Risk Assessment in Medical Laboratories

Irini D. Leimoni

Country Quality Assurance Manager & Data Protection Officer,

AFFIDEA Greece

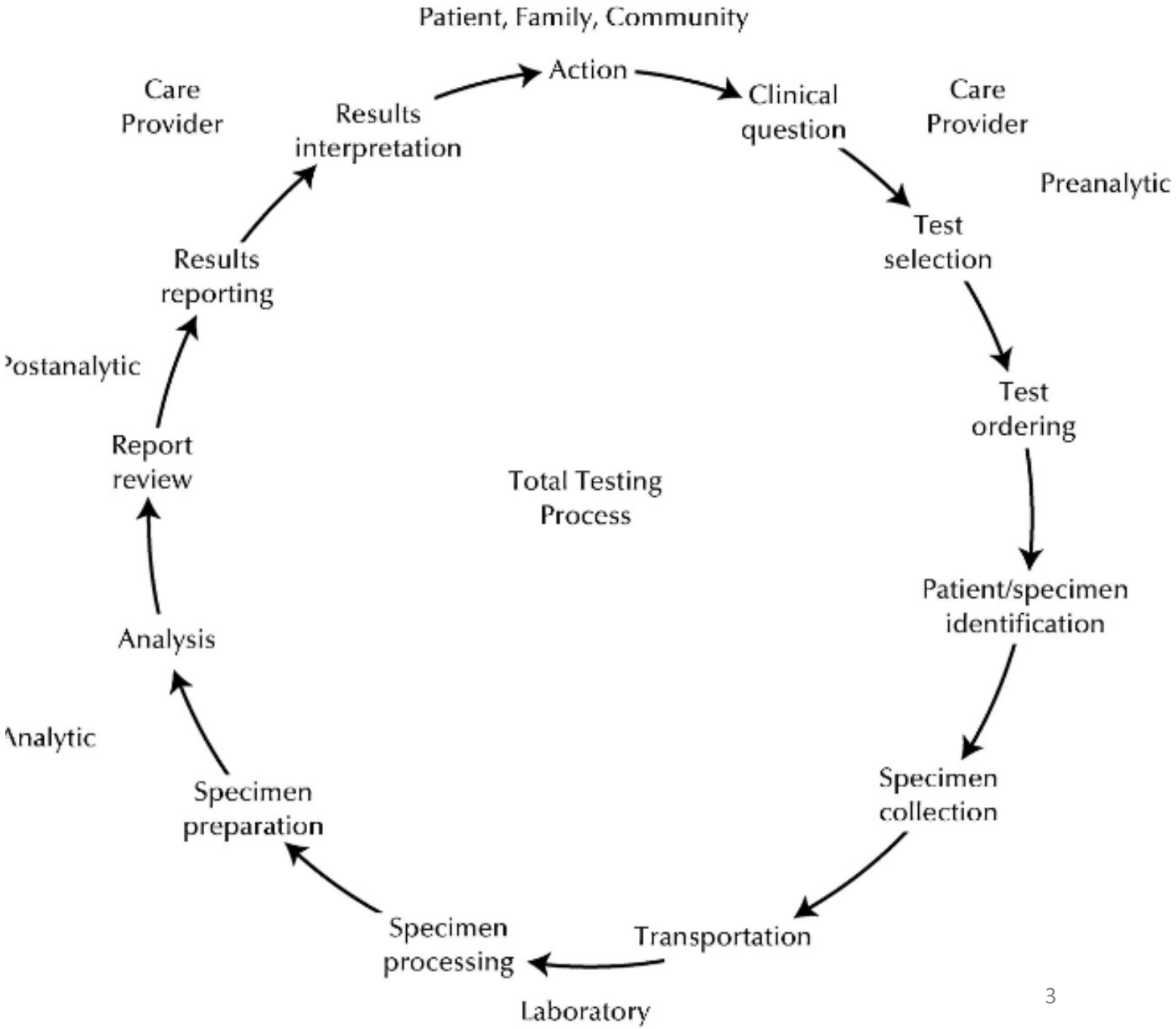
Contents

- Total laboratory process
- What is Risk?
- Risk Definitions
- Pre-analytical Laboratory Risk
- Analytical Laboratory Risk
- Post-analytical Laboratory Risk
- Failure Mode Effects Analysis (FMEA)
- Severity – Occurrence Analysis_Case

Total Laboratory process

- The clinical laboratory is increasingly integrated with patient care, assisting diagnosis, monitoring therapies and predicting clinical outcomes.

- There are many procedures and processes that are performed in a laboratory



What is Risk?

Combination of the probability of occurrence of harm and the severity of that harm

- **hazard** – potential source of harm
- **harm** – physical injury or damage to the health of people
- **severity** – measure of the possible consequences of a hazard

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 can not either foresee or control.

The Medical Laboratory has a wide Risk footprint

The Risk Management Framework

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

Risk Definitions

- **Risk analysis** – systematic use of available information to identify hazards and to estimate the risk

- Information from the manufacturer
- Information from patient satisfaction surveys
- Information from technical records (QC, Calibration, Maintenance)
- Information from process mapping and brainstorming
- Preanalytic, analytic, post analytic (ISO language: pre-examination, examination, post examination)
- Information from other laboratory records
- Information from gap analysis using accreditation or ISO standards
- Organizational information (agreements between organizations)

Risk Definitions

- **Risk assessment** – overall process comprising a risk analysis and a risk evaluation
- **Risk estimation** – process used to assign values to the probability of occurrence of harm and the severity of that harm
- **Risk evaluation** – process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk:
  - Failure mode and effects analysis (FMEA)

Risk Definitions

Risk management – systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk

Application of risk mitigation measures

- Frequency and character of quality control testing

- Training

- Accreditation to a recognized standard (ISO 15189:2012)

Contributors to Pre-analytical Laboratory Risk

- Information regarding pre-analytical steps or processes that could affect the quality of the result may be lacking.

- Can a sample be collected in a gel separation clot tube.

- What affects do gels have on the analytical component if not properly centrifuged?

- "Ideal" conditions (type of sample, differences between collection tubes, anticoagulants, centrifugation RPMs and time) for the sample are often not described by the manufacturer.

- Adequate patient preparation/instruction may not be given.

- Transport of medical samples from collection sites to the analytical laboratory, especially when the analytical laboratory is some distance from the site of collection.

Measures to Minimize Pre-Analytical Laboratory Risk

- Urge professional societies to educate laboratories about key information that should be provided by or asked of manufacturers.
- Require the patient condition/diagnosis be shared with the laboratory when tests are requested so that results can be evaluated in the medical context.
- Require documentation that patient has been given and UNDERSTANDS instructions to prepare for the test.
- Ensure that laboratory manuals/procedures are CURRENT.
- Countries need to adopt appropriate transport standards

Contributors to Analytical Laboratory Risk

- The analytical process is an integral part of the overall quality system. Its contribution is significant, but the laboratory should maintain focus on the overall system.
- There is often no appreciation for an individual's contribution to the quality of the test result.
- There is often NO PLAN for analytical quality.
- Laboratories that don´t follow maintenance and calibration instructions from manufacturers are risking their patients.
- Laboratories that do not validate the methods they use are risking their patients.

Contributors to Analytical Laboratory Risk

- There is limited understanding of QC theory and application.
- High staff turnover creates training challenges, and these must be addressed.
- Technical communications between laboratory staff at change of shift are often unclear or not given.

Measures to Minimize Analytical Laboratory Risk

- Each person performing testing should be made aware they can cause error with each action they may take.
- The culture of the laboratory needs to change from hiding errors and problems.
- Laboratories need to encourage staff to communicate problems to Management without fear of retribution.

Measures to Minimize Analytical Laboratory Risk

Laboratories should PLAN for quality. They should know the total error for each test (bias and imprecision) and what is acceptable/not acceptable.

Frequency of QC should be planned, particularly for:

-High volume laboratories

-Immediacy of treatment

- All patient samples should be treated with equal vigilance
- Some situations may require more vigilance however
- Critical lab specialties (blood banking, infectious disease, molecular)

Contributors to Post-Analytical Laboratory Risk

- Validation of the test result may be performed by someone other than the person who performed the test. Sometimes, staff do not communicate key information regarding the result.
- Lack of information technology (LIS, QC Software) in the laboratory. Lack of these technologies often increases transcription errors and decrease efficiencies and delay of treatment while waiting for printed reports.
- The laboratory should have documented procedures for result validation and ensure these procedures are followed.
- Management should provide resources to implement information technologies that will improve both efficiency and quality in the laboratory.

Contributors to Post-Analytical Laboratory Risk

- There needs to be regular retrospective review of QC data to identify weaknesses in the control of the analytical process.
- Laboratories should determine the reference range for their laboratory based on the instrumentation/methods they use and the community they serve (gender and age).
- When two or more instruments/methods are used to produce results for the same test, the laboratory must demonstrate the comparability of results and reference range for those instruments/methods.
- Laboratories need to have a formal mechanism to communicate results, both critical values and others, to the physician.


Surveys
Six Sigma
Lean
Statistics
Metrics
RISK
FMEA
The Quality Toolbox

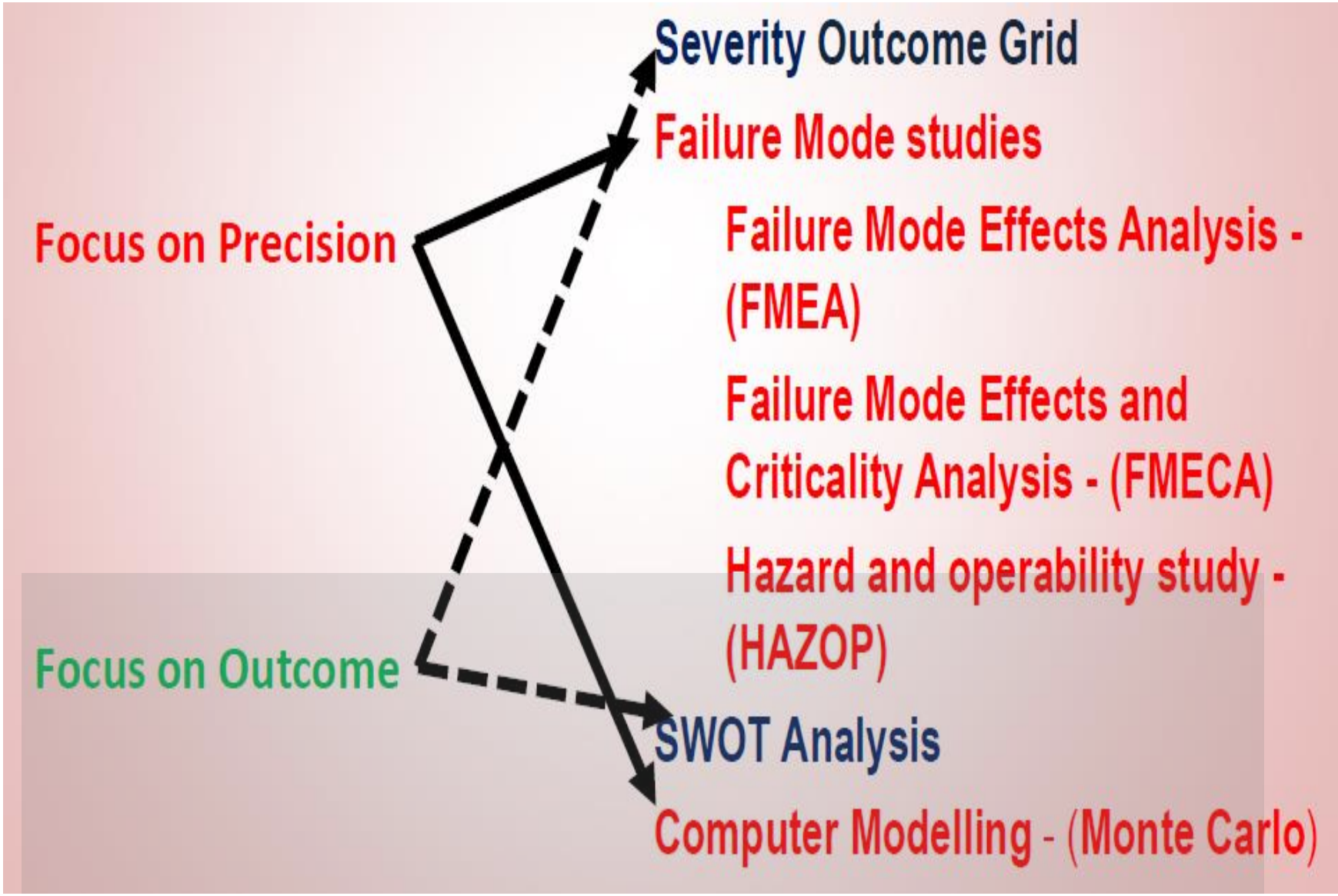
Published International Standards on Risk Management

- **ISO 14971:2007** (Medical devices - Application of risk management to medical devices)
- **ISO/TS 22367:20**08 (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:200**0 (Department of Defense – Standard Practice: System Safety
- **ISO Guide** 73 (Risk management – Vocabulary)
- **(CLSI EP23-A)** (Laboratory Quality Control Based on Risk Management (2011)

Never forget…

- You can never completely predict a cause or an outcome.
- Risk is not a fixed measurement; it is mutable by events and susceptible to change
- **Look to the best, but plan for the worst**.
- **To the extent possible, reduce surprise by increasing information**

Risk Reduction Tools



Failure Mode Effects Analysis

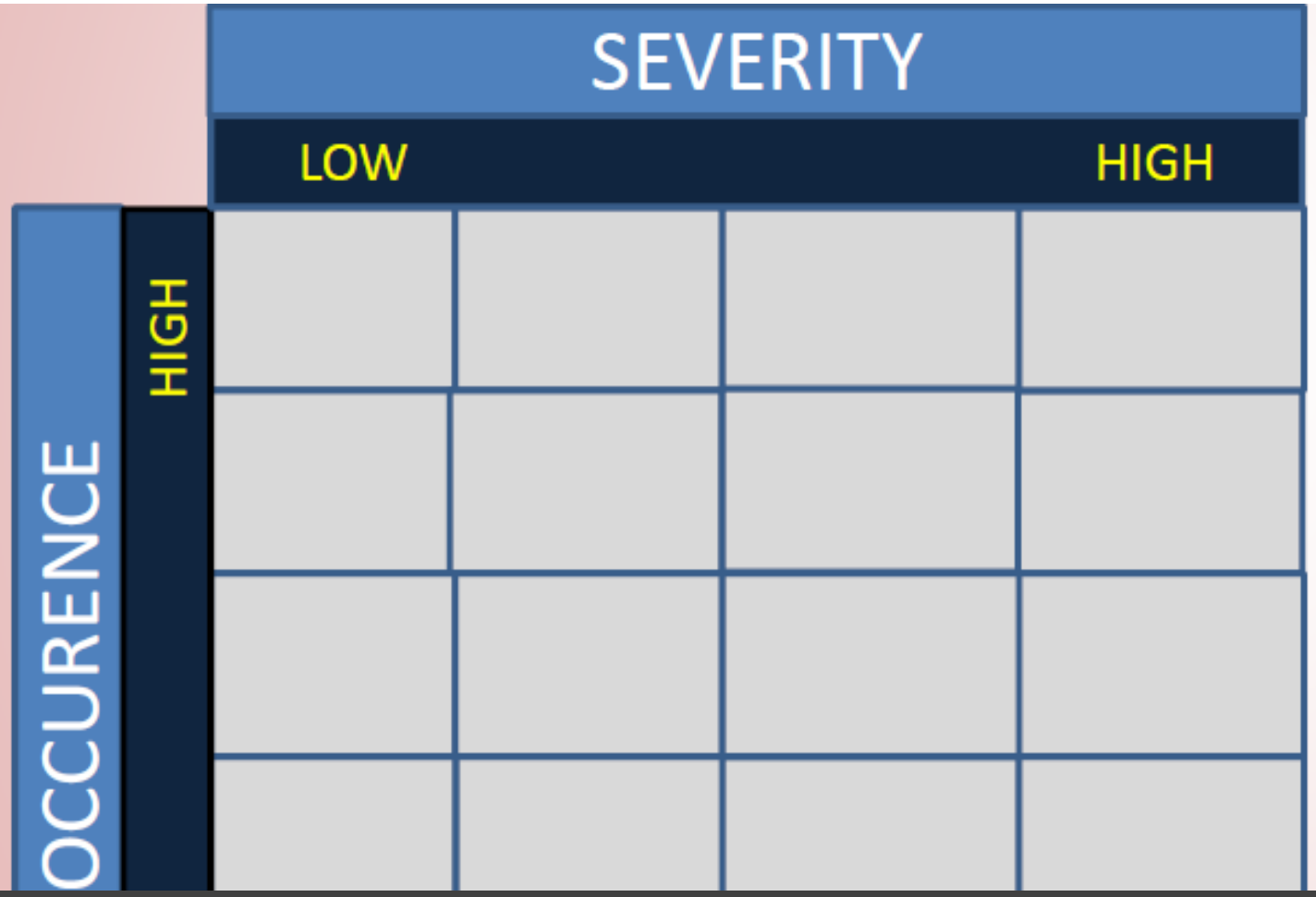
(FMEA)

- 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.

Severity Outcome Grid

Consider only two major issues about potential negative outcomes

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



(MIL–STD–882D:2000)
DEPARTMENT OF DEFENSE
STANDARD PRACTICE FOR
SYSTEM SAFETY

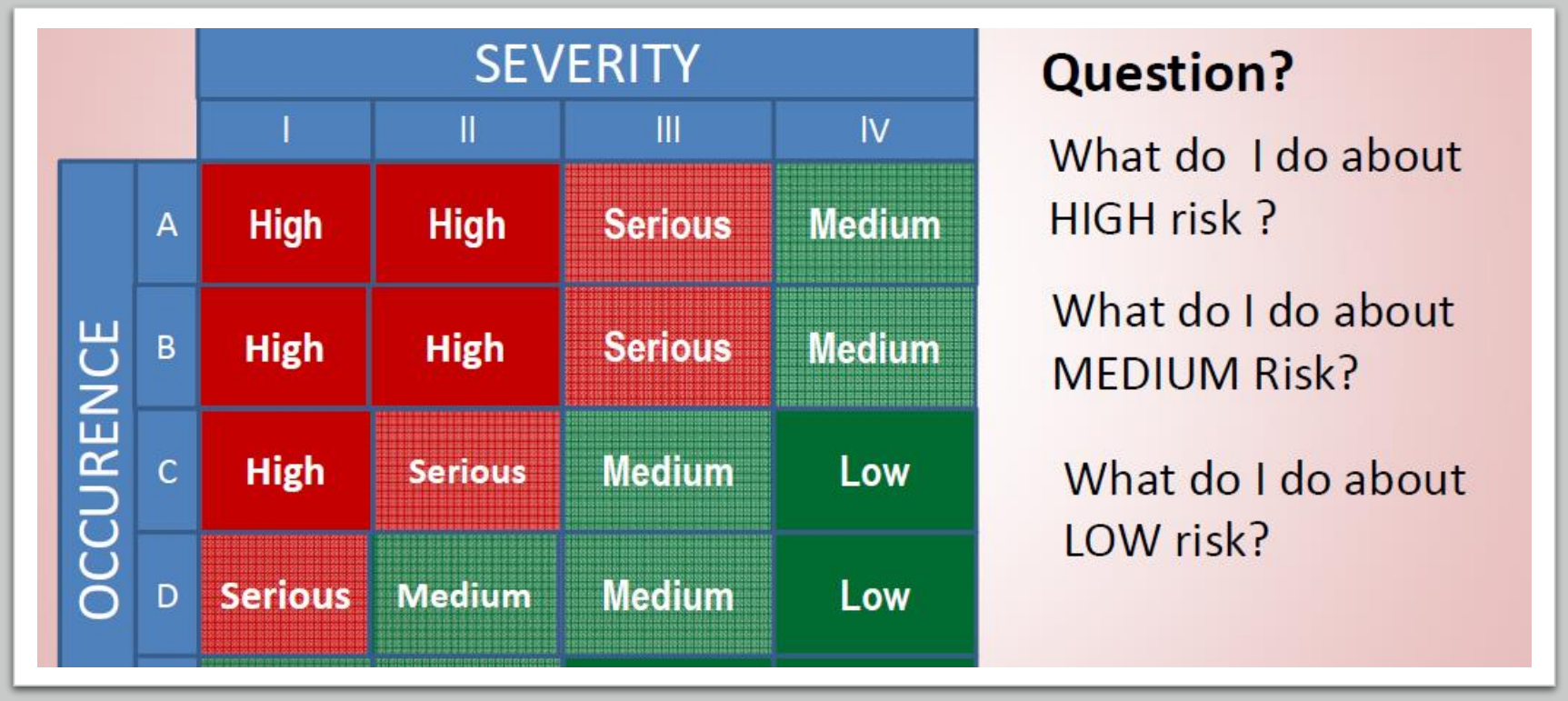
Severity – Occurrence Analysis

Failure Probability Levels (MIL–STD–882D:2000)

Description	Level	Individual Item	Fleet
Frequent	A	Likely to occur often through the life of the item	Continuously experienced
Probable	B	Will occur several times in the life of an item	Will occur frequently
Remote	C	Likely to occur some time in the life of an item	Will occur several times
Occasional	D	Unlikely but possible to occur in the life of an item	Unlikely, but can reasonably be expected to occur
Improbable	E	So unlikely, it can be assumed occurrence may not be experienced	Unlikely to occur, but possible

Mishap Severity Categories (Microbiology Laboratory)

Category	Description	Criteria
I	**Catastrophic**	Diagnostic false –negative ARO failure leading to missed nosocomial or community outbreak and laboratory closure. Environmental accident leading to laboratory closure
II	**Critical**	Diagnostic false-positive special pathogen leading to reporting of pseudo-epidemic. Equipment/reagent failure leading to testing restrictions
III	**Marginal**	PT failure requiring review of a test performance. Recurrent delay in release of STAT sample reports requiring RCA review.
IV	**Negligible**	Recurrent delay in release of routine samples reports requiring review



Severity – Occurrence Analysis

- 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 priority to address.

Risk Matrix

RISK OUTCOME

- Low
- Moderate
- Significant
- High

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

Risk Matrix

Frequency:

- 1 - Low = Practically impossible (appearance rate: <5%)
- 2 - Medium - Low = not likely to occur (appearance rate: 5-20%)
- 3 - Medium = could show up (appearance rare: 20-30%)
- 4 - Medium - High = Has appeared in the lab (appearance rate: 30-40%)
- 5 - High = common occurrence (appearance rate: > 40%).

Severity:

- 1 - Low = negligible severity
- 2 - Medium - Low = can lead to a client / doctor complaint
- 3 - Medium = can lead to wrong medical decision
- 4 - Medium - High = can lead to wrong medical decision with negative consequences for the patient
- 5 - High = can cause death (fatality)

Risk Matrix

Risk Significance:

1-5: LOW
6-10: MEDIUM-LOW
11-15: MODERATE
16-20: MODERATE-HIGH
21-25: HIGH

Risks rated below 10 shall be controlled by the necessary measures.

Risks rated above 10 are considered unacceptable and need to be addressed through the development of preventive measures

Risk Assessment _ Case

PHASE	RISK	PREVENTIVE ACTION	FREQUENCY	SEVERITY	SIGNIFICANCE	RISK OUTCOME	CORRECTIVE ACTIONS
Pre-analytical	Inappropriate or inadequate sample	A relevant Working Procedure with sample quantity information	1 1 lipemic & 1 hemolyzed blood sample out of 21.286 samples: 0.009%	2	2	LOW	No need
Pre-analytical	Incorrect or insufficient vial marking	A relevant Working Procedure	1 No case	4 No case	4	LOW	No need
Pre-analytical	Wrong Biological Substrate (e.g. serum, urine, plasma)	Updated Working Procedures, easily available to patients & staff	1 1 sample out of 21.286 samples: 0.0046%	4	4	LOW	No need

Risk Assessment _ Case

PHASE	RISK	PREVENTIVE ACTION	FREQUENCY	SEVERITY	SIGNIFICANCE	RISK OUTCOME	CORRECTIVE ACTIONS
Analytical	Detection of gel in the sample	Visual check of samples, prior the measurement	1 2 samples out of 11.430 full blood count: 0.017%	4	4	LOW	No need
Analytical	Failures of external quality control-not further investigated	Strict implementation of the criteria for the QC acceptance rules	1 7.5% failures-effectively investigated	4	4	LOW	No need

Working with Quality Partners can Help Reduce or Spread Risk


© Original Artist
Reproduction rights obtainable from
www.CartoonStock.com
CENTER FOR THE STUDY OF "MURPHY'S LAW"
CLOSED TODAY BECAUSE EVERYTHING THAT COULD GO WRONG, DID GO WRONG.
SCHWADRON

Thank you very much !!!