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Evaluation of Quality Control Data of Hormones Using Six Sigma Metrics Tool in Clinical Laboratory

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: In health care system it is necessary to provide high quality and reliable test results to the patients. Many clinical laboratories are using six sigma as a tool to improve the quality control in health care system. Keeping this in mind, the present study was conducted using the quality control data of hormones under NABL(National Accreditation Board for Testing and Calibration Laboratories) which were assayed in our clinical laboratory.
Materials and Methods: In this retrospective study, both the internal and external quality control data of 11 hormones were collected for a period of 6 months from April 2020 to September 2020 and the six sigma analysis was done.
Results: Testosterone level 1(6.8), level 2(6.5) and Folate level1(6.9), level 2(6.6) showed sigma level more than 6 and hence excellent performance. The hormones, FT3 level 1(3.7), level 2(4.8), HCG level 2(3.6), TSH level 1(4.8), level 2(4.7) and Vitamin B12 level 1(4.4), level 2(4.5) showed average performance with sigma level between 3.5 and 6. The hormones, FT4 level 1(1.7), level 2(2), HCG level 1(2.2), Prolactin level 1(3), level 2(3.3), FSH level 1(1.9), level 2(2.0), LH level 1(2), level 2(1.9) and Progesterone level 1(3.4), level 2(3.3) showed poor performance with sigma level less than 3.5.
Conclusion: Stringent rules need not be applied for hormones with sigma>6. Moreover, control limits can be relaxed to 3S so that false rejections can be minimized. For hormones with sigma< 6, internal QC rules have to be strictly applied and the root cause analysis has to be done. To conclude, six sigma metrics is a powerful quality control tool which helps to improve the performance of the clinical laboratory and hence the efficiency of the health cares system.

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1. INTRODUCTION

Six sigma is a quality control tool which helps to define measure, analyze, improve and control the clinical laboratory performance. It has set a benchmark for excellence. Six sigma is a quality assurance approach which tends to raise the standards of Quality management system. Sigma metrics helps to quantify the errors which occur during analytical phase of measuring system [1]. Six sigma, a quality management tool was first introduced by Sir Bill Smith to Motorola in 1986 for the process improvement [2,3]. Itquantify the errors by combining the precision, bias and Total allowable error (TEa). Precision is obtained from internal quality control data while bias is obtained from external quality control (EQAS). External quality control involves analysis and reporting of Quality control sample provided by external agency. The external agency then studies the results of all participants and provides feedback [4].Sigma level≥6 infers good performance of the laboratory while sigma level between 3.5 and 6 infers average performance. Sigma level<3 indicates poor performance [5]. The focus of the current study was to measure and analyze sigma metrics of hormones under the scope of NABL (National Accreditation Board for Testing and Calibration Laboratories) accreditation.

2. MATERIALS AND METHODS

The current study was a retrospective study conducted in Central clinical Biochemistry laboratory, Chettinad hospital and research institute, Kelambakkam. The Hormones control that were assayed includes Free T3, Free T4, TSH, Luteinising hormone, Follicle stimulating hormone, Prolactin, Progesterone, Testosterone, Folic acid, Vitamin B12 and Human chorionic gonodotrophin. Both Internal and External Quality control material were procured from BIO-RAD (Name of the company which manufactures specialized products for clinical diagnostic laboratory). Internal quality control data of both level 1(Normal) and level 2(pathological) of 11 hormones under NABL scope were collected for a period of 6 months from April 2020 to September 2020. Mean, Standard deviation and Coefficient of Variation were calculated for each level separately.

Coefficient of Variation was calculated using the formula:

Coefficient of Variation = (Standard deviation/Mean) x 100

Bias percentage for each hormone was calculated from External Quality control data. Bias percentage is the systematic difference between the expected result obtained from lab test method and that of the reference method. Clinical Laboratory Improvement Amendment (CLIA) has given acceptable performance for each hormone in terms of Total allowable error [6].

Sigma metrics for each hormone was calculated using the formula:

Sigma = Total allowable error – Bias/Coefficient of Variation

Quality Goal Index ratio (QGI) was calculated for those hormones with sigma value less than 6 using the formula:

QGI = Bias/1.5 x CV%

Table 1. Quality goal index ratio

QGI	Problem
< 0.8	Imprecision
0.8-1.2	Imprecision and inaccuracy
>1.2	inaccuracy

QGI= Quality Goal Index ratio

3. RESULTS

The hormones, testosterone level 1(6.8), level 2(6.5) and folic acid level1 (6.9), level 2(6.6) showed sigma score more than 6.The hormones, FT3 level 1(3.7), level 2(4.8), HCG level 2(3.6), TSH level 1(4.8), level 2(4.7) and Vitamin B12 level 1(4.4), level 2(4.5) showed sigma score between 3.5 and 6.The hormones, FT4 level 1(1.7), level 2(2), HCG level 1(2.2), Prolactin level 1(3), level 2(3.3), FSH level 1(1.9), level 2(2.0), LH level 1(2), level 2(1.9) and Progesterone level 1(3.4), level 2(3.3) showed sigma score less than 3.5.

Table 2. Sigma metrics of 11 hormones calculated from Total allowable error, average percentage of Coefficient of variation and Bias from April 2020 to September 2020

Hormone	Total allowable error	Average Bias %	Average CV%		Sigma score	
			Level 1	Level 2	Level 1	Level 2
FT4	15	-0.783	74.1	8.9	1.7	2.0
FT3	30	-4.275	9.5	7.3	3.7	4.8
TSH	20	-6.131	6.1	6.4	4.8	4.7
HCG	18	4.026	6.6	3.9	2.2	3.5
Prolactin	20	-1.868	5.7	6.8	3.0	3.3
FSH	18	2.559	7.9	7.2	1.9	2.1
LH	20	0.257	11.0	12.8	2.0	1.8
Folic acid	30	-2.205	5.1	5.1	6.9	6.6
Progesterone	25	2.066	7.5	7.4	3.4	3.3
Testosterone	30	2.8	4.4	4.7	6.8	6.5
Vitamin B12	25	-2.398	7.3	6.6	4.4	4.5

FT4 – Free T4; FT3 – Free T3; TSH – Thyroid Stimulating Hormone; HCG – Human Chorionic Gonadotropin; FSH – Follicle Stimulating Hormone; LH – Luteinising Hormone

Table 3. Shows quality goal index ratio of hormones with sigma less than 6 and its interpretation

Hormone	Level	Sigma score	Quality Goal Index	Cause
FT4	Level 1	1.7	0.1	Imprecision
	Level 2	2.0	0.2	Imprecision
FT3	Level 1	3.7	0.3	Imprecision
	Level 2	4.8	0.4	Imprecision
TSH	Level 1	4.8	0.8	Imprecision and inaccuracy
	Level 2	4.7	0.6	Imprecision
HCG	Level 1	2.2	0.4	Imprecision
	Level 2	3.6	0.7	Imprecision
Prolactin	Level 1	3.0	0.2	Imprecision
	Level 2	3.3	0.2	Imprecision
FSH	Level 1	1.9	0.2	Imprecision
	Level 2	2.0	0.2	Imprecision
LH	Level 1	2.0	0.2	Imprecision
	Level 2	1.9	0.1	Imprecision
Progesterone	Level 1	3.4	0.2	Imprecision
	Level 2	3.3	0.2	Imprecision
Vitamin B12	Level 1	4.4	0.2	Imprecision
	Level 2	4.5	0.2	Imprecision

FT4 – Free T4; FT3 – Free T3; TSH – Thyroid Stimulating Hormone; HCG – Human Chorionic Gonadotropin; FSH – Follicle Stimulating Hormone; LH – Luteinising Hormone

4. DISCUSSION

In the current study, the hormones, testosterone and Folic acid showed sigma score more than 6 and hence excellent performance. Stringent rules need not be applied for Testosterone and Folic acid. Moreover control limits can also be relaxed to minimize false rejections. The hormones, FT3, HCG level 2, TSH and Vitamin B12 showed average performance with sigma level between 3.5 and 6. Quality goals for these hormones can be met by applying more elaborate quality control strategies. The hormones, FT4, HCG level 1, Prolactin, FSH, LH and Progesterone showed

poor performance with sigma level less than 3.5. For these hormones, reduction of analytical bias and imprecision is the two remedies available to improve the quality. Westgard rules and guidelines proposed by cooper et al can be implemented according to the sigma values in the clinical laboratory.

Simple Westgard rules as follows [7]:

≥6σ : 2 levels of QC per day with a 13.5s greater rule
5σ : 2or 3 levels of QC per day with a 12.5s or 13s rule
4σ : 3or 4 levels of QC per day with a 13s / 2 22s / R 4s / 4 1 s rule
3.5σ : 6 of QC per day with a 13s / 2 22s / R 4s / 4 1 s rule
<3.5 σ : Maximum affordable levels of QC per day with a 13s / 2 22s / R 4s / 4 1 s rule

Another guideline proposed by Cooper et al as follows [8]:

>6σ (excellent tests) –one QC per day (alternating levels between days) and a 13s rule.
4σ–6σ (suited for purpose) –two levels of QC per day and the 12.5s rule.
3σ–4σ (poor performers) –combination of rules with two levels of QC twice per day.
<3σ (problems) – maximum QC, three levels, three times a day. Preferably testing specimens in duplicate.

5. CONCLUSION

Six sigma methodologies is a powerful tool in clinical laboratories. It should be used in health care system, until the quality improves to six sigma level. This can be achieved by using an optimal Westgard rule and thereby highly reliable results of diagnostic tests can be delivered.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation. They are used only for advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors and the organisation.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

ETHICAL CLEARANCE

Ethical Clearance for this study was got approved from the Institutional Human Ethical Committee.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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