>Sample includes 1-log greater or lesser pathogen concentration than planned. Delay in sample transport not exceeding 24 hours. Sample cost over-run greater than $2,000, but less than $4,000</td>
</tr>
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### Severity – Occurrence Analysis

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<td>E</td>
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<td>Medium</td>
<td>Low</td>
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#### Question?

- What do I do about HIGH risk?
- What do I do about MEDIUM Risk?
- What do I do about LOW risk?
Risk Level and Decision Making

High Risk does not necessarily mean Absolutely Avoid
Low Risk does not necessarily mean Forget about it

Risk Level sets the Level of Responsibility for RISK DECISION MAKING
Decision Making for Risk

The Higher the Risk Level, the higher the decision level.

The Lower the Risk Level, the more delegated the decision level.

Minister
Health Authority
Institutional CEO
Department Head
Administrative Head
Discipline Head
Supervisor
Decision Making for Risk

Factors that may impact

Risk Decision Making

Safety?
Cost?
Liability?
Confidence?
Reputation?
Alternatives / Choices
Can you Mitigate the Risk?
Can you Share the Risk?
Using an S-O Plot to drive Risk Mitigation
Severity – Occurrence Calculation

Mitigate Against Severity of Outcome by preventing critical reporting errors

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<tr>
<td>A (Frequent)</td>
<td>High</td>
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<td>B (Probable)</td>
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<td>Serious</td>
<td>Medium</td>
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<td>C (Occasional)</td>
<td>Serious</td>
<td>Medium</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>D (Remote)</td>
<td>Medium</td>
<td>Medium</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>E (Improbable)</td>
<td>Medium</td>
<td>Low</td>
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I: Catastrophic  
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ALL CRITICAL RESULTS MUST BE REVIEWED BEFORE RELEASE
Severity – Occurrence Calculation

Mitigate Risk of False Positive or False Negative Reporting Errors

Avoid screening tests on worried well by limiting testing only to people at risk. Do not test any sample that is outdated...ever.
### Severity – Occurrence Calculation

Mitigate Both Severity and Occurrence

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Working with Quality Partners can Help Reduce or Spread Risk

- Standards Development
- Accreditation
- Proficiency Testing
- Educator Bodies
- Suppliers
- Professional Organizations
If you plan to implement an S-O program…

• Risk management tools require a team effort and require some thoughtful time.
  – Don’t leave it as a single person task
  – Create a small team, if they don’t know specific information, they do know where to get it.
  – You can’t do create an effective Severity-Occurrence table (and an FMEA) in a hurry
An easy exercise for introducing risk management strategies...

• It is common in a routine bench internal audit that you will find 2, 3 or 4 OFIs.

• For each OFI ask the questions:
  – What can happen if I don’t fix this?
  – What is the likelihood or potential frequency of a bad outcome?
  – Plot out the potential outcomes on an S-O table.
  – Determine which should be the first priority to address.
In summary...

- Risk is the effect of uncertainty on outcomes.
- Risk is a mathematical concept, but cannot be solved by statistics.
- Modern mathematical theory indicates that the best strategies are those that reduce the opportunities for worst outcomes.
- Control the things you know, learn more about the things you know you don’t know, be diligent for those things that you didn’t know that you didn’t know.
- There are many situations where medical laboratories can benefit by introducing Risk Management Strategies.
Reality check...

- Accept that the nature of risk is uncertainty
  - Medical laboratory testing has a broad footprint and is fraught with opportunities for uncertainty.
  - There are likely far more unknown unknowns than known knowns.
  - A risk strategy **CANNOT** prevent all bad things from happening, **BUT IT WILL CATCH and PREVENT SOME**
  - Having a Risk Management strategy will **ALWAYS BE BETTER** than not having a Risk Management strategy
in conclusion...

When it comes to managing Risk...

Be aware
Be sensible
Do No Harm
(including to yourself)