Managing Good Internal Quality Control by Adopting Risk Analysis Framework

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Abstract

Topic:
Managing Good Internal Quality Control by Adopting Risk Analysis Framework
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Background:
Internal Quality Control (IQC) is the heart of quality assurance and plays a pivotal role in not only ensuring accurate and reliable patient results but also ensuring high standards of quality in materials, method performance and manpower. SUNMED lab has implemented newly designed Analytical Quality Control (AQC) strategy and it could actually improve overall assays monitoring and performance.

However, the question on whether the newly designed AQC strategy alone is it effective enough for managing good analytical quality? Our objectives are to determine whether adopting Risk Analysis Framework could actually reduce analytical and the probability of medical error, comply with accreditation standards and improve customers' outcomes.

Method:
We have adopted Six-Step Risk Analysis Framework and came up with Quality Control Plan (QCP). We did the following:

- Firstly we identified the potential failures in incorrect test results.
- After that we estimated the risk using the probability, severity and detectability.
- The identified risks were evaluated using criticality matrix and prioritize the risks (for example on staff competency, IQC and test algorithm)
- In addition to that we identified control measures to reduce the prioritized risk
- We further implemented the mitigation plans into QCP (for example on staff competency gap analysis, training strategies, test algorithm and AQC strategy).
- We also reviewed the system for effectiveness of QCP

Results: The results showed
- Significant risk reduction from the average criticality rating of 35 (unacceptable) down to 12 (acceptable); hence reducing the probability of medical error.
- Marked improvement in the ISO 15189:2007 audit nonconformance from 17 in the year 2010 to 3 in the year Jan 2013 audit.
- Improved overall customer satisfaction rate by 15% in the 2013 against the year 2011.
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Conclusion:
By adopting Six-Step Risk Analysis Framework and implementing it in QCP enables our SUNMED lab to mitigate but also assist in preventing possible hazard or risk that may occur before incorrect results are reported to health care providers and clinical action being taken.

Introduction

As we all know , many international guidelines, regulatory standards and accreditation requirements has made the manufacturers to practice and being responsible for risk management of measuring systems and reagents. But today great emphasis is given to medical laboratories to adopt risk management and develop laboratory specific quality control plans.

Quality control is one of the major aspect of patient safety, thus erroneous result can endanger patients health. Historically, studies in the 1990s and 2000s seems to support and focus on pre analytical and post analytical processes, often assumption are made on the analytical portion saying robust and highly automated measuring systems with computerized facility ensures the process to be in excellent condition. Unfortunately the analytical errors are still in the rise, therefore, it is crucial to have a properly designed analytical quality system in order to guarantee an accurate and reliable test results.

Internal Quality Control (IQC) is the heart of quality assurance and plays a pivotal role in not only ensuring accurate and reliable patient results but also ensuring high standards of quality in materials, method performance and manpower. SUNMED lab has implemented newly designed Analytical Quality Control (AQC) strategy and it could actually improve overall assays monitoring and performance. However, the question on whether the newly designed AQC strategy alone is it effective enough for managing good analytical quality? Therefore, this study will take a preliminary investigation on Risk Management at SUNMED laboratory which are committed to total quality management system and continuous improvement.

Objectives

This study aims in investigating whether adopting Risk Analysis Framework could actually reduce analytical and the probability of medical errors, increase the compliance to requirements of accreditation standards and to improve customers' outcome on satisfaction.

> "Our IQC practies have been the heart of this system in the past, but must now be expanded to provide a more comprehensive plan for managing analytical quality"
> - Dr James Westgard, 2011

Method

EP23 Clinical and Laboratory Standards Institute (CLSI) was the essential tool in guiding our SUNMED Lab to develop a customised Quality Control Plan based on risk management. We have adopted the Six-Step Risk Analysis Framework and came up with Quality Control Plan (QCP).

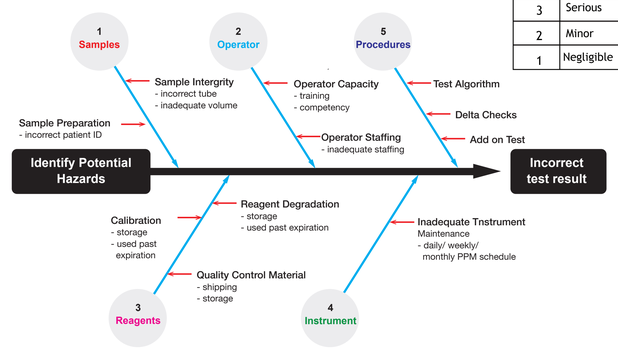
> "The first step in the risk management process is to acknowledge the reality of risk. Denial is a common tactic that substitutes deliberate ignorance for thoughtful planning"
> - Charles Tremper

6 Steps in Risk Analysis Framework and establishing QCP

Step	Procedure
1. Hazard Identification	a. Create process map b. Identify potential failures in each steps (refer to fishbone chart below)
2. Risk Estimation	Root cause analysis and determine the risk (using probablity, severity and detection)
3. Risk Evaluation	Risk acceptability based on the critical matrix
4. Risk Control	Identify control measures to reduce risk
5. Establish Laboratory QCP	Document and implement mitigation procedures into QCP
6. Monitoring of QCP	Review system for effectiveness of QCP

EP23-A Laboratory QC Based on Risk Management, Approved Guideline

Hazard Identification- Fishbone

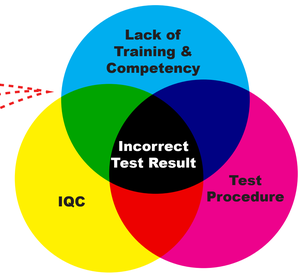


Risk estimation & evaluation

Targeted failure mode	Cause of Hazard	S	P	D	Hazard score	Risk acceptability
1. Samples	1. Incorrect tube	1	4	3	12	A
	2. Inadequate volume	1	4	2	12	A
	3. Incorrect patient ID	4	3	2	24	U
2. Operator	1. Lack of Training & Competency	3	4	3	36	U
	2. Incorrect and inadequate staffing	1	4	3	12	A
3. Reagent	1. Reagent and control degradation	2	4	2	16	A
	2. QC materia	2	3	3	8	A
4. Instrument	1. IQC	3	5	3	45	U
	2. Instrument failure	1	3	1	3	A
5. Procedure	3. Inadequate instrument	3	3	1	9	A
	1. Test algorithm	2	4	3	24	U
	2. Delta check	2	5	1	10	A

S Severity of Harm **P** Probability of harm **D** Detectability

Three major contributing factors to incorrect test result



	Severity		Probability		Detectability	
Rating	Terms	Description	Terms	Example	Terms	Example
5	Catastrophic	Patient death	Frequent	More than 1x/week	Low	Control is effective
4	Critical	Permanent impairment	Probable	Once every few months		Control less likely to detect the failure
3	Serious	Injury or impairment	Occasional	Once a year		Control may or may not detect the failure
2	Minor	Temporary injury	Remote	Once every few years		Control almost always detects the failure
1	Negligible	Inconvenience	Improbable	Unlikely to happen	High	Control can detect the failure

Criticality (Lab Risk)

- Multiply = Frequency x Severity x Detectability

Criticality	Result
Low	< 10
Mid	10 - 20
High	> 20

- Higher criticality numbers must have QC actions in place

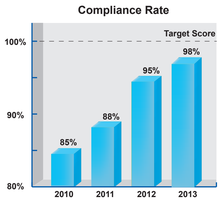
Risk Control and Implementation

Hazard	Cause of hazard	Control plan	Measurand
1. Operator	Lack of training & competency	1. Gap analysis 2. Individual internal 3. & external training plan Training Policy	1. CME hours 2. Competency scoring 3. Incident report 4. External audit compliance 5. Internal Customers' Satisfaction
2. Instrument	IQC (Chemistry)	1. AQC Strategy	1. Sigma metric 2. EQA performance
3. Procedure	Test algorithm positive case	1. Revised test algorithm 2. Reflex test for	Incorrect reported HIV test result

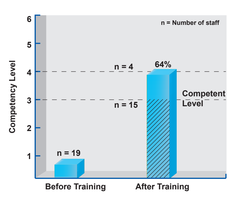
Results

QCP : Internal & External Training

1. Continuous Medical Education

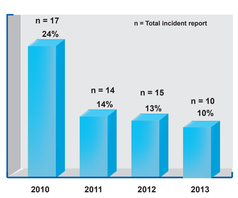


2. Gap Analysis on Competancy

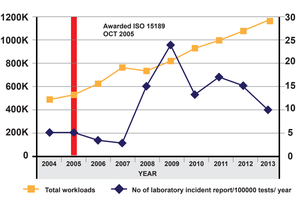


3. SOP

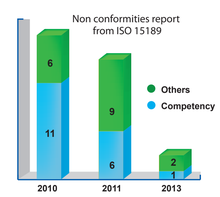
4. Incorrect test result



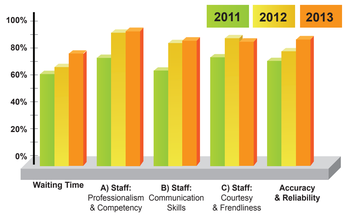
5.Total incident report over workload/ year



6. External Audit Compliance

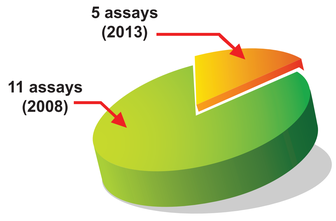


7. Internal Customers' Satisfaction Rate

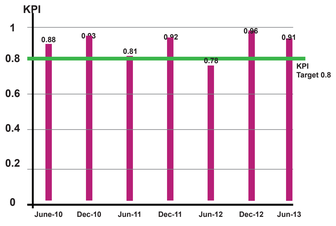


QCP : AQC Strategy

Sigma metric less than 4 for Chemistry

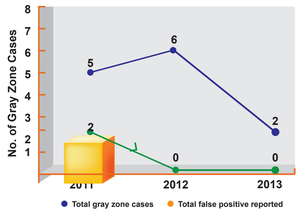


KPI RCPA Chem. Performance

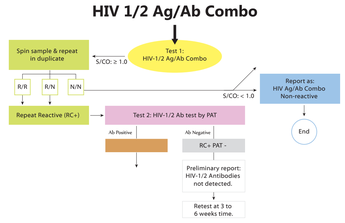


QCP : Revised HIV test algorithm

False positive HIV test result reported



Algorithm for HIV 1/2 Ag/Ab Combo



- New requirement by MOH in year 2011 that every positive HIV test should be repeated with additional method e.g. agglutination test PAT.
- Automated trigger rule setting in LIS.
- Amended WI with the newly established test algorithm
- Training & communicate to all staffs.

Summary of results

1. The risk analysis can result in reduction of risk:

Cause of hazard	Criticality Before	Criticality After
Lack of Training & Competency	36/UA/High	12 / Acceptable / Mid
Improper IQC Strategy	45/UA/High	15 / Acceptable / Mid
Incorrect test result - HIV	24/UA/High	8 / Acceptable / Low

2. Reduces probability of analytical error:

Sigma metric < 4	Before 2008	After 2013
Assays	11 assays	5 assays

3. Improved overall customers satisfaction:

2011	2013	Total Improvement
73%	88%	15%

Discussion & Conclusion

We at SUNMED Laboratory adopted a risk management approach to develop a customised quality control plan. This quality control plan ensures proactively in addressing potential risk before a wrong or unreliable results are released. Although we faced many challenges in terms of budget constraint for training of staff, sustaining the momentum in continuous improvement and to get the buy in from the stakeholders, we are still able to show the substantial improvement with the QCP. By adopting the Six-Step Risk Analysis Framework and implementing it in QCP enables our SUNMED lab to mitigate, sustain and also assist in preventing possible hazard or risk that may occur before incorrect results are reported to health care providers and clinical action being taken. By applying 6-step risk analysis framework, our Sunmed lab demonstrates:

1. Substantial risk reduction from the average criticality rating of 35 (unacceptable) down to 12 (acceptable); hence reducing the probability of medical error.
2. Marked improvement in the ISO 15189:2007 audit findings from 17 Non Conformances in the year 2010 to 3 Non conformances in the year 2013.
3. Improved overall customer satisfaction rate by 15% in the 2013 against the year 2011.