Wednesday, July 29, 2015

Poster Session: 9:30 AM - 5:00 PM

Management

B-139

QC Failure Rates Assessed by Assay Specific Sigma Metrics in a Six Sigma Based QC Program

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Introduction: A Six Sigma Based Quality Control program was implemented in our laboratory two years ago to improve our ability to detect clinically important errors and decrease the number of false rejections. This type of QC program decreases laboratory costs in reagents, supplies and labor by minimizing unnecessary investigations due to false rejections of QC rules. A Six Sigma based QC program should result in reduced false rejection, while maximizing detection of the clinically significant errors. Since methods that are 5 Sigma or greater require fewer QC challenges per run and simpler "Westgard Rules" to monitor the method, it is important to select instruments with methods that deliver 5 Sigma performance or greater.

Objective: The goal of this study was to determine the rate of QC rules violations for a method depending on its Sigma metric. We also determined the number of QC points that were outside of 2 SD limits, but within the limits of the QC rule used to monitor the 5 and 6 Sigma methods.

Methods: QC values were reviewed for 70 different chemistry, TDM and immunoassay methods over a three month period. Methods were grouped by their Sigma Metric: 5 Sigma, 6 Sigma and 4 Sigma or less. For the 5 and 6 Sigma methods, the number of QC values outside 2 SD limits, but less than 3 SD (5 Sigma methods) or 3.5 SD (6 Sigma methods), were also tallied.

Results: Over 40,000 QC values for 70 chemistry, TDM and immunochemistry methods on two Abbott ARCHITECT c8000 and three Abbott ARCHITECT i2000SR were evaluated for QC rules failures. Six Sigma methods, using 1-3.5s Westgard Rule, had a QC failure rate of 0.9%, with 40% of the failures due to the wrong control being tested. Five Sigma methods, using 1-3s Westgard Rule, had a QC failure rate of 2.3%, with 23% of the failures due to the wrong control being tested. Sigma metric methods of 4 Sigma or less had a QC failure rate of 14.7%, requiring the use Multiple "Westgard Rules" to monitor the methods. For the 5 and 6 Sigma metric methods, 6.0% of the QC values were outside 2 SD limits but within 3 SD limits.

Conclusion: 5 and 6 Sigma methods had 85% fewer QC failures than the 4 Sigma or less methods when a Six Sigma Quality Control program was put in place. 5 and higher Sigma metric methods also require fewer QC challenges per run, resulting in lower costs in reagents, QC material and calibrators. Fewer QC failures mean less time required by staff to investigate the failures. By eliminating the need for the 1-2s rule for 5 and 6 Sigma metric methods, another 6% in QC failures were avoided. The combination of high quality methods with optimized QC design resulted in significant resource and labor savings, assuring quality while providing needed savings.

B-140

The need for a comprehensive and updated Medical Decision Levels database: TSH test as an example of this requirement

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Introduction: Medical Decision Levels (MDL) are used by laboratory professionals to verify analytical performances; set quality specifications; establish quality control plans and by IVD providers to validate analytical performance of their methods; select concentrations of their control materials. MDL presented in different guidelines and expert opinions, may not agree. Available databases collating MDL (Westgard and CLIA) provide a resource for potential users, but they are infrequently updated and not comprehensive. This could provide a significant issue for users of databases if the MDL do not reflect current guidance and opinion.

Aim: To investigate recommended MDL for Thyroid stimulating hormone (TSH) published in contemporary guidelines and to compare them with those held in current MDL databases.

Material and methods: TSH was chosen as a complex example for study. It has a high request rate; there are issues with standardization and has multiple MDL applying to many clinical situations.

We searched biomedical databases (MEDLINE, EMBASE, Cochrane, NICE) to identify relevant clinical practice guidelines related to thyroid diseases. MDL were collated taking into account diagnosis, follow-up or ongoing treatment.

Results: The Westgard and CLIA databases present a simplified strategy with two MDL: lower and upper limits (0.3 and 5.0 mU/L).

The table summarizes the MDL for TSH (mU/L) gathered from guidelines of 3 selected Thyroid Associations. These guidelines passed critical appraisal using Agree II (www.agreetrust.org).

Thyroid Clinical Condition	**Thyroid Associations**		
	European	**American**	**British**
Adults Reference Range	0.4-4.0	0.4-4.0	0.4-4.5
Hypothyroidism			
Adults	>4.0	>4.0	>4.5
Elderly (>70-80 years)	>7.0	>7.5	-
Subclinical (not need for treatment)	4.0-10.0	4.0-10.0	4.5-10.0
Subclinical (cutoff for treatment)	>10.0	>10.0	>10.0
Treatment objective	0.4-2.5	0.5-2.5	*
Hyperthyroidism			
Subclinical (consider for treatment)	-	0.1-0.5	0.1-0.4
(depends on clinical and/or freeT4)			
Subclinical (cutoff for treatment)	-	<0.1	<0.1
Others Clinical Conditions			
Pregnancy 1st trimester	0.1-2.5	0.1-2.5	0.4-2.0
Pregnancy 2nd trimester	0.2-3.0	0.2-3.0	**
Pregnancy 3rd trimester	0.3-3.5	0.3-3.0	**
Pregnancy with high risk of thyroid tumor	-	0.1-0.5	-
Pregnancy period considered tumor free	-	0.3-1.5	-
Thyroid surgery deferred until postpartum	-	0.1-1.5	-
Neonates clinical evaluation			>20.0
Thyroglobulin assay	-	-	>30.0
Objective treatment post thyroidectomy	-	-	<0.1
* Within Reference Range,	** Trimester-related reference ranges.		

Conclusions: For TSH, the existing MDL databases are not comprehensive. Many clinical scenarios and important clinical situations are not considered.

Current databases will not support user choice of the most appropriate MDL for their intended use or clinical requirements.

There is a need for a comprehensive database, similarly to the existing for Biological Variation but with granularity to support user choice. A systematic evidence based medicine initiative is required to assure its elaboration, harmonization and update.

B-141

HbA1c assay management: a commutability evaluation between cobas c501 and HPLC

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Background: Presently HbA1c is a powerful tool for both monitoring long-term glycemic control, and to diagnostic diabetes. Several methods are available to assay HbA1c, thus medical laboratories should use method certified by the NGSP. Our laboratory personnel have a prejudice regards to assay HbA1c by turbidimetric inhibition immunoassay (TINIA) and prefer to use high-performance liquid chromatography (HPLC). This study was aimed to assess the commutability between two methods certified by the NGSP - TINIA and HPLC - to assay HbA1c.

Methods: The protocol from CLSI EP14-A3 document was used to perform both the sample selection and statistical analyses. Briefly, twenty K2EDTA samples previously assayed by HPLC (G8 Tosoh) were selected to assess the commutability with Tina-quant Hemoglobin A1c Gen.3 in cobas c501 (Roche Diagnostics). The both analyzers (G8 and cobas c501) were previously calibrated against appropriate proprietary reference standard material traceable to both DCCT and IFCC, and verified using

third-party internal quality control. Moreover, a single lot of proprietary reagents was used, and all samples were assayed in triplicate. Appropriateness of data for linear regression analysis was checked regards CLSI EP09-A3 document, then performed both linear regression and difference plot analyses (Figure 1).

Results:

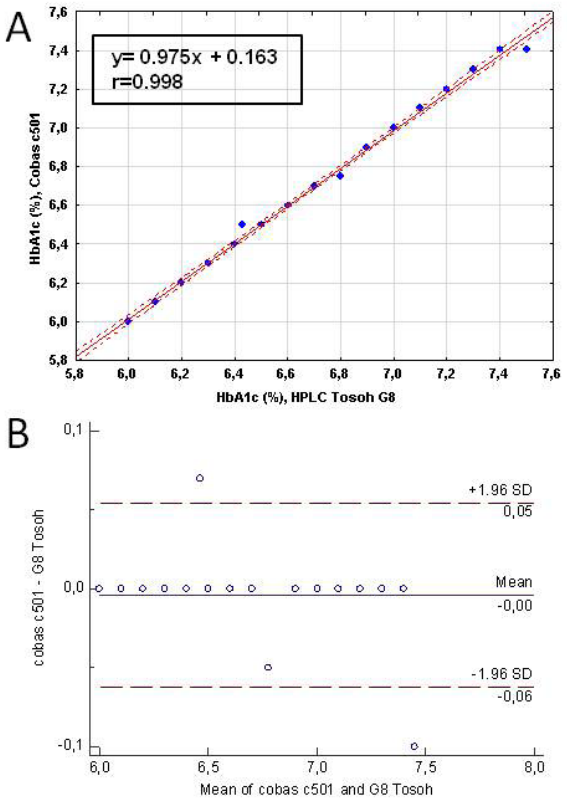

Figure 1. Comparison of HbA1c patient samples assayed by cobas c501 (Roche) and G8 (Tosoh).

A. Linear regression analyses. B. Difference plot.

Conclusion: Since the good correlation between TINIA in cobas c501 and HPLC in G8 for HbA1c assay (r=0.998), the commutability can be established by the equation:

HbA1c in cobas c501 = -0.142 + (1.022 * HbA1c in G8)

Consequently, our laboratory will can guarantee both analytical quality and patient safety using either TINIA or HPLC to assay HbA1c. Moreover, one possible advantage to assay HbA1c by TINIA onboard a robust analytical platform (i.e., cobas c501) connected to a preanalytical automation system, could be to reduce both turnaround time and human resource necessity.

B-142

Evaluation of test ordering patterns for serum Vitamin B_{12} and folate

B. M. Katzman, D. R. Block, R. Nett, W. Katrangi, N. A. Baumann. *Mayo Clinic, Rochester, MN*

Background: Serum Vitamin B_{12} (B_{12}) and folate testing are commonly ordered as part of the assessment of macrocytic anemia or when patients present with physical symptoms suggesting deficiency. Although B_{12} deficiency is more common than folate deficiency, deficits in both of these vitamins are predominantly associated with the elderly population. The aim of this study was to assess the frequency of serum B_{12} and folate test ordering in our institution and the prevalence of deficiency.

Methods: Serum B_{12} and folate test orders spanning one year (July 2013-July 2014) from Mayo Clinic in Rochester, MN were extracted from the laboratory information system. The prevalence of folate and overt B_{12} deficiency, defined as <4.0 mcg/L and <150 ng/L, respectively, was determined. Data were also analyzed to identify how often B_{12} and folate were ordered together, how often tests were ordered multiple times for the same patient, and the frequency of repeat test orders. The "appropriateness" of multiple test orders was evaluated based on the time interval between orders using literature reported intervals of 30 days when first test result indicated deficiency and 90 days when the first test result indicated no deficiency.

Results: A total of 18,126 B_{12} and 11,138 folate tests were ordered on 19,523 unique patients (9,115 male, 10,408 female; median age 61 y, age range 18-103 y). The prevalence of B_{12} and folate deficiency in the patient population was 2.5% (428 patients) and 0.8% (89 patients), respectively. 38% (8,057) of orders included both B_{12} and folate. Within the year studied, B_{12} or folate tests were ordered more than once on 1,104 (5.6%) patients. In 1029 patients with initial results indicating that B_{12} or folate were not deficient, 488 (47%) patients had the same test ordered more than once within 90 days of the original order. There were 111 patients with test results indicating B_{12} or folate deficiency, and 12 (11%) patients had the same test ordered again within 30 days.

Conclusion: Vitamin B_{12} and folate tests are frequently ordered together despite the rarity of folate deficiency in the patient population. The prevalence of B_{12} and/or folate deficiency in this study was comparable to previously published reports. The high frequency of test orders and interval between repeat test orders suggests that these tests may be over-utilized in patients without deficiency. These findings should encourage laboratories to investigate interventions that help guide appropriate utilization of Vitamin B_{12} and folate testing.

B-144

Summary and Analysis of Nine Years' Point-of-care Glucose Meter External Quality Assessment Programs in China

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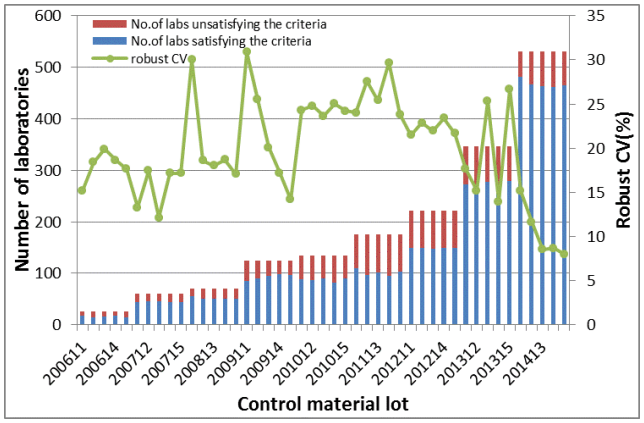
Background: With the increasing use of Point-of-Care(POC) glucose meters all over China, the accurate measurement of blood glucose with POC glucose meters seems more and more essential for correct treatment decisions for glycemic control. Despite the frequent use of POC glucose meter in hospital settings, its quality assurance is still challenging for many institutions.

Methods: External quality assessment(EQA) programs for POC glucose meter was organized by NCCL in china from 2006 to 2014, respectively. Five lots of control materials provided by Bio-Rad at different concentration were assigned to each participant laboratory in each year. The participants were asked to measure the concentration of each analyte and report their data through clinet-EQA reporting system V1.5. Percentage difference was calculated for each laboratory and each control material lot in each year. The measurement performance was then evaluated based on the minimum system accuracy performance criteria in ISO 15197. Robust coefficient of variation(CV) based on ISO 13528 for each control material lot was also calculated to evaluate the degree of variation among different laboratories in China.

Results: Number of laboratories satisfying and unsatisfying the accuracy performance criteria as well as the robust CV for each control material lot was shown in the picture below, respectively. The number of participant laboratories increased gradually from 26 to 531 while the pass rate increased gradually from 57.69%(15/26, lot 200612) to 90.77%(482/531, lot 201411) in nine years from 2006 to 2014. Although robust CV fluctuated largely among different lot, there was no obvious change trend among different years.

Conclusions: The POC glucose meter measurement performance in China has been improved gradually from 2006 to 2014. Laboratories should make persistent efforts to obtain better results in the future.



B-145

Implementing Lean Six Sigma Methods to Improve Workflow in the Clinical Flow Cytometry Laboratory

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Introduction:

Lean and Six Sigma process improvement methods have been utilized in the manufacturing industry for decades, and are now being applied to healthcare settings. In order to meet increased demand for Flow Cytometry evaluation for oncology and HIV patients in VT and NH while decreasing overtime; currently in excess of 20K annually for our laboratory section, now is the time to create capacity within Hematology and Flow to take on additional work without additional staffing.

An opportunity exists in the Flow Cytometry Lab to align the work load & staffing. Having the right person doing the right tasks with a goal to reduce the amount of technologist time spent on redundant and inappropriate tasks such as; manual ordering, paperwork, checking pending lists & bone marrow logs or physically checking the in basket for samples.

Materials and Methods:

The clinical Flow Cytometry workflow improvement project had multiple phases: documentation of the current state to establish baseline performance; workflow observations to determine areas for improvement; and review of work practices to determine/establish best practice for improvement. Process maps were created to document the current state of the workflow and a fishbone diagram was used to focus the group.

Laboratory or hospital information system solutions and technology were used wherever possible to simplify processes. Printers, worklists and pending lists were implemented during this phase. An additional goal was set to have the right duties assigned to the right role; i.e. technical staff performing technical tasks, clerical staff performing clerical tasks.

In the analysis phase, new process maps were created showing the reduction in steps with the improved workflow. Calculations were performed to determine the number of samples with automated/electronic orders versus those ordered by the flow cytometry technical staff.

Results:

At the start of this project the technical staff was ordering 80% of the immunophenotyping testing; they are currently ordering 6%. All workflows were improved, some as much as 80%. The laboratory has been able to implement a TAT monitor for immunophenotyping. The original goal set for this monitor was 24 hours; however the longest TAT since project completion was 20.50 hours.

Conclusions:

Within three months, the implementation of Lean workflow processes improved employee satisfaction, TAT, overall patient care and reduced waste in the clinical flow cytometry laboratory. Process improvement strategies, like Lean, should be embedded into all workflow analyses in a clinical laboratory.

B-146

Use and overuse of Immunofixation electrophoresis and Serum Free Light Chain assays

S. G. Vyas, G. Singh. *Georgia Regents Univ-MCG, Augusta, GA*

Background: We examined the usage of serum protein electrophoresis (SPEP), serum immunofixation electrophoresis (SIFE) and serum free light chain assays (SFLCA) at a tertiary, medical school affiliated, 500 bed hospital. These tests are generally used as screening tests for diagnosis of monoclonal gammopathies. International Myeloma Workshop Consensus Panel 3 recommendation for diagnosis includes testing for SPEP, SIFE, urine protein electrophoresis, immunofixation electrophoresis, serum free light chain assay, bone marrow examination, cytogenetic studies and skeletal survey for diagnosis. Many of these tests are repeated to assess the response to treatment.

Methods: We assessed the utility of repeat SIFE and SFLCA to evaluate the status of patient on follow-up visits using the following criteria: if a monoclonal spike was not detectable on SPEP or was not quantifiable, SIFE and SFLCA were considered to be warranted. If monoclonal spike was detectable and quantifiable by densitometric scanning on SPEP, then SIFE and SFLCA were considered to be not warranted. If there was any doubt about the added value of SIFE and SFLCA, it was considered warranted. Serum immunoglobulins were also measured frequently, but we lacked objected criteria to judge the utility of this assay.

Results: Data from 184 patients yielded the findings shown in the table below.

Patients	SPEP	Peak	IFE	# Warranted	% Warranted	SFLC	# Warranted	% Warranted
184	1211	718	862	386	53.76	743	325	43.74

Using these criteria, nearly half of the SIFE and SFLCA were judged to be non-value added.

Conclusions: We recognize the value using these tests to establish a diagnosis of monoclonal gammopathy, but repeating of the tests does not add value. We are proposing that ordering option for these tests be limited to "SPEP for monoclonal gammopathy" and the pathologist signing out have the discretion to order additional tests as needed. This process has been shown to reduce the inappropriate utilization of SIFE by 53.7%. We believe that the same can be accomplished for SFLCA.

B-147

Implementation of six sigma as a quality control management tool

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Introduction: A priority for healthcare providers is to improve patient care with the overall objective of achieving patient satisfaction. Since laboratory results contribute significantly to patient diagnosis, the clinical laboratory plays an important role in improving patient care. The aim of this study was to see how Six Sigma implementation could improve our QC management.

Method: QC data for quantitative routine assays performed on the ADVIA 1800 Clinical Chemistry System (Siemens Healthcare Diagnostics, Tarrytown, NY) in our reference core laboratory were used for calculation of sigma metrics. Most of the selected quality goals were based on biological variation (BV) quality specifications; others were based on external quality assessment (EQA) peer capability and CLIA regulations. Biorad Unity software was used in calculation of sigma metrics and Westgard rules. Analyzer performance was compared to that of the market best performer as the standard.

Results: The ADVIA 1800 system's performance placed it among the world-class instruments. We were able to benchmark 62% of tests on-board at higher quality goals (at least the desirable BV quality goal). In addition, 89% of the tests under the study achieved sigma metrics greater than 4 ("fit for purpose"). Chol, Urea, Triglyceride, ALT, GGT, Fe and CK were some of the assays that were comparable to the industry best performers. Others with sigma metrics greater than 6 but not as good as the top performers included LDH, CREA, GLU, AST, PHOS, UA, HDL, AMY, DBIL, and TBIL. K and ALP had acceptable performance, with sigma metrics greater than 4 but less than 6. Others, with sigma metrics less than 4, included NA, CA, CL, TRF, ALB, and TP.

Conclusion: Our first experience with a Six Sigma quality approach was positive. Sigma metrics not only served as a quality indicator but also helped us to focus more on problematic assays. We were able to optimize error detection and minimize the false-rejection rate. As a result, patient care has benefitted from improved QC management and higher quality analyses.

B-149

An Analysis of Specimen Rejection Rates in a Clinical Laboratory in a Medical Center

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Background

Specimen quality is crucial to laboratory reporting accuracy. Based on the previous researches, 50 to 70 percent of errors in the medical laboratory are from pre-analytical phase. Monitoring sample rejection rates can be an effective way to track pre-analytical errors, prevent avoidable errors, and provide better health care.The study aimed to determine the performance for the pre-analytical phase in an ISO 15189 accredited laboratory of a medical center.

Methods

The one-year period specimen rejection rates from emergency department, inpatient department, and outpatient services were evaluated. Moreover, types of error were investigated to discover the underlying causes of the problem.

Results

A retrospective review showed that 21,867 of the 1,188,120 specimens in 2014 were rejected, indicating an overall rejection rate of 1.8%.The rejection rates for the emergency department, inpatient services and outpatient services were 2.9% (6,629/232,589), 4.2% (14,572/345,403), 0.1% (666/610,128) respectively. The main reasons for rejection were hemolysis (44%) and inappropriate clotting samples (22%). According to the testing groups, chemistry ranked first (41.8%, n=9132), followed by hematology (22.8%, n=4977), coagulation (16.0%, n=3495) and gas analysis (5%, n=1096). Further analysis showed that the median turnaround time for the emergency department was 14 minutes, but 23 minutes for the redrawing.

Conclusion

Specimen rejection delayed the turnaround time, increased costs, and caused clinical problems. Hemolyzed and clotted samples were found to be the primary factors resulting in specimen rejection. Also, the rejection rates varied considerably in different departments. A rejection rate improvement project in the emergency department was conducted in 2004, leading to the decrease of the rejection rate from 4.4% to 1.1% that year. Therefore, the study recommended that the importance of specimen quality be addressed and continuous training programs be provided periodically.

B-150

Early comunication of non-critical, but clinically relevant, results to physicians by a medical team based outside the central lab.

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Background: Quality and safety accreditors place increased emphasis on the effectiveness with which critical laboratory results are reported to caregivers. CAP Q-Probes Study of 121 Institutions observed that, for all critical results combined, no rapid notification took place for only 10 (0.3%) of the 3545 critical results. On the other hand, notification of a wider group of clinically relevant results, although not considered critical, may benefit patient's health and be convenient to physicians in their daily practice, playing an important role in the relationship between prescribing professionals and the private lab.

Methods: Medical laboratory staff selected 57 tests to have a range of results notified to prescriber physicians, according to previous patient's results. After development and parameterization of LIS based tools and reports, lab medical staff, remotely based outside the central lab, daily accessed the LIS feature, in order to telephone to prescriber and inform the result. If the physician were not reached, patient was not contacted. The team goal was to successfully report 50% of detected results. The aim of the study is to access the dimension and efficiency of a new process of early notification of non-critical, but clinically relevant, results by a remote medical team, during year 2014.

Results: From January to December 2014, out of 63.4 million tests performed at the central lab, the LIS tool detected 1,943 (0.003%) test results parameterized for physician telephone notification. The medical team successfully reported 1,258 (64.8%) of them. We experienced instability of the LIS tool in the first months, and some of its features are still being continuously improved. The major cause of failure in reporting was insufficient prescriber data at LIS to allow proper contact.

Discussion: Although failure to notify caregivers of non-critical, but clinically relevant results may not represent an important patient safety vulnerability, it represents a lost opportunity in building a strong and reliable relationship between the private laboratories and the prescribers. We believe that having selected non-critical results notified by lab physicians brings a ense of higher standard of care for patients and prescribing physicians. Notifications done by a medical team, remotely based outside the central lab, and supported by LIS tools and reports, also allow lab staff to focus in critical results reporting and in lab routines, and may increase lab staff productivity.

B-151

Evaluation of the Analytical Performance of Creatinine in the Medical Decision Points

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Introduction: Given that commercial materials of internal control do not generally cover all the concentrations that represent the Medical Decision Points (MDPs) -where is relevant to evaluate the analytical performance of the tests-, this work shows a model of estimation of the analytical performance in the MDPs for creatinine in serum expressed like sigma metric.

Materials and Methods: A homogenous system, the analytical platform Architect ci8200 and Abbott reagents were used. The method used for the determination of creatinine was kinetic alkaline-picrate. The theoretical MDPs (0.60, 1.60, 6.00 mg/dL) were selected from the tables in Statland BE, Clinical Decision for Levels Laboratory Tests, Second Edition [Oradell NJ; Medical Economics Books, 1987]. In order to estimate the sigma metric in the MDPs, the ETa (Total Allowable Error) was selected from CLIA 88' (0.3 mg/dL and 15%), and it was calculated with the formula Sigma = [ETa (%) - Bias (%)] / CV (%). The bias that represents the systematic error of measurement was estimated as the absolute difference in percentage between the theoretical and estimated MDP, where the estimated MDP was obtained by interpolating the theoretical MDPs in the Deming linear regression obtained by charting the creatinine concentrations from 24 external quality control surveys which ranged from 0.56 to 11.30 mg/dL. The CV (%) which represents the random error was estimated in the MDPs through the equation obtained by charting different creatinine concentrations as a function of the coefficient of variation (precision profile). These data were collected by processing the internal quality control and pools of samples from patients with 11 different creatinine concentrations daily during a minimum of 30 days, together with the results obtained for the limit of quantification verification; the creatinine concentrations ranged from 0,05 to 6.44 mg/dL.

Results and Discussion: The slope of the Deming linear regression was 1.012 (CI 95%: 1.001 to 1.023) and the y-intercept -0.0110 (CI 95%: -0.0622 to 0.0402). The estimated MDPs obtained from the Deming regression were 0.60 mg/dL, 1.61 mg/dL and 6.06 mg/dL, the bias being of 0.00%, 0.63% and 1.00% respectively. The estimated CV (%) in the MDP of 0.60 mg/dL was of 2.84%, in 1.6 mg/dL of 1.71% and in 6.0 mg/dL of 0.86%. The sigma performance obtained in the MDP of 0.60 mg/dL was of 17.6, in 1.60 mg/dL was of 10.6 and in 6.00 mg/dL of 16.3.

Conclusions: The analytical performance calculated for creatinine in the MDPs by using the six sigma metric was highly satisfactory, which allows us to assure the quality of the results in the MDPs. The laboratory considers applying this complementary tool in the future to evaluate the analytical performance of those assays for which the concentrations of the internal quality control are far from the MDPs.

B-152

Statistical analysis and management of quality control data in clinical toxicology laboratory

S. Y. Wu, F. Hassouna, G. Sweeney. *Confirmatrix Clinical Laboratory, Lawrenceville,, GA*

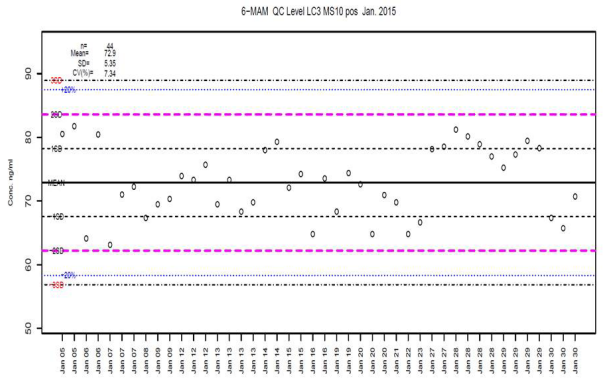
Background. Varieties of high-throughput liquid chromatography with tandem mass spectrometry (LCMSMS) techniques have been applied to clinical laboratory. These include multiplexing liquid chromatography systems, ultra-high chromatography flow rate, high throughput sample preparation and multiple reactions monitoring (MRM) that analyzes multiple target analytes within a single assay. Over the past decades, the amount of data generated each day from each mass spectrometry instrument has continually increased. Researchers and laboratory managers are constantly faced with the challenge of collecting, processing and storing large amounts of data on a daily basis as the result of an increase in samples processed each day and stringent regulatory requirements. A portion of these data are quality control (QC) sample data. We have used an effective method to manage and statistically analyze these data.

Method. The method used multiple scripts written with R statistical programming language to read QC data from multiple output files generated from mass spectrometry

instruments and performed statistical analysis. The scripts sorted QC data based on the analyte name, QC level, test panel, and instrument. User-defined functions, control structure, reshaping data, and other data management techniques have been used. By executing scripting programs, multiple tables and plots were produced.

Results. Monthly QC results including mean, outlier, standard deviation, correlation variation (CV), bias and six sigma for each of QC levels were calculated and summarized in tables for each instrument. The format of these output tables could be in latex, pdf, htm or excel files. Each QC data point was also presented in Levey - Jennings plot. More than 20 tables and 2500 Levey-Jennings plots were produced monthly.

Conclusions. The method simplifies data management, saves time, and reduces costs. It significantly facilitates the process of periodical review and evaluation of QC data by laboratory managers and researchers.



B-153

Evaluation of events involved in the pre-analytical phase and the financial impact: a case of risk management study.

J. P. Padilha, M. Provasi, A. C. S. Ferreira, T. F. Barros. *Hermes Pardini Institution, Belo Horizonte, Brazil*

Background: The pre-analytical phase is a complex process that involves a series of steps, among them, first consider the request of the examination by the medical application, patient preparation and identification, collection of diagnostic specimens, transportation, preparation or screening. In addition to cost the patient's health, since about 70% of clinical decisions are informed in laboratory tests, there is a financial cost to the clinical laboratory generating impact on the overall revenue of the institution.

Objective: This study aims to quantify the cost of recollect caused by errors in the pre- analytical phase, of a private laboratory. To survey the costs involved industry-focused where it is performed sample collection of the patient in an outpatient clinical laboratory and verify the financial impact of this occurrences.

Methods: All data presented in this study were collected through computerized system of data collection (Sadig Análises®). Data on recollect one of a large private laboratory service unit were selected in the period of eleven months (Jan / 14 - Nov / 14). Based on these data was quantified the cost of labor added to the cost of material used to make the procedures for collection of diagnostic specimen. All financial data used were based on the Income Statement Report, of the same reporting period. The costs of process, analysis and sample transport were not included.

Results: In this scenario, were raised in 1442 pre-analytical occurrences, of which 24,48% of samples were contaminated to microbiology analysis, noting as the occurrency that was more frequent in the collection. Values obtained at the Income Statement Report were respectively of R$ 3,34 per test of personnel costs and R$ 0,48 per test; resulting of the total of R$ 3,82 of the total cost of recolletc of one exam . This total value was multiplied by total data of recollection requested, resulting in a financial impact of about R$ 5,508.40 per year.

Conclusion: We must consider the current quality internal processes that directly reflect the results of this study. Was performed about 754.000 examinations during the study period resulting in a percentage of pre-analytical cases of approximately 0,2 %, resulting, a low percentage, owing to intense work training, and optimization flows/processes focusing on progressive decrease in the number of recollect. Within this Optics, we can reflect that this cost when compared with a high percentage of pre-analytical occurrences, will rise significantly. As seen in studies, when we estimate the value of the pendencies, the cost can rises to 55,6 %, at least. So, we might consider that from the moment that raises the number of recollections cases, consequently the cost will raises persistently, therefore, the absence of a continuous improvement working with emphasis on recollect reduction has an important impact in the financial health of the private laboratory.

B-154

Verify the Analytical Measurement Range (AMR) in the clinical laboratory: a proposed tool

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Background: The linearity range evaluation defined by the manufacturers for analytical systems is a guarantee of the results' accuracy and reliability in the lower and higher values of the method range. Moreover, it is a requirement for many clinical laboratories quality accreditation programs. The development of a statistic protocol to aid Analytical Measurement Range (AMR) monitoring is a challenge for laboratories managers who need to guarantee workflow and quality with a low cost in the clinical laboratory. Objective: To present a new statistical tool and a protocol procedure for the monitoring of the AMR based on the CLIA '88 requirements and concepts review to verify the linearity for analytical systems. This tool named Easy Linearity Curve (ELC) provides a quick and effective data evaluation for clinical assay systems. Methods: The ELC was used as a monitoring tool for clinical chemistry and immune-hormone analytical systems in a clinical laboratory. The tool suggests the preparation of patients samples' pools selected from laboratory routine, including lower, zero, and higher concentrations within manufacturer's linearity range. In order to prepare them, samples storage and stability conditions were observed and five samples were processed in duplicate or triplicate during the laboratory routine. Then, ELC performed statistical analysis including the estimated bias, total error, coefficient of variation, linear regression, second and third degrees polynomials regressions. As the results were inserted at ELC, it generates statistical analysis, linear regression and scatter plots for each measured point. The criteria tools were based on CLSI guidelines and Dr. Westgard's established rules that consider appropriated results if they were within criteria of analytical quality specifications.**Results:** The method is considered linear if coefficient of regression is above 0.99 for the first degree polynomial model and if the coefficients for the cubic and quadratic terms are statistically equal to zero for the second and third degree polynomial model at 5% of the significance level. ELC monitored analytical systems according to Quality Assurance expectative when following tool's recommendations. Below an example of immune-hormones studies made in the laboratory: **Conclusion:** This tool establishes a self-inspection program and assures the efficiency and accuracy of procedures and results. The use of an AMR tool to evaluate assay linearity under four different statistical criteria provides additional safety and reliability to clinical laboratory results. After ELC implementation the laboratory could evaluate costs reduction, guaranteeing internal management of quality processes ensuring the accomplishment of accreditation programs and process standardization.

B-155

Enhanced performance of a Clinical Laboratory with the use of Auto-verification

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Background:

LEAN principles, focused on the reduction of unnecessary operational steps, were previously applied to the pre-analytical portion of the Clinical Laboratory. The improved performance was measured by the reduced time to release test results or turn-around time (TAT). In the spirit of continuous process improvement (CPI), the Clinical Laboratory strove to further reduce the laboratory's TAT for release of patient results. The Clinical Laboratory targeted the post-analytical, result-releasing process for the next step of improving TAT goal achievement, by the implementation of auto-verification.

Methods:

The TAT results for 36 routine Chemistry and Immunology assays were calculated from the operational timestamp data in the Laboratory Information System (LIS), spanning pre-analytical, analytical and post-analytical processes. Flanking data from one week before and one week after implementation of auto-verification were compared to determine the performance impact of auto-verification on the percentage of TAT goals achieved.

Results:

The TAT achievement goals of 49,310 tests before, and 48,273 tests after auto-verification implementation, were compared to evaluate the impact upon TAT. The following results were observed:

Laboratory Process	Before	After	Change
Total tests reviewed	49,310	48,273	
Pre-Analytical Process	21 min	22 min	4.76%
Analytical Process	43 min	39 min	9.30%
Post-Analytical Process	11 min	6 min	45.45%
Average TAT	75 min	68 min	9.33%
Achievement of TAT goals	**97.10%**	**98.90%**	

Auto-verification assisted the lab to realize an overall reduction of 7 mins in the average TAT, with the greatest improvement in the post-analytical processing time (45.45% reduction).

Conclusion:

The implementation of auto-verification in the post-analytical processes enabled the Clinical Laboratory to achieve performance improvement. The results demonstrated significant reduction of TAT in the post-analytical process, leading to an overall increased percentage achievement of TAT goals.

B-156

Celiac disease diagnosis. Are endomysial antibodies still necessary?

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Background:In the last 20 years the diagnosis of celiac disease (CD) has changed. The development of the tissue transglutaminase type 2 (tTG2) antibodies as the target antigen of the endomysial antibodies (EMA) and the subsequent development of anti-tTG2 immunoassays has by far contributed to this new scenario. Anti-tTG2 was the recommended first-line serologic screening tool for identifying individuals at risk for CD, replacing the EMA for this purpose. The longer and more expensive EMA measurement procedure, the operator dependence, subjective interpretation and variability between observers and centers, has also contributed. However the new European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) guidelines for the diagnosis of CD, states the need to confirm positives anti-tTG2 results with EMA measurement. Also that serological tests are sufficient for diagnosis (avoiding intestinal biopsy (IB)) in certain cases: children or adolescents with symptoms or signs suggestive of CD (including atypical symptoms) presenting a tenfold multiple of the upper limit of normal (equivalent to the optimal cut-off) of anti-tTG2 test (anti-tTG2>10x ULN), or if EMA and human leukocyte antigen (HLA) DQ2 or DQ8 are both positives.

The aim was to compare anti-tTG2, EMA and IB results in children presenting anti-tTG2>10x ULN, to find out if EMA measurement is necessary or if it is just a redundant test; also the concordance between serological tests and IB, when requested.

Methods:Our laboratory is located at a public University Hospital that serves a population of 234551 inhabitants. From January 1st 2012 to December 31th 2014 children suspected of having CD with anti-tTG2>10x ULN were prospectively included in the study. Patients having immune globulin A deficiency or gluten-free diet were excluded. EMA immunofluorescence methodology used sections of distal monkey esophagus and anti-tTG2, an enzyme-linked immunosorbent assay using human recombinant tissue transglutaminase (ELiA Celikey IgA kit Phadia AB, Uppsala, Sweden). Through a retrospective database search in our Laboratory Information System every children or adolescent (patients younger than 16 years old) with an anti-tTG2>10x ULN was searched. Every patient medical record was reviewed to find out IB result and final diagnosis.

Results:In the period of the study there were 66 anti-tTG IgA>10x ULN. EMA was requested in 22 cases and all results were positive. All of this 22 patients expressed HLA-DQ2 or HLA-DQ8. 12 patients were diagnosed as CD without a IB and in 10 IB was requested. Of them, 9 had a positive result and one did not confirm the diagnosis of CD. In that case faecal test indicated the presence of Giardia Lamblia.

Conclusion:Serial use of EMA and anti-tTG2 to CD diagnosis when anti-tTG2>10xULN could be redundant, and IB is frequently demanded despite ESPGHAN guidelines. Giardia Lamblia infection is a cause of false positive anti-tTG2 and EMA test. More studies are necessary to demonstrate the utility of the confirmation of the anti-tTG2>10xULN with EMA, and the serological tests sufficiency for CD diagnosis in certain cases.

B-157

A Prospective Assessment and Physician Satisfaction Survey of Repeated Chemistry and Hematology Critical Results

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Background: Critical results alert healthcare providers of imminent danger that requires prompt intervention. Although not mandated at the national level, many clinical laboratories confirm critical results prior to their release; a practice that is not performed for non-critical results. Studies have examined the utility of confirming critical results but have not fully assessed the physicians' perspective regarding this practice. Our objectives were to corroborate that repeated critical results are unnecessary and to examine our physicians' opinions regarding the clinical laboratories' critical value procedures.

Methods: First, we prospectively evaluated selected critical results across five large hospitals (3 adult academic, 1 adult community, and 1 pediatric) during a 2-month period. The tests included hematocrit, hemoglobin, INR, platelet counts, PT, aPTT, WBC, ammonia, blood urea nitrogen, calcium, chloride, creatinine, cortisol, ethanol, glucose, lactate, magnesium, phosphorus, potassium, sodium, TSH, total bilirubin, total protein, troponin I, carbamazepine, digoxin, gentamicin, lithium, phenobarbital, theophylline, free phenytoin, and vancomycin. Blood specimens routinely submitted to the clinical laboratory were analyzed on the following instruments: hematology, DxH800 (Beckman Coulter, CA); chemistry, AU5822/AU680 (Beckman Coulter) or Dimension Vista 1500 (Siemens, DE); and immunoassay, DXI800 (Beckman Coulter). All specimens with critical results were reanalyzed to confirm the initial result per our laboratory protocol. The percent change was then compared with total allowable error criteria using the CAP and CLIA guidelines except for ammonia and troponin I, for which the American Association of Bioanalysis proficiency testing guidelines were applied. Subsequently, the clinical significance of repeated specimens via patient chart review and calculated paired t-tests were evaluated. Secondly, we developed and electronically distributed a survey (REDCap electronic data capture tools hosted at the University of Pittsburgh) to assess physician opinions concerning the current critical value list, procedures for confirming critical results prior to release in the EMR, and current and potential new methods to communicate critical results to healthcare providers.

Results: A total of 2,060 critical results were examined, and 34 exceeded the total allowable error. One result was clinically significant when repeated: ammonia (89 µmol/L versus 6 µmol/L). The discrepancy was attributed to a delay in re-analysis. Eighty-three percent of repeated analyte delta values were statistically significant (p value >0.05). There were 149 physicians with medical privileges across 11 hospitals representing anesthesia, emergency medicine, family medicine, internal medicine, surgery, and radiology that participated in the survey. Overwhelmingly, 92% of the physicians were satisfied with the current critical result list. Eighty-nine percent of physicians were in favor of the laboratory re-analyzing specimens before reporting the critical results. Interestingly, 72% preferred the current procedure in which the laboratory calls the results to healthcare providers, compared with 44% who welcomed the opportunity to have critical results communicated via HIPAA-compliant text message and email (percentages reflect physicians' selecting more than one preference).

Conclusion: Our data suggest that confirming critical results may not be warranted, but physicians prefer that the laboratory confirm and verbally communicate critical results. Communication of our findings with the physicians may impact their preference and collaborative efforts utilizing evidence-based laboratory medicine will be used as a model.

B-158

Internal service culture and its influences on the quality of external customer service (investigation - SERVQUAL)

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Introduction: The quality of the production services in Diagnostic Medicine was always a present worry. Meanwhile, support activities (services offered within organizations to their own employees) have been relegated to a lower-level position, with unknown consequences.

Objective: The objective of the study was to evaluate the quality of service of 14 corporate processes and their possible impacts on the external client.

Method: It deals with a descriptive, quantitative investigation, whose data was given statistic treatment to analyze the results. The investigation consisted of 260 participants. The quality of service was measured for each of the five dimensions of the SERVQUAL scale and the identified satisfaction gap. The data collected was subjected to statistic calculations: medium, mode, and standard deviation. To ensure the consistency of the questionnaire, the linear correlation was calculated for both of the modules, Expectations and Perceptions, assuming a value of $r \geq 0.30$ for affirmative validation.

The quality of support services was calculated by the P-E (Perceptions - Expectations) difference, using the scores attributed to each affirmative module.

Results: The lowest average of service quality perceived was registered in three affirmatives related to Reliability: Services carried out by the promised deadline (-1.59); User informed about when the service will be carried out (-1.52); Services carried out correctly the first time (-1.47). **Conclusion:** The results indicate priority aspects to be improved (a) the communication with users regarding data for carrying out requested services; (b) the conclusion of the services by the promised deadline, and (c) the trust that the user has that their problem will be resolved. These critical points mostly reflect the importance that clients give to aspects related to reliability and show that they expect their support-related requests to be addressed correctly and reliably.

B-159

Is CV related to Productive Efficiency in the Clinical Laboratory Setting?

R. A. A. L. Cardoso. *Laboratório Sabin, Brasilia, Brazil*

Background: In the evaluation of renal function, estimating glomerular filtration rate (GFR) is the most used laboratory test. In our Laboratory we used Jaffe based test with low productive efficiency and proposed to change to aminohidrolase/oxidase method. We aimed to optimize production efficiency and to improve the accuracy of creatinine test, combining productive efficiency with the accumulated biannual inaccuracy of the results of the internal quality control.

Methods: The creatinine test was changed from colorimetric (Jaffe) to traceable enzymatic (Amidinohidrolase / Oxidase). We calculated the production efficiency and the accumulated biannual imprecision from 2013 to 2014. Productive efficiency is the ratio between the quantity of tests performed by presentation and the quantity of tests reported by the manufacturer. The biannual cumulative inaccuracy of the results of level 1 and 2 related to the internal control materials was calculated by the Pooled CV = $\sqrt{}$ (Σ CVi2 / n). We used chi-square test to evaluate if the Productive Efficiency of the test increased when occurred the decreasing Pooled CV of Level 1 and Level 2.

Resultados: The main problem observed was the presentation of each reagent bottle. Dedicated reagents optimized the onboard stability, precision and accuracy. An association between increased production efficiency and reduction of CV Pooled Level 1 ($p = 0.0014$) and level 2 ($p = 0.0240$) was observed.After mapping the daily demand and the activities we requested the manufacturer a new bottle size compatible with daily consumption, optimizing onboard stability and obtaining an effective reduction of 76,5% over budget.

Conclusions: Mapping the daily demand demonstrated that the use of a specific, precise and accurate test for creatinine facilitates obtaining higher productive efficiency and optimizes the financial resources of production.

Table 1 CV = Coefficient of variation EP = Productive efficiency

Metrics	1st Semester 2013	2nd Semester 2013	1st Semester2014	2nd Semester 2014
Pooled CV Level 1	7,06	5,81	1,78	2,12
Pooled CV Level 2	4,94	2,79	1,41	1,5
EP	45,82%	48,62%	95,72%	84,22%

B-160

Follow up of Productive Efficiency on a Clinical Laboratory

R. R. L. Cardoso. *Laboratório Sabin, Brasilia, Brazil*

Background: Productive Efficiency occurs when a productive model explores the full potential of is installed capacity. We aimed to determinate the importance of periodic measurement of Productive Efficiency in production lines in a Clinical Laboratory.

Methods - We Adaptated the concept of Overall Equipment Effectiveness (OEE) on sample processing lines, followed by periodical measure of overall production efficiency of inputs directly connected to production of clinical laboratory tests. Productive input efficiency was calculated as:

EP (%) = Cr/Ci. Where EP (%) = productive input Efficiency; Cr = actual production capacity of the input; Ci = Ideal capacity of input output.

We stated the premise of 100% of maximum performance considering as high performance indicator the number of tests described by the manufacturer. The complementary of EP(%) (100% - EP(%), represent the global lost in the production line. This value was followed as an internal indicator of performance, focusing on investigation of causes of low efficiency (defined as 30%) such as loses or fails.

Results:After the 1st measurement with efficiency below designed by the manufacturer, were mapped all line for production processes, indicating the points of improvement and barriers in all production system.

Over the period and implementation of improvement actions we eliminated five barriers identified as impact points to low overall productive efficiency, reaching the "state of the art" in 4th quarterly measurement.

The importance of implementing the periodic measurement of Efficiency of Production Lines on a Clinical Laboratory context could be measured as maximization of resources in high-volume production. Applying periodic monitoring and promoting improvement actions in production processes, the efficiency indicator improved the budget in 23.13%. Implementation of production efficiency monitoring enables a simple way to evaluate the availability of tests described in the manufacturer specifications, in addition to monitor quality problems and other interference tests on the overall production system efficiency.

Global Production Efficiency Ratio measures in quarterly period.

Period	1st Measurement	2nd Measurement	3rd Measurement	4th Measurement
	75,82%	82,59%	91,47%	98,95%

B-161

Nonconforming Event Reporting: Essential Element of a Quality Management System

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Background: Errors in the clinical laboratory can lead to adverse clinical outcomes and significant financial and health system costs. Identifying these errors and preventing them is a key part of the quality assurance system of the laboratory. Analysis of nonconforming events, that is, events that are not according to rules or expectations, has been seen in other industries, such as aviation, as a way to prevent adverse events and help to develop a culture of safety. These events, even though they may not lead to significant errors in and of themselves, can be used as part of the continual improvement process. Ongoing monitoring of these events can show the effectiveness of the plan-do-check-act cycle. Capturing these events in an analyzable format can be challenging: the only system available that even approximated capturing these events was almost totally paper based and used a variety of forms and event criteria that varied across divisions.

Methods: A subcommittee was established to address capturing nonconforming events. A policy was drafted describing guidelines for accomplishing this within the laboratory. Three separate forms were created on the laboratory intranet Sharepoint site, incorporating the information previously captured on the paper logs throughout the lab and at the same time fulfilling the regulatory requirements. These included a Nonconforming Event Log, A Customer Complaint Log, and a Downtime/QC Issues Log. Workgroups at all levels, bench technologists through management, provided feedback on the forms to further refine their utilization in each division. It was decided that these forms were to be filled out by the person recognizing the nonconforming event, in real time, and not by a supervisor or manager. Criteria for reporting an event were made as uniform as possible across laboratory divisions and the relationship to the UHC event reporting system used by the hospital was established.

Results: The rollout of the new nonconforming event reporting system went live in February 2014.Staff were encouraged to document their nonconforming events in the appropriate Sharepoint log. Management was asked to support the transition and begin reviewing the information entered. There was some initial resistance to the electronic system and implementation was not totally uniform across laboratory divisions. Eventually, however, the number of events recorded increased to approximately 1300/month and totaled 15383 in one year. The increase in reported events which carried over into the hospital event system actually caused concern in the hospital outside the laboratory until the new program was explained.

Having the logs in Sharepoint provided a central database from which each divison could create custom reports to analyze these events. Reports can be created from numerous criteria to isolate specific information, such as all events of Critical Severity within a time period. Several divisions in the laboratory have developed specific programs to address recurrent events and prevent potential serious errors. There is a monthly meeting to discuss the nonconforming events and projects related to them across the laboratory.

Conclusion: A nonconforming event reporting system with support across the laboratory staff can be an effective and essential element of a quality management system.

B-162

Laboratory utilization of HbA1c, PSA and BMP in an academic medical center

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Objective: Testing with little or no diagnostic value is a significant source of unnecessary cost to the health care system. Using data available from an academic medical center we evaluated testing patterns for three diagnostic test scenarios to quantify test utilization patterns. The objective of the study is to quantify overutilization of Hemoglobin A1c (HbA1c), Prostate Specific Antigen (PSA), and Basic Metabolic Panels (BMP) to understand the effects of soft stops (warnings with information about indications) in improving utilization.

Methods: Using evidence-based guidelines, we determined test scenarios for which at least one test was largely unnecessary. The patient's medical history was reviewed to understand the indications of the test. The data was collected for one year (October 2013 to October 2014) and additional BMP data (October 2012 to March 2013) to compare the effect of soft stops on lab requisitions. An HbA1c ordered within 90 days is considered overutilization. The PSA ordered in patients less than 40 years, greater than 75 and ordered within 84 days is considered overutilization without any indications. The BMP ordered within 4 hours without any acute indication is considered overutilization. We also analyzed overutilization patterns in different departments, types of practitioners and time trends in utilization. We would like to extend this framework to other tests and regularly monitor the changes to improve overall laboratory utilization.

Findings: The HbA1c was over utilized in 15.16% cases (1112 tests) and the test was performed more than once on the same day in 94 patients. The top 5 departments that over utilized the test (more than 100 tests in last one year) were Neurosurgery/Neurology, Pediatric endocrinology, outpatient lab, Transplant division and gastroenterology divisions. Surprisingly, the top five attending physicians that over utilized HbA1c were from pediatric endocrinology, neurology, infectious diseases and emergency medicine. The PSA was over utilized in 20% (34 tests) tests. The BMP was over utilized only in 3.75% tests (5677). The comparison of before and after soft stop implementation for BMP order shows that overutilization has decreased from 7.01% (October 2012 to March 2013) to 3.77% (October 2013 to March 2014).

Conclusions: The amount of overutilization is significant in attending physicians, which may lead to continuation of these patterns in trainees. Education in divisions where overutilization is common may help improve the laboratory utilization. The data can also provide insight into financial impact on hospital and effect of warnings implemented in electronic health record systems.

B-163

Strategic Planning in the Clinical Laboratory: aligning greater participation of professionals, management excellence criteria and execution effectiveness

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Background:

A structured process of Strategic Planning is critical to the organization success, including clinical laboratories. This process, often have limited participation to directors and managers of companies and has huge challenges in the strategic actions implementation and results monitoring phases. The aim of this study was to propose, implement and validate a new model of strategic planning and execution applied to the clinical laboratory. In this model we propose a broad participation of laboratory personnel, at different levels of depth, alignment with excellence criteria (by Brazilian National Quality Foundation - FNQ, similar to Malcolm Baldrige Excellence Program), balanced structure of strategic objectives (Balanced Scorecard) and execution monitoring with a "Strategic Implementation Chart" for each different process, by the Consultive Board of laboratory.

Methods: The new model was validated in a medium clinical laboratory, in southern Brazil. The process began with a questionnaire distributed to all laboratory personnel. In this questionnaire each professional examined: mission, vision, organization values and comparative market informations (benchmarking). Strengths and weaknesses of the lab, and market opportunities and threats could be analyzed and marked in the questionnaire, according to different criteria of excellence (FNQ). From all this analysis, each team/process suggested strategic objectives balanced across different dimensions: Financial, Customer and Market, Innovation, Processes, Sustainability and People/Organizational Learning. These suggested strategic objectives were validated in one-day seminar, with all the leaders of the company. From this leadership consensus, strategic objectives were defined and, for each of these, were defined responsibility, and an action plan was approved. The strategic actions were shares to all organization professionals by a "Strategic Map" and monitored with the "Strategic Implementation Chart" and using key performance indicators, analyzed quarterly by the Consultive Board of the laboratory.

Results: Among the positive results obtained with the new model, the more important was a higher participation of the laboratory professionals in the strategy formulation process, which led to greater commitment to the proposed goals. The generation of ideas, which resulted in the strategic objectives defined, was more abundant and with greater depth and adaptation level to the current status of the organization and respective market challenges. The new strategy formulation model, aligned to excellence criteria and balanced strategic dimensions, facilitated the consensus of the strategic objectives and definition of responsibilities, with gains in the process of strategic actions execution control.

Conclusion: The new model of strategic formulation and execution proved to be fully adaptable to the clinical laboratory, aligning management excellence criteria and balanced performance dimensions. The biggest advantages were identified as being a broad participation and commitment of professionals, as well as more control in strategy implementation. The effectiveness of the strategic actions positively impacted the laboratory's customers, particularly related to improvements in processes and services, deployed with greater agility and safety.

B-166

Utilizing Lean Six Sigma to Improve Processes in Hematology

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Introduction: The Dartmouth Hitchcock hematology laboratory supports the established medical and research programs that make DH a world class medical and teaching facility. The hematology lab, through specimen analysis, actively supports the bone marrow and organ transplant program and trauma center. Seeking out and using the latest automation and fluorescent flow cell technology allows us to process over 800 CBCs per day. Hematology still relies heavily on manual methods for peripheral blood scans and differentials. These efforts support the needs of our inpatients, outpatients for the Norris Cotton Cancer Center, and outreach clients throughout NH and VT. An opportunity exists to utilize lean and six sigma process improvement methods to align the 24 hour staffing model in the Sysmex automated hematology work block, including the volume of peripheral blood differential slides and scans. **Materials and Methods:** The original stated goals in the project proposal were to improve staff satisfaction while maintaining turn-around times (TATs). Pre- and post-

improvement staff satisfaction surveys were conducted. TATs were continuously monitored. The results of this survey were evaluated using various charts and affinity diagrams. Standard work processes were created and work was redistributed among the various work benches (a work bench is a collection of related tasks assigned to a person on a given day). These processes were then piloted and observed on all shifts. Job aids were created to facilitate the change. Pilots were designed to redistribute a small amount of the work in the early morning hours. The goal of the pilot was to shift some of the early morning diffs from a time with few staff to a time with more staff. The two inpatient heme/onc units (HSCU and 1WST) were selected as they generate the most manual microscope work; these samples are often the most time consuming due to decreased WBC counts or abnormal cells. Quick Wins: We were able to relocate our most frequently used printer to where the staff does most of their work. This printer is used for 2 hour TAT reports, pending lists and work lists. Additionally, we implemented automatic printing of requisitions for smear reviews, fluid reviews, hemoglobin electrophoresis and thrombosis screens upon arrival of the specimen in-lab. This relieved the tech of the task of manually printing each of these, which saves time and also serves as the visual trigger to perform the test. **Results:** The final survey results showed significant improvement in staff satisfaction. 100% employees responding to the survey were positive about the improvements made and there was no degradation in TATs. **Conclusions:** Lean and Six Sigma tools, although developed for manufacturing, are easily applied in the healthcare setting. Use of these tools improved employee satisfaction while maintaining TAT's and quality patient care.

B-167

Retrospective Analysis of Patient Data for Reference Range Verification Following Implementation of New Chemistry Analyzers

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Background:

Our institution transitioned from chemistry analyzers based on dry slide technology (the OCD Vitros®) to one based on wet chemistry (Siemens ® Dimension Vista 1500). Reference ranges were verified for all assays on the new instruments before going live with at least 40 healthy individuals as recommended by the CLSI guideline (C28-A3). Following the implementation of the Vista instruments, clinicians began reporting an increase in the number of patients with hypoalbuminemia without clinical explanation, and questioned the appropriateness of the serum/plasma albumin reference range (3.9-5.1 g/dL for 1-54 years old). Therefore, we investigated the need for a potential change in albumin reference range using retrospective analysis of patient data from the electronic medical record (EMR).

Methods:

JMP software was used to analyze the histogram distributions of 169 and 185 patient albumin results over a period of one month before and after transitioning to the Siemens® Dimension Vista 1500 analyzer, respectively.

Results:

For albumin measurements, the OCD Vitros used bromocresol green dye-binding method whereas the Siemens® Vista uses bromocresol purple (BCP). While the BCP method is known to be negatively biased compared to the BCG method due to its greater specificity for albumin, our initial method comparison using 46 samples showed only a minimal negative bias of 0.13 g/dL for the Vista method. Given this minimal constant bias in the initial method comparison, the reference range of 3.9 - 5.1 g/dL for ages 1-54 years old was not changed with implementation of the Vista analyzer. However, after receiving feedback from clinicians on increased rates of hypoalbuminemia, we compared the distributions of patient albumin results before and after implementation of the new analyzer which revealed a larger negative bias. Specifically, the albumin results before go-live had a median of 4.1 g/dL (with the 2.5th to 97.5th percentile range of 2.6-4.8 g/dL) whereas the albumin results after go-live had a median of 3.8 g/dL with the 2.5th to 97.5th percentile range of 2.2 -4.6 g/dL. The difference in the medians of the distributions indicated a larger negative bias of 0.3 g/dL for the Vista method, larger than the negative bias of 0.13 g/dL seen on the initial method comparison. This was consistent with the observations made by clinicians that the reference range for albumin of 3.9-5.1 g/dL was inappropriately high, leading to overdiagnosis of hypoalbuminemia in healthy patients. Therefore we lowered the reference range of albumin to the Siemens® recommended reference range of 3.4 - 5.0 g/dL.

Conclusions:

While performing method comparison with 40 samples is recommended per CLSI guidelines, analysis of larger volumes of patient data post-implementation may unmask discrepancies between methods that are not apparent from comparisons using 40 samples. In this case, clinician input triggered a re-evaluation of the albumin reference range, which identified a larger negative bias than was apparent during instrument validation. Therefore, post-implementation data mining and retrospective analysis is a useful tool in lab management for re-evaluation of reference ranges.

B-168

RDC20: What has changed in the Brazilian legislation concerning the transport of biological material?

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Background: The samples to be representative, its integrity should be maintained during the pre-analytical phase, including transportation and handling of the material. In order to set health standards for the transport of biological material of human origin, was published RDC No. 20 on 04.10.2014. The resolution determines the standardization of processes and management of errors, with record of non-compliance in order to ensure the quality of the results of the analysis of these materials.

Objective: Review proposed by the resolution, and indicate what is needed for the health service to suit, in the routine of a large private laboratory.

Methods: Analysis of current legislation and checking each item in the processes adopted in the routine of a private laboratory.

Results: As analysis has been verified as a very important factor, the right direction of the sender's responsibilities, carrier and the recipient, which should be defined and documented. In addition, all the people engaged should receive proper training. It is up to the sender to ensure compliance with the requirements for packaging material, which must be done according to their biological risk category, including packaging, which should be considered the specificity of biological material and the purpose of transport, preserving its integrity and stability as well as the safety of personnel involved in the process. And yet maintain document validation and standardization of the process. The transporter must ensure the necessary infrastructure to process, porting document enabling cargo traceability, and check the packing conditions upon receipt. To outsource the transport, the provider must be licensed and trained. The recipient must ensure that the opening of packaging occurs in an appropriate and safe manner site, according to the specifics of each material.

Conclusion: Observed the importance of the standard from the Brazilian regulatory institutions, the evaluation of processes for compliance is essential, we identified several conducts that already is consistent with the regulator text in our service, and new procedures were implemented. Such as use of bags (packaging) for transport by identifying and seal, housed in a standardized process, in writing, like the standard operating procedure of transport; and other necessary documents and validations necessary. In addition to the traceability of cargo and sample system, the RDC 20 clarifies the procedures necessary to ensure the quality and stability of samples to be analyzed for diagnostic purposes, and it's in the Guide of ANVISA for Transport of Human Biological Material for Clinical Diagnostic Purposes, this manual was published in 2014, and will be updated soon. It is essential to adequacy of all health services, as well as ensuring sample integrity for accuracy of results, non-compliance constitutes a health violation. Those involved in the handling of samples must obey the rules of biosafety and worker health. Also emphasizing the need for ongoing training to all involved.

B-169

Westgard Sigma Verification Program, as a Tool to Improve Laboratory Performance

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Background:

Quantification of improvements in laboratory performance is essential for continuous quality improvement (CQI) programs. The use of Sigma metrics to quantify changes of analytical performances, however verification of performance changes are not addressed by internal or external quality control programs. The Westgard Sigma Verification Program represents an independent external assessment to validate improved Sigma performance to supports CQI goals.

Methods:

The performance of analytical process is still the most important part of laboratory services, then the analytical performances were calculated by Sigma metrics using Sigma metric equation of "Sigma = [(TEa-%Bias)/%CV]".

Results:

The Sigma values of 28 chemistry assays during Q3 and Q4 2014 were calculated as part of the laboratory implementation of the Westgard Sigma Verification Program. We found that at the beginning of the program during Q3, there were 21 assays (75.0%) with performance equal or better than 6-Sigma, 3 assays (10.7%) with performance between 5- to 6-Sigma, 2 assays (7.1%) with performance between 4- to 5-Sigma, 1 assay (3.6%) with performance between 3- to 4-Sigma, and 1 assay (3.6%) below 3-Sigmal. After the second round of the program during Q4, there were 23 assays (82.1%) with performance at or above 6-Sigma, 2 assays (7.1%) with performance between 5- to 6-Sigma, 1 assay (3.6%) with performance between 4- to 5-Sigma, 1 assay (3.6%) with performance between 3- to 4-Sigma, and only 1 assay (3.6%) with performance below 3-Sigma.

Conclusion: We found that participation in the Westgard Sigma Verification Program aided our laboratory in understanding the analytical performance of our assays as well as the choice of quality requirement for each assay. This further allowed us to focus our continuous quality improvement (CQI) activities to target the most problematic assays. We also identified which assays were significantly impacted by the choice of allowable total error (TEa), particularly when comparing performance between laboratories. We plan to implement multi-stage SQC designs to ensure equivalent analytical quality throughout all patient testing cycles.

B-170

Strategies to increase General Practitioners awareness of clinical decision making laboratory results: The vitamin B12 experience.

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Background: It is considered that laboratory workers should also think about the steps that occur outside the laboratory and thus prevent errors related to the interface between laboratory and clinician.

However, post-post-analytical phase, when the test result is received, interpreted and acted upon, is less studied. In fact, 25 to 46% of laboratory errors are referred to be generated for delayed or missed reaction to laboratory reporting, incorrect interpretation, inadequate follow-up plan or failure to order the appropriate consultation.

Vitamin B12 deficiency should always be immediately treated, because may lead to DNA damage, cognitive decline or dementia and because the lack of toxicity of vitamin supplementation. However in our setting a percentage of primary care patients presenting vitamin B12 results below 100 pg/ml did not receive vitamin B12 supplements.

The aim was to find out if General Practitioners (GPs) awareness of vitamin B12 deficits results has improved after strategies design and implementation.

Methods: The laboratory is located at a Public University Hospital that serves a population of 234551 inhabitants and receives samples from inpatients, outpatients and primary care patients. Laboratory requests are made electronically from the primary care patient's electronic medical record (PEMR) by the GPs and the reports are automatically sent from the laboratory information system (LIS) to the PEMR.

Through a retrospective database search in our LIS (from 1st January 2007 to 31th May 2014) primary care patients with a result of vitamin B12 lower that 100 pg/ml were studied. Every PEMR was reviewed to find out if patients had visited their GP, if the result was communicated (laboratory report available in PEMR) and received by the doctor, and if the result was reviewed (patient treated with vitamin B12 supplements before one year period).

Through 2 meetings, laboratory personnel and GPs agreed the criteria to consider that low vitamin B12 results were "interpreted correctly and taken the consequently action": when the patient received intramuscular treatment prescription before one month after phlebotomy.

On 1st November, 2014 to 31th January (post intervention period), a strategy was designed in consensus with GPs to improve clinician awareness of vitamin B12 results lower than 100 pg/ml: firstly automatically (via LIS) is recommended, through a comment on the laboratory report, to treat the patient. Secondly a laboratory report is printed on garish colour paper and lastly in PEMR is signaled the convenience for a patient appointment.

In pre and post intervention periods was compared the rate of vitamin B12 results communicated, received and interpreted correctly and taken the consequently action.

Results: 100% of the 197 low vitamin B12 results of the 197 patients in the pre intervention period were communicated and received. 85% were reviewed and 65 % interpreted correctly and taken the consequently action. In the post intervention period there were 12 patients. 100% of the results were communicated and received, and 92% were interpreted correctly and taken the consequently action.

Conclusion: From the Laboratory and in consensus with clinicians, strategies can be designed to increase GPs awareness of clinical value laboratory results.

B-171

Laboratory Information System utilization as a previous step of guidelines implementation: HbA1c as a tool to Diabetes diagnosis.

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Background: American Diabetes Association recommends requesting HbA1c to every person older than 45, when it was not measured the previous 3 years, as a tool to diagnose type 2 diabetes mellitus (DM).

The prevalence of DM in Valencia Community among subjects older than 18 years is 13.3%; however 6.25% is unknown. By applying recommendations the detection of the disease could improve and hence its prognosis. However, previous to guidelines implementation it is necessary to find out the current pattern of HbA1c requesting to be able to calculate and predict the cost if recommendations were followed. The aim was to find out how many additional HbA1c would have been measured if the test would have been processed in every primary care patient above 45 years with a lab test requested, no HbA1c measured the previous 3 years, not demanded by General Practitioner (GP) and sample availability in the current request.

Methods: The laboratory is located at a Public University Hospital that serves a population of 234551 inhabitants. It receives samples from inpatients, outpatients and primary care patients. Laboratory information system (LIS) (OMEGA 3000, Roche Diagnostic®, Barcelona, Spain) manages laboratory requests of every inhabitant independently of attendance as an inpatient, emergency patient, outpatient or primary care patient.

The strategy consisted in a "quality test", that was automatically registered by the LIS in the request of every primary care patient above 45 years and no HbA1c measured the previous 3 years. It was also studied in which cases HbA1c was not requested by GP, when a Cell Blood Count (CBC) was also demanded (sample availability to measure HbA1c) and the cost if HbA1c would have been measured in CBC specimens as a strategy to detect DM patients.

Results: In one year period, 91219 primary care patients' requests were received. 61955 were older than 45 years. 25242 had not a HbA1c requested the previous 3 years. In 7894 HbA1 was requested by GPs. However in 17348 (68.7%) HbA1c was not requested by the GP in the current request. In 13085 patients, in whom a CBC was requested, there was sample availability for HbA1c measurement. The cost if the sample would have been processed would be 18004 dollars.

Conclusion: Guidelines implementation for DM diagnosis by GPs is insufficient in our population. From the Laboratory and through LIS, it is possible to gather information to be evaluated in communication with all the figures involved in medical process to decide the convenience of strategies design and implementation in order to improve clinical decision making.

B-172

Occupational Safety Management in Clinical Laboratory

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A Clinical Laboratory in Brasilia, Brazil, has an occupational safety management system in place since 2003 and, among the indicators monitored and followed up, one of them is the work-related accidents. These accidents are classified as typical (when they occur in the laboratory and are inherent to the activities of the professionals involved), needle-stick injuries (during the collection of biological material) and transport accident (Transport home-work, work-home). Methods: when accidents occur, they are reported immediately to the health sector and company security, which communicate this accident to the governmental organ.The worker is sent for medical care where an investigation around the cause of the accident is made to take

such actions as prevention and control and retraining. Results: In 2014 there were 23 occupational accidents, 7 typical, 8 needle-stick injuries and 8 transport accident. In 1.796 million customers served, there were 12.8 accidents per million. Conclusion: According to the security and control measures established, training and routine inspections, and compared to national benchmarking, the series of work-related accidents is small, concluding that the rules and occupational safety management practices have been satisfactory.

B-173

Risk-Based Quality Grades - An Alternative to Sigma Metrics

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Objectives

1.to introduce the Risk-Based Quality Grade© (R-B-Q Grades©) as a metric to:

a.combine the current risk of the analytical process producing a medically-unreliable result with

b.the potential risk of the quality control process failing to detect a clinically significant error

2.to compare the R-B-Q Grade to sigma as a metric to manage patient risk

Methodology:

1.We examined analytical process quality and quality control practices from three distinct groups separated by dates and QC practice, with a total of 46 laboratories, 274 methods, and 612 QC samples for a total of seven analytes.

2.For each Q.C. sample, we gathered: 1. Measured mean; 2. Measured SD; 3. Peer mean; 4. TEa limit, 5. Q.C. Chart assigned mean; 6. Assigned SD; and 7. Q.C. rule(s)

3.We used Quality OptimiZer™ software to:

a.measure the Current Risk Level as the percent of results that currently fail TEa limits and may be medically-unreliable;

b.simulate a shift that would cause 2.3% of results to fail TEa limits;

c.recommended a mathematically-optimized 5-part Q.C. process;

d.measure the Potential Risk Level as the probability that a patient tested after the simulated error will be exposed to unacceptable risk

e.compare the effectiveness of current and recommended QC processes to detect this significant shift

f.grade patient risk based on current and potential risk

g.measure Margin for Error (to calculate sigma)

4.We compared the interpretation of acceptability of quality and probable action based on R-B-Q Grades and sigma

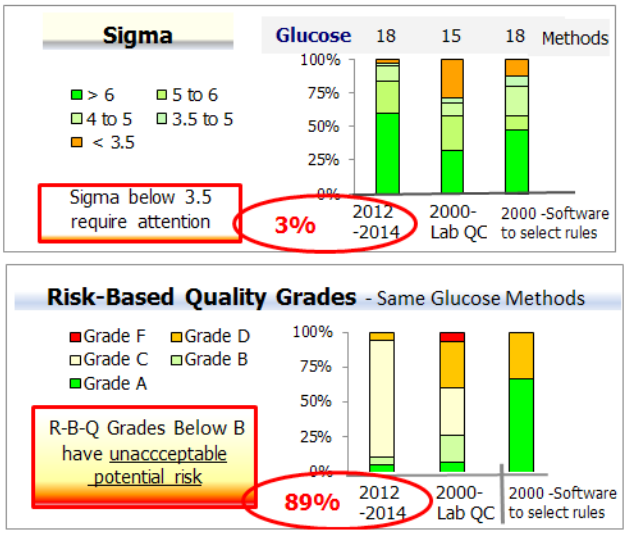
Results

Sigma metrics would indicate that 3% of methods require attention.

R-B-Q Grades would indicate that 89% of methods have unacceptable potential risk

Conclusions

The Risk-Based Quality Grade© should be further investigated as a metric to manage patient risk



B-174

Issue and Complaint Management in a Large Integrated Laboratory System Using a Web-based Electronic Tool

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The North Shore LIJ Health System Laboratories is a large health system based laboratory comprised of a central core lab, 12 hospital based labs performing approximately 16 million billable tests/year servicing the New York area including Long Island, Brooklyn, Queens, Manhattan and Staten Island. The Core Laboratory performs approximately 8 million of those billable tests. Currently there are approximately 1400 clients, including outreach, faculty practice, hospitals, nursing homes and in 2014, The New York City Health and Hospitals Corporation Laboratories has partnered with the NSLIJ Health System Laboratories. Since 2013, our client base has been growing rapidly, by approximately 8% per year, with a large increase in test volume (20%) and complexity. Concomitantly, there has been an increase in the number and complexity of client complaints and issues. Due to the number of new EMR interfaces, there have been many more LIS related issues. There was an associated increase in accessioning related errors, such as the ordering of incorrect tests and missed orders, as well as an increase in client generated issues such as incorrect specimen collection, unavailable specimen pick-up, amongst others. Our standard process of receiving complaints through our call center, logging cases into a front-end complaint management software system and resolving issues by assigning cases to management responsible for the lab section where the error occurred, has become less than optimum in providing excellent client satisfaction. To address this situation and provide clients requiring immediate information about corrective and preventive actions (CAPA), we have supplemented this process with the implementation of a real-time web-based solution to enable clients to view the progress of our complaint resolution on-line. This change also involves daily oversight by our Quality Management (QM) department of any new issues and complaints which may arise. QM expedites issue resolution by identifying process related issues , by ensuring immediate follow-up, and by implementing appropriate CAPA. On a monthly basis, the QM department then evaluates and trends occurrences and performs additional in depth analysis to make existing processes more robust. The incorporation of an electronic web-based tool allows for not only better enhanced real-time communication between the laboratory and its clients, but also engages the laboratory team in expediting complaint resolution. This new technology will allow for more effective communication, documentation and issue resolution for our prospective client complaints.