

Perspective

Risk based quality management: the way forward to improve quality in medical laboratories

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Key words: accreditation, safety, risk, quality management

Abstract

Risk based quality management is not new. Many different standards including CLSI standard EP23-A, ISO 14971, ISO 31000, and ISO 22367 address risk management in laboratories. Risk and safety are addressed in quality management systems, introduced to provide accreditation and recognition of health care institutions. Laboratory quality is different from other quality targets as quality of a test report begins and ends with the same individual; the patient. Therefore, it is a closed loop having direct repercussions to the patient. In addition, medical laboratories are unique in safety as there are biohazards and chemical hazards. When managing laboratories, we should ensure patient safety as the top priority while ensuring safety of the employees and the environment. The latest version of ISO15189:2022 standard emphasises more on safety and risks. The probability of hazards occurring should be understood, and the repercussions of a risk should be given consideration. Combining probability of occurrence and repercussions of risks will enable laboratories to prioritise and plan actions. This

review is to provide insight on how quality management can be improved based on risk evaluation specially focusing on the ISO15189:2022 standard.

Introduction

Medical laboratories should ensure safety of patients by issuing reliable reports in a timely manner. The report should be of the same patient from whom the sample was collected. The report should carry correct information including measurement units, reference intervals, interpretations and recommendations. Can any of these go wrong? Yes, we come across ample records related to these failures. Now is the time to focus on risks associated with patient care. From a delay in generation of reports due to machine breakdown, internal quality control (IQC) failure to issuing of reports with incorrect information all carry risks to the patient which can be quantified. We need to manage and prevent occurrence of these in a proactive manner. This is the focus of ISO15189:2022 standard^{1,2,3}.

World Health Organization classifies safety levels and the general medical laboratories are categorised under safety level two. The medical laboratories handling highly virulent and infective microbes or viruses require level three facilities of biological safety.

Have you ever felt uncomfortable to walk or drive underneath a half-built bridge? Felt uncomfortable to walk near a falling tree? Climb up a very old ladder? If so, why? The answer is that you are worried about the related hazards and your safety, as you know you are at risk. When we work in health care institutions, we have a high risk of infection transmission. In a laboratory, in addition to infections, we get exposed to chemicals. Risks

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Conflicts of interest to declare:

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of fire, electric hazards, accidental falls and other physical injuries are almost the same as at home or office. Perhaps the fire hazard could be more with the usage of heating equipment, flammable gasses etc. Therefore, all these need to be included in the quality management program (QMP) of laboratories^{1,2,3}.

To begin with, we should first focus on a few definitions in risk management. What is harm? Harm is defined as injury or damage to the health of people, property or environment. Therefore we should eliminate, mitigate or control harmful elements in laboratories. What is hazard? Hazard is a source of potential harm. We fear to walk under a half-built bridge or to climb an old ladder, because they all are related to a potential harm or a hazard. What is risk? Risk is the combination of probability of occurrence of harm and the severity of the effect caused by that harm. Risk gives a weightage to a hazard. i.e. a risk shows the likelihood of occurrence of hazard and if ever occurs how dangerous it is going to be^{2,4,5,6,7}.

If we consider common and routine practices and requirements important to assure safety in medical laboratories, which of the following should be the priority to rectify and why?

1. Absence of an eye wash station.
2. Absence of fire alarms.
3. Absence of employee vaccination against hepatitis B.
4. Absence of critical or alert results informing system.
5. Absence of back up machine or process for a machine breakdown.
6. Absence of competency evaluation of employees for the tasks assigned.
7. Absence of policy and procedures for the acceptance of compromised samples.
8. Absence of preventive maintenance established fully as per the manufacturer's instructions.
9. Absence of calibration at least once, upon installation of an automated full count analyser.

You would agree that rectifying all these is important. However, you cannot prioritise them unless you have a procedure to prioritise them. ISO 22367: 2021 standard gives insight on how to apply risk management to medical laboratories, and how to prioritise and control them.

Imagine a hypothetical laboratory having all the above listed nine issues. Where should we begin? Can we give a weightage to the potential harm of each safety issue mentioned? Can we tolerate and accept the risk and continue surveillance? When making decisions, 'gut feeling' or instinct may be valid in some circumstances, but without objectivity, we are unable to standardise a situation and take appropriate action against it. Thus, objective decision making is a necessity when taking actions.

How do we recognise potential hazards and risks?

Hazards of medical laboratories are documented in literature and in textbooks. Yet, those are generic. Practices between laboratories can vary. Therefore, risks must be individualised and focused to each laboratory. The important tools for recognition of harm or potential failures or potential risks in a laboratory include following;

1. Customer complaints.
2. Incident records.
3. Failure investigations.
4. Audits.
5. Nonconformity reports.
6. Publicly available incident data of similar laboratories.
7. Standards and practice guidelines.
8. Expert opinion.
9. Literature.

Having a comprehensive system to obtain, evaluate and rectify customer complaints appropriately in a timely manner provides a laboratory an opportunity to evaluate hazards. Traumatic venepuncture, not giving proper instructions on patient preparation, delay in release of results, errors in reports, failure to inform critical results

within 20 minutes to the clinician or to the patient, and delay in collecting blood for a request labelled urgent are few potential examples of customer complaints which address very important patient safety issues. Based on each complaint, the laboratory should perform risk analysis. In addition, documentation of every complaint is important as it gives objective evidence of occurrence such as where, when, how, by whom, and why it occurred. This is the foundation for continual improvement when planning to prevent or control the occurrence of these risk related activities. In addition, laboratories should develop a comprehensive surveillance to foresee potential patient harm to take preventive measures. Preventive actions should be proactive and evidence based. Sound evidence on the potential harm may be obtained from literature, incidence data of other laboratories, instinct or professional judgement of experts^{1,2,3,5,6,7,8,9,10}.

What do we do with identified risks?

Identified risks should be analysed, evaluated, controlled, eliminated, mitigated, re-evaluated to and continuously monitored. In risk evaluation, a decision is made on whether the risk is acceptable or not. Titan underwater expedition could have been stopped if they evaluated the measurable or potential risk of implosion by several underwater expeditions. They focused only on the technical success of continuous manoeuvring and the number of repeated successful trips. They ignored the potential wear off, pressure related weaknesses of carbon fibres etc.

In risk analysis, the first decision that should be taken is whether the risk is acceptable or not. Acceptance of a deteriorated sample and issuing a report on it can save a life or can totally mislead the clinical decision. Considering the urgency, testing of an under filled or overfilled sample received for coagulation tests will not give reliable results to support the management of a patient. Not only will the result be unreliable, but it will carry a risk too. However, under filled samples received for blood counts or blood picture should not necessarily be rejected. If it is from a neonate or from emergency care, the information obtained by analysis can be useful in the initial decision

making. In such instances, accepting compromised samples can be lifesaving. Therefore, the judgement of the acceptability of the risk should be an expert opinion and a well-informed opinion. If the risk is unacceptable, we must estimate how bad the effect will be and prioritise and plan the corrective or preventive actions.

Risk based quality management includes implementation of an appropriate and comprehensive risk based internal quality control program^{1,2,4,7,8,9,10}. Moving averages and sigma metrics also have been implemented successfully in small scale laboratories⁴. Online platforms of computer database and artificial intelligence related applications can also be incorporated easily into risk analysis.

The failure mode and effect analysis (FMEA) provide objective estimation of risks in routine practice. FMEA explores all the possible ways a procedure or a process can go wrong leading to failure or error generation. In medical laboratory practice, pre-analytical phase, analytical phase, and post-analytical phase are the key areas needing risk assessment^{2,3}. These areas are too broad and provide no directives on what to assess or where to focus. We have to break every process or procedure into smallest possible tasks and then consider all possible ways these can fail.

Table 1 gives an idea on few key steps in the pre-analytical phase and its potential failures.

In addition, fault tree analysis (FTA) is also applied in risk assessment. FTA starts from a hazard and analyses downward to find root causes. FTA can be built like a story, unravelling the causes one by one for each failure. In FTA, a fault tree diagram is created to identify failure events, initiators and contributors. Finally it helps to evaluate the relationship between failures and initiating events or contributing factors. These are prepared as flow charts using symbols to signify different components³. For example, if a fire had erupted, FTA is created to find the cause for fire ignition, cause for the LP gas leak, how the Bunsen burner was ignited, whether there was a gas leak sensor and if so why it failed, why the burner was not switched off when the flame was blown off by the

AC blower, why the last officer involved in wire loop sterilisation was compelled to respond to an urgent call, why there had been limited number of officers on duty, whether it was a holiday,

whether the emergency response team member to whom the task was assigned was in a remote place etc. In this way, the analysis generates a pyramid with associated factors for each failure.

Table 1. Potential failures in the pre-analytical phase

Process/step	Potential failure	Reason for failure	Consequences of failure
Test request generation	Failure in identifying and guessing the test	– Illegible handwriting	– A wrong test will be done – Delay in performing correct test as verification takes time
	Absence of important clinical information in the request form for blood picture	– Not updated on correct filling of test request forms – Lack of knowledge on the importance of giving clinical details – Busy clinic	– Inability to interpret or comment – Suggesting further unnecessary investigations
	Absence of sample collection for urine haemosiderin	– Not knowing the requirement	– Random sample collection instead of early morning first voided urine sample – False negative results
	All the above; test guessing when bill is generated, no clinical details and timing of sample collection	– The laboratory uses a bill generated by reception as the test request. – Laboratory receives the bill with list of tests. – No procedure to obtain a test request form	– All the above can occur as a consequence of using a reception generated bill as the test request received at the laboratory
Providing information on patient preparation	Collection of a non-fasting sample	– Information on fasting not available in the sample collection manual	– Collection of a random, non-fasting sample leading to error results generation
Sample tube filling	Failure to adhere to sample filling order	– PT/APTT tubes collected after EDTA tube using vacutainer	– Contamination of coagulation sample with EDTA – Incorrect PT /APTT results
Anticoagulant mixing	Inadequate mixing	– New phlebotomist is not aware about the correct procedure	– Sample rejection – Incorrect results (platelet/PT/APTT)

Once such data sets for each and every failure are completed, we should estimate the likelihood of occurrence of such failures and grade their consequences. There are many different risk matrices available. The laboratories can use any of those as per their discretion. For example, in the risk matrix given below which quantifies the risk (Figure 1), any value above 15 needs urgent attention.

If a particular laboratory rates the probability of occurrence of a failed test identification is due to illegibility of handwritten test requests, it is likely we would give a score of 4. Consequences of wrong test identifications can have many repercussions on the patients thus, we would give a score of 4 to that as well. Then the weighted risk is $4 \times 4 = 16$. As per the matrix adopted (Figure 1), 16 is above 15. Therefore, failed test identification is a high-risk scenario needing urgent attention. Thus, the laboratory should implement remedial actions immediately².

Introduction of a printed “check list – test request form” will eliminate the misidentification issue. The remaining risk after introduction of such test request forms can be considered negligible. Any action other than introduction of test request forms

such as contacting the doctor who has written the request to verify the test or getting help from the most experienced technical officer to read the request will carry a significant residual risk to the patient if the wrong test is performed.

A study conducted on risk management related to “not received samples” by Troiano et al. shows success in evaluating the errors. They have noted that more errors occur during night shifts and weekends. They have identified high patient load, less nursing staff, sleep deprivation and work-related stress as issues affecting error generation related to laboratory tests. They have proposed employee sensitisation on errors as an effective method of minimising errors¹².

When should laboratories conduct the risk analysis?

If a laboratory can perform a risk analysis using FMEA and risk matrix, it can plan continual improvement based on the risks identified. We describe this as risk-based quality management. However, as a routine practice, laboratories can implement risk analysis on following instances to prevent occurrence of serious risk related issues as a proactive measure.

5x5 Risk Matrix Example

Impact
How severe would the outcomes be if the risk occurred?

	Insignificant 1	Minor 2	Significant 3	Major 4	Severe 5
5 Almost Certain	Medium 5	High 10	Very high 15	Extreme 20	Extreme 25
4 Likely	Medium 4	Medium 8	High 12	Very high 16	Extreme 20
3 Moderate	Low 3	Medium 6	Medium 9	High 12	Very high 15
2 Unlikely	Very low 2	Low 4	Medium 6	Medium 8	High 10
1 Rare	Very low 1	Very low 2	Low 3	Medium 4	Medium 5

Probability
What is the probability the risk will happen?

Figure 1. An example of a risk matrix.

1. Before introducing a new test method, alteration of test method, purchasing a new analyser, or changing reagent brand.
2. Before recruitment of new members to the laboratory.
3. When there are any incidents, accidents, customer complaints.
4. Before renovations, shifting the laboratory to a new location.
5. Before changing key policies, procedures and processes affecting quality.
6. Before making any changes into key systems.

The way forward to strengthen laboratory network practices and standardisation

This needs leadership through professional organisations. Wisconsin laboratory network USA, shows a successful story on effective implementation of activities such as establishing a technical advisory group and coordination of workshops, training programmes, regional meetings etc. Facilitating networking in an organised manner ensures complete implementation of biosafety programmes in regional laboratories. Sri Lanka College of Haematologists (SLCH) can coordinate such activities focusing on how to address key issues pertaining to laboratory safety, quality management and standardisation. Developing consensus agreement on risk assessment and related procedures through SLCH will support the accreditation process with no ambiguity in decision making as assessors¹³.

In addition, a model described in Zhejiang province, China, provides some directives on how to successfully manage biosafety in level 2 laboratories (1721 laboratories) through implementation of a coordinated model called “Standardisation, informatisation, normalisation, and systematisation” (SINS model). Through SINS model, they have implemented different programmes and thematic presentations as “prevention first” “clear responsibilities” “reasonable management of incidents” etc. They have shown improvement of knowledge base on appropriate safety from 52.7% (in 2009) to 83.7% (in 2017). ISO 15189:2022 standard as well stresses the need for defining

responsibilities rather than job descriptions or activity lists for laboratory employees^{14,15}.

Wolfgang et al. describes the importance of repeated laboratory benchmarking based on a global study done in over seven hundred laboratories across Europe, Middle East and Africa. As standards for quality and safety increase, Sri Lanka should also take steps to set benchmarks and restructure its laboratories to meet new challenges¹⁰.

Laboratories should implement failure reporting and corrective action program (FRCAP). As any failure is a learning process, sharing such information at professional forums and network laboratories provide optional preventive measures to be adopted in other laboratories when appropriate⁴.

Quality control program (QCP) or quality management program (QMP) of laboratories should analyse potential weaknesses in the processes in a proactive manner. Collecting information on systems, processes and procedures in place and expected performance of each with allowable deviations and potential unhealthy deviations or occurrence of failures should be identified as potential risks. For a given set of identified risks, control measures should be introduced to mitigate potential deviations or lapses. If hazards are identified, actions to be taken should be defined. It is a continuous process with surveillance and with any failures, after corrections, it has to be included in QCP/QMP. As an example, internal quality control (IQC) failures due to mishandling of an IQC sample can generate incorrect results. The delay in sample analysis can occur due to troubleshooting etc. thus we can identify it as a potential risk. We should implement a method to ensure that all the technical personnel always handle IQC samples in the same manner defined by manufacturer³.

The risk-based quality management of medical laboratories ensures health care quality and safety. Therefore, implementing risk-based quality management is a major social responsibility of all medical laboratories to ensure safety of patients, employees and environment. For this we are

accountable as specialists in the field. I hope this article will provide all of us with some directives on how to start risk based quality management in our laboratories^{2,3}.

References

1. ISO 15189:2022
2. ISO 22367:2021
3. Njoroge SW, Nichols JH. Risk management in the clinical laboratory. *Ann Lab Med* 2014; **34**(4): 274-8. doi: 10.3343/alm.2014.34.4.274. Epub 2014 Jun 19. PMID: 24982831; PMCID: PMC4071183.
4. Lukic V, Ignjatovic S. Integrating moving average control procedures into the risk-based quality control plan in small-volume medical laboratories. *Biochem Med (Zagreb)*. 2022; **32**(2): 020711. doi: 10.11613/BM.2022.020711. PMID: 35799981; PMCID: PMC9195605.
5. Seki A, Miya T. [Medical safety management in the setting of a clinical reference laboratory-risk management efforts in clinical testing]. *Rinsho Byori* 2011; **59**(3): 288-92. Japanese. PMID: 21560411. (preventive actions)
6. Lestari F, Kadir A, Miswary T, Maharani CF, Bowolaksono A, Paramitasari D. Implementation of Bio-Risk Management System in a National Clinical and Medical Referral Centre Laboratories. *Int J Environ Res Public Health* 2021; **18**(5): 2308. doi: 10.3390/ijerph18052308. PMID: 33652769; PMCID: PMC7956505.
7. Zeng Y, Peng S, Meng L, Huang H. Establishment of risk quality control charts based on risk management strategies. *Ann Clin Biochem* 2022; **59**(4): 288-95. doi: 10.1177/00045632221086468. Epub 2022 May 3. PMID: 35196900.
8. Westgard JO. Perspectives on quality control, risk management, and analytical quality management. *Clin Lab Med* 2013; **33**(1): 1-14. doi: 10.1016/j.cll.2012.10.003. Epub 2012 Dec 20. PMID: 23331725.
9. Karadag C, Demirel NN. Continual improvement of the pre-analytical process in a public health laboratory with quality indicators-based risk management. *Clin Chem Lab Med* 2019; **57**(10): 1530-8. doi: 10.1515/cclm-2019-0019. PMID: 31050651.
10. Yoshida H, Kisugi R, Koike M. [Medical safety management in the blood collection center of clinical laboratory]. *Rinsho Byori* 2011; **59**(3): 293-8. Japanese. PMID: 21560412.
11. Huf W, Mohns M, Bünning Z, Lister R, Garmatiuk T, Buchta C, Ettl B. Benchmarking medical laboratory performance: survey validation and results for Europe, Middle East, and Africa. *Clin Chem Lab Med* 2022; **60**(6): 830-41. doi: 10.1515/cclm-2021-1349. PMID: 35344647.
12. Troiano G, Nante N, Fanelli A, Rossolini GM, Pecile P, Bordonaro P, Peruzzi B, Lo Rubbio M, Tanini T, Duranti C, Piccinno G, Niccolini F. The experience of Careggi Hospital (Florence) regarding Not Received Samples (NRS): a pilot study of Risk Management in the Clinical Laboratory. *J Prev Med Hyg* 2020; **61**(1): E6-E8. doi: 10.15167/2421-4248/jpmh2020. 61.1. 1218. PMID: 32490262; PMCID: PMC7225659.
13. Bateman AC, Bowles EJ, Munson E, Podzorski RP, Beck ET, Dern R, Sterkel AK, Warshauer DM, Shult PA. Strengthening Public Health in Wisconsin Through the Wisconsin Clinical Laboratory Network. *Public Health Rep* 2019; **134**(2): 6S-10S. doi: 10.1177/0033354919837196. PMID: 31682556; PMCID: PMC6832034.
14. Cornish NE, Anderson NL, Arambula DG, Arduino MJ, Bryan A, Burton NC, Chen B, Dickson BA, Giri JG, Griffith NK, Pentella MA, Salerno RM, Sandhu P, Snyder JW, Tormey CA, Wagar EA, Weirich EG, Campbell S. Clinical Laboratory Biosafety Gaps: Lessons Learned from Past Outbreaks Reveal a Path to a Safer Future. *Clin Microbiol Rev* 2021; **34**(3): e0012618. doi: 10.1128/CMR.00126-18. Epub 2021 Jun 9. PMID: 34105993; PMCID: PMC8262806.
15. Qiu X, Weng J, Jiang Z, Yan C, Gu H. SINS model in the management of biosafety level 2 laboratories: exploration and practice. *Biosaf Health* 2019; **1**(3): 129-33. doi: 10.1016/j.bshealth.2019.12.004. Epub 2019 Dec 17. PMID: 32501445; PMCID: PMC7148668.