Discussion Table 4
Risk Management in the Clinical/Medical Laboratory
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What is Risk?

• Combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51)
  
  – hazard – potential source of harm (ISO/IEC Guide 51)
  
  – harm – physical injury or damage to the health of people (ISO/IEC Guide 51)
  
  – severity – measure of the possible consequences of a hazard (ISO 14971)
Risk Definitions

**Risk analysis** – systematic use of available information to identify hazards and to estimate the risk (ISO/IEC Guide 51)

- 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 (ISO/IEC Guide 51)

Risk estimation – process used to assign values to the probability of occurrence of harm and the severity of that harm (ISO 14971)

Risk evaluation – process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk (ISO 14971)
  – 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 (ISO 14971)

- Application of risk mitigation measures
  - Frequency and character of quality control testing
  - Training
  - Accreditation to a recognized standard
Contributors to Pre-Analytical Laboratory Risk

- Information regarding pre-analytical steps or processes that could affect the quality of the result may be lacking.
  - EG: Can a sample be collected in a gel separation clot tube.
  - EG: 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

- MESSAGE: 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.
- Some Latin American laboratories do not routinely report interfering substances to the physician (EG: Icterus, Lipemia).
Measures to Minimize Analytical Laboratory Risk

- Each person performing testing should be made aware they can cause error with each and every 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.
  - Such communications should at least be recognized.
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)
  • Insufficient competency (low volume tests)
Measures to Minimize Analytical Laboratory Risk

• Labs must UNDERSTAND, it is not just testing QC, it is understanding the theory and application of QC.
• Laboratories and Management must provide or support continuing training and education programs.
• Some form of competency assessments should be performed regularly and at least two times per year. Labs with high turnover should probably have more frequent assessments.
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 (EG: 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.
Contributors to Post-Analytical Laboratory Risk

- Laboratories do not always retrospectively analyze QC data for shifts, trends, total error.
- Laboratories do not always verify or have correct reference ranges for interpretation of test results.
- Sometimes laboratories produce results for the same test using two different instruments/methods without accounting for differences between the two instruments/methods.
Measures to Minimize Post-Analytical Laboratory Risk

• 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.

• There needs to be regular retrospective review of QC data to identify weaknesses in the control of the analytical process.
Measures to Minimize Post-Analytical Laboratory Risk

- Laboratories should determine the reference range for their laboratory based on the instrumentation/methods they use and the community they serve (e.g., 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.
Regulatory Contributors to Laboratory Risk

- Some governments have no rules or regulations for certifying all components of test systems (reagents, hardware, software)
  - Reagents could be made in someone’s garage and that would be legal.
- If a government has no enforcement mechanism, rules and regulations can be ignored.
- If a particular country is not a member of ISO, laboratories in that country are unable to influence rules, regulations and guidances for laboratories and medical devices.
Regulatory Contributors to Laboratory Risk

• When a country is a member of ISO, laboratory professionals do not actively participate because they are not aware of the opportunity or there is no financial assistance to participate.

• Giving results directly to a patient creates a point of risk if no controls are in place to assure proper use and interpretation of the result. Some tests (e.g., HIV) should require the patient to visit the laboratory or physician to obtain the result.

• Sometimes Government requires certain testing to be done under specific circumstances but does not regulate that testing.
Measures to Minimize the Risk Associated with Regulations

• Laboratories should implement programs for PUBLIC education about laboratory services and tests. The patient is our reason for existing as a laboratory so our obligation to the patient is great.
  – Use the internet.
• Laboratories should also have education programs targeted to the medical staff that use the laboratory’s services.
• Professional societies should work with Government to accomplish change.
• Laboratories should identify which tests, if any, can be reported directly to the patient.
• Government must regulate laboratory testing.
Management’s Contribution to Laboratory Risk

• MESSAGE: If Management loses sight of the patient and focuses solely on revenue and cost reduction, poor decisions can be made.

• Management does not always ask for or understand the needs of the laboratory.

• Management does not always have a defined goal or objective for the overall organization. As a part of the organization, laboratory operations do not always match Management objectives.

• Sometimes Management delegates responsibility for POCT programs to others outside the laboratory.
Measures to Mitigate Management’s Contribution

• Implement a quality system
• Obtain accreditation
• Retain responsibility for POC programs.
Controlling Risk in Areas of Complex Testing

- Areas of complex testing include but are not limited to:
  - Infectious disease
  - Blood banking
  - Genetics
  - Molecular

- Should the laboratory’s approach to risk management vary for these areas?
  - Need a process flow map of activities in areas of complex testing to identify potential hazards.
    - Need to identify unique active and passive risks in these special testing areas.
    - EG: airflow, prevention of contamination, segregation of samples to avoid mixup
    - EG: lack of control materials for some of the tests in these special areas of testing puts the quality of results at risk.
Role of the Laboratory in Patient Care

• The laboratory is central to patient care.
• Sometimes the laboratory loses sight of the patient and fails to follow-up with the patient or the physician.
Measures to Improve Laboratory Image and Involvement

• Regular meetings with physicians to discuss, analyze laboratory usefulness and problems during the last period.
  • Improve feedback from physicians
    • The impact of results on treatment and diagnosis
    • Clinical correlations
• Mechanisms should be put in place to PERSONALIZE the patient to laboratory staff.