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COST $AVINGS

By Applying Six Sigma Metrics for Internal Quality Control

SUNWAY HEALTHCARE
SUNWAY MEDICAL CENTRE

Abstract

Cost Savings By Applying Six Sigma Metrics for Internal Quality Control

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Background: Internal Quality Control (IQC) is the middle piece of the laboratory quality asurance and plays an important role in monitoring accuracy and precision of all tests. However, quality is not free and often comes with a price. In this era of cost awareness and the constant reminder that time equals money, SunMed laboratory is urged to perform better by reducing the costs without compromising quality of results. Central part of every laboratory is, its obligation to assure that the whole testing process is accurate, reliable and ultimately, useful to the clinicians. The objective of the study is to investigate whether applying six-sigma metrics for internal quality control could actually reduce the running costs of quality control (QC) materials and costs of failures without compromising patient outcomes.

Methods: A retrospective comparative study of costs of QC materials, frequency of QC runs and costs of failures in Chemistry department performed between pre new IQC strategy implementation in 2009 and post new IQC strategy implementation in 2010 and 2011 were reviewed and analyzed. We followed the recommended guideline in setting up our QC system as stated in CLSI (C24-A2, section 5). Firstly, we determine the quality requirements of each assay, in which we used the biological variation information from Ricos et al.After determining the quality required for the assays, we evaluated the test performance of the 22 assays. The method performance was assessed on monthly IQC data transmitted online from Architect ci8200 into Unity Real Time Software. Our test accuracy or bias was obtained from the peer group mean. We then utilized the Westgard Advisor available tool in Unity Real Time to calculate and display the sigma-metric of each assay. This helps us in implementation of the proper rejection criteria and selection of control rules that enables us to decide on the frequency of QC runs for each assay.

Results: The results showed 17 out of 22 assays that were evaluated have a six sigma metric performance of 4 and above; therefore it is only required to perform QC runs once a day for two levels instead of twice a day for two levels. The costs of QC materials and costs of failures spent in 2009 before six-sigma implementation were USD 31,819 and after six sigma implementation in 2010 and 2011 were USD 19,314 and USD 19,038 respectively.

Conclusions: The application of six-sigma metrics for internal quality control appears to significantly reduce the cost of QC materials and cost of failures by 39 % or USD 12,500 annually with improved performance characteristics on most assays thus patient safety is not compromised at all. The new QC strategy has been hailed as an "evolution in quality management" leading to improvement in process reliability, operating costs go down and customer satisfaction increasing.

Introduction

Industries have shown tremendous cost savings as a result of implementing Six Sigma Quality management. Does the same principal applies to health care set up. In our Laboratory, six sigma tool is applied in monitoring the performance of assays based on the internal quality control data. Internal Quality Control (IQC) is the middle piece of the laboratory quality assurance and plays an important role in monitoring accuracy and precision of all tests. Central part of every laboratory is, its obligation to assure that the whole testing process is accurate, reliable and ultimately, useful and helpful to the clinicians. However, quality is not free and often comes with a price. Private hospital laboratories are urged to perform better with lesser budgets. In our effort to reduce expenditure without compromising quality of results, we at Sunway Medical Centre (SUNMED) adopted the new IQC procedure using TEa and Six Sigma. We hypothesize that careful and proper design of IQC procedures would lead to reduction of false rejection of analytical runs, thus reducing the cost of QC materials and internal failures. Traditionally we used to practice the Conventional IQC design as illustrated in Figure 1.

a  2 levels quality control material with known value concentration for multiple chemistry assays.

b  Running 2 levels QC material inside the analyzer twice a day. (am & pm)

c  Control date monitored graphically in Levey-Jennings chart with 2 SD control limits versus time.

d  Apply rejection rules either to accept/ reject the run. Violation of rules means systematic/ random ERROR is happening. Results on hold. No six sigma - metric assessment

Figure 1: Conventional IQC design [2]

Objectives

The objective of the study is to investigate whether applying six-sigma metrics for internal quality control could actually reduce the running costs of QC materials and costs of failures without compromising patient outcomes.

Method

1. Determine the quality requirement (analytical goal) of each assays: TEa % Biological Variation from Dr. Ricos Carmen

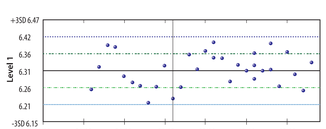
Table 1: Allowable Total Error % (TEa)[5]

Assay	Unit	TEa Biological Variation (%)
ALT	U/L	26
AST	U/L	15.2
Calcium	mmol/L	2.41
Chol	mmol/L	8.49
CK	U/L	15.2
Chloride	mmol/L	1.5
Creatinine	µmol/L	8.9
GGT	U/L	22.2
Glucose	mmol/L	7.19
UHDL	mmol/L	11.1
Iron	µmol/L	15.3
K	mmol/L	5.8
Na	mmol/L	1.32
Phosphate	mmol/L	10.2
Total Protein	g/L	5.15
Trig	mmol/L	14
Urea	mmol/L	15.7
Uric Acid	µmol/L	12.4
Total bill	µmol/L	31.1
ALP	U/L	11.7
Amylase	U/L	14.6
Albumin	g/L	3.9

2. IQC data were transmitted online to Architect ci8200 into Unity Real Time software by Unity Connect (UC). Established own mean and SD

Figure 2: Levey-Jennings Chart

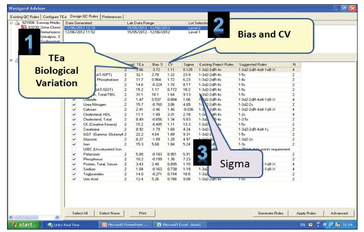
Lot: 1441U, Assayed Chemistry, Serum, Bio-Rad, 30, 04, 2014
CHolesterol, Total, CHolesterol oxidase, esterase, peroxidase, Abbott ARCHITECT c8200, Dedicated Reagent, mmol/L, No Temperature
Cum Mean/SD/CV: [1] 6.31/0.05/0.83, [2]2.52/0.03/1.29



Summary Statistics	Month	Cumulative	Month	Cumulative
18/06/2012 04:22				
Mean	6.32	6.31	2.52	2.52
SD	0.05	0.05	0.03	0.03
CV	0.75	0.83	1.06	1.29
Points	22	34	21	38

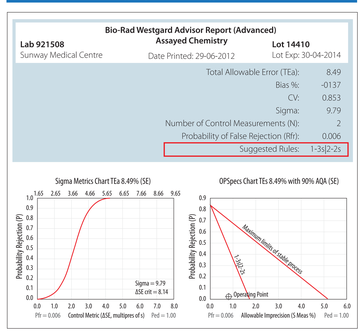
3. Evaluate test method: CV, %bias (peer related) and sigma metric calculated

FIgure 3: Generate sigma from Westgard Advisor



4. Following that, rules for each assay, number of measurement and run were determined using OPSpec Chart and sigma power function graph in Westgard Advisor.

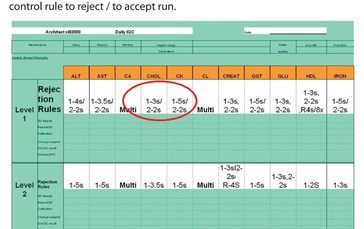
Figure 4: OPSpec Chart and sigma power function graph in Westgard Advisor



5. Implement the new IQC design

Figure 5: Staff Training(Architect ci8200 Daily IQC Monitoring Log)

Provide staffs with clear and easily understood information on which control rule to reject / to accept run.



Results

As a result of implementing the six sigma IQC design, less stringent IQC rules were applied in many of the analytical test procedures leading to fewer alarms for false rejection, significant reduction in number of reruns, calibration runs and technical interventions. The results showed 17 out of 22 assays that were evaluated have a six sigma metric performance of 4 and above (Figure 6 & 7); therefore it is only required to perform QC runs once a day for two levels instead of twice a day for two levels. The reduction of QC and calibrator materials for chemistry assays on annual basis shown in table 2. We also calculated the Internal Failure cost for the pre New IQC design and the new IQC design by using the Quality Cost Worksheet: Waste & Rework adopted from Six Sigma Quality Design and Control, 2nd Edition by James O. Westgard. The worksheet is used to calculate cost of internal failures for all the 22 assays individually, example as stated below for cholesterol assay (Table 4). The costs of QC materials and costs of failures in 2009 before six-sigma implementation were USD 31,819 and after six sigma implementation in 2010 and 2011 were USD 19,314 and USD 19,038 respectively (Figure 8).

Table 2: Average use of QC and Calibrator-material 2009-2011

Year	QTY Ordered	Months Used	QTY/month	Difference %
2009	33	12	2.75	-
2010	24	12	2.00	-27
2011	15	12	1.25	-38

Difference 2009 - 2011 is 55%

Table 3: False rejection rates of Common Control Rules [4]

Control Rules	# Controls per run			
	1	*2*	*3*	*4*
1_{2s}	5%	9%	14%	18%
$1_{2.5s}$	1%	3%	3%	4%
1_{3s}	0%	0%	1%	1%
$1_{3.5s}$	5%	0%	0%	0%
$1_{3s}/2_{2s}/R_{4s}$	-	1%	2%	2%
$1_{3s}/2_{2s}/R_{4s}/4_{1s}$	-	-	-	3%
$1_{3s}/2\ of\ 3_{2s}/R_{4s}$	-	-		-
$1_{3s}/2\ of\ 3_{2s}/R_{4s}/3_{1s}$	-	-		-

Table 4: Quality Cost Worksheet: Waste & Rework [4]

Test	Cholesterol	Pre new IQC design	New IQC design
Method	Cholesterol Peroxidase		
System	ci8200		
No.	Description		
1	Runs/ Day	2	1
2	Days/ Year	365	365
3	Control Rule in Use	1-2s	1-3s, 2-2s
3a	False Rejection (Pfr) - Use Table 3	0.09	0.01
4	Number of Controls per Run	2	2
5	Estimated cost per Control	0.50 (USD)	0.50 (USD)
6	Number of tests in each test group	30	60
7	Cost per test	1. 00 (USD)	1.00 (USD)
	False Rejection test cost: If you repeat the entire test group. (Multiply 1x2x3ax6x7)	1971 (USD)	219 (USD)
	False Rejection control cost: If you only repeat controls (Multiply 1x2x3ax4x5)	65.70 (USD)	3.65 (USD)
8	Average Hourly Rate of employees who perform the rework (repeat run)	7 (USD)	7 (USD)
9	Average amount of time consumed when one run of this test must be redone.	1.0hour	1.0hour
	Rework labor cost (Multiply 1x2x3ax8x9)	459.90 (USD)	25.55 (USD)
	TOTAL COST OF WASTE & REWORK (Control cost Test + cost Rework+ labor cost)	2496.60 (USD)	248.20 (USD)

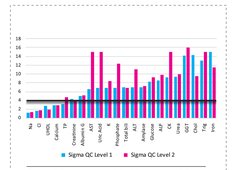


Figure 6: Sigma-metric of the 22 assays by IQC level monitored on monthly basis.

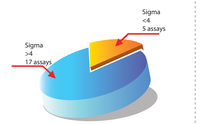


Figure 7: Performance of chemistry assays by sigma-metric

Figure 8: Total Cost of QC materials and internal failures

Discussion & Conclusion

The implementation of this new IQC design, six sigma quality strategy reduce total cost of QC materials and cost of failures by 39 % or USD 12,500 and at the same time provides the right QC rules for the 22 assays to improve quality in our Laboratory. In summary, the conventional IQC practise in our laboratory contributed to financial waste through high false rejection and low error detection. The six sigma quality planning process helped us at SUNMED laboratory to choose control rules that are high in error detection and low in false rejection, by doing so we were optimizing the quality without jeopardizing patient safety furthermore we were also minimizing the costs. This is supported by the evidence of Sunway Medical Centre Laboratory Department winning the "Best ISE Coefficient Variation (CV) Performance" during the Malaysian Association of Clinical Biochemist (MACB) seminar on November 2011. Introduction of the new approach in IQC design is definitely very challenging, especially in terms of investment of time for educating our laboratory scientist on the better way of monitoring IQC and appropriate corrective action taken for alarms that appears. The best part of this new IQC strategi is there are no more worries for our scientist on solving "false alarms". The new QC strategy has been hailed as an "evolution in quality management" leading to improvement in process reliability, operating costs go down and customer satisfaction increasing.

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