Wednesday, August 3, 2016

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

Management

B-130

Sigma Metrics as Performance Indicator Contributes to Effective Cost and Man-hour Saving in Chemical Pathology Laboratory

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Backgrounds: Sigma metrics as performance indicator allows analyzing control materials (IQC) in a flexible manner according to analyte performance, thus avoids repeated testing of IQC in a period when the system was performing stably, consequently minimizes un-necessary cost expenditure and man-hours wastage.

Methods: Starting from 1 January 2010 our laboratory applied sigma metrics in internal quality control plan. Instead of analyzing IQC for 29 chemistry and 15 immunoassay analytes, in Cobas 6000 (Roche Diagnostic), every eight hours, frequency became analyte performance specific. Performance of each analyte was reviewed every 8 months according to IQC data with sample size ranged 200 to 700 per analyte. During which more than one lot of reagent, calibrator and control were involved. Sigma metrics of each analyte was calculated using the formula [Sigma metric = (TEa-bias)/ CV]. TEa, bias and CV were obtained from respective defined allowable limit of performance of the Royal College of Pathologists of Australasia Quality Assurance Program, in-house observed inaccuracy and imprecision respectively. Performance of each analyte was assessed on the sigma scale. Frequency of analyzing IQC for analyte of sigma >=5, 4 and 3 was once, twice and thrice respectively.

Results: Among 44 analytes, daily IQC analysis frequency of 31 (sigma>=5), 7 (sigma=4) and 6 (sigma=3) analytes was once, twice and thrice respectively. These changes contributed to over 50% reduction in control materials and reagents consumption, which accounted for an annual cost saving of over HKD 1,200,000. Time reduction in IQC preparation, analysis and reviewing stably performed analytes contributed to an annual man-hour saving of 0.3 full time employee which was valuable for new service development while facing manpower constraint.

Conclusions: Applying sigma metrics as performance indicator, our laboratory executed an analyte performance specific internal quality control plan. While maintaining overall service quality, the plan contributed to an effective cost and man-hour saving.

B-131

Determining the utility of creatinine delta checks: a large retrospective analysis

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Background:

Delta checks use two successive test results to detect changes greater than expected for physiological variation. A flagged delta check holds the result for further review by laboratory staff – a long-standing practice for identifying errors that are not detected by other routine quality control measures in the lab. However, now with relatively fewer errors since the introduction of modern automated clinical chemistry analyzers and laboratory information systems (LIS), excessive or "false alarm" delta checks can increase workload, inefficiency of staff, and turnaround times. As a result, the utility of delta checks in detecting true error is unclear. In our laboratory, we experienced a small number of erroneously high creatinine results over a 6 month period that were determined to be analytic, or instrument-related errors. Therefore, the objective of this study was to perform a retrospective analysis of creatinine results to determine whether establishment of a creatinine delta check would be an effective means for capturing true laboratory error going forward.

Methods:

All patients with a minimum of two creatinine results during March of 2015 were selected for preliminary review (n = 23,410). Of the analytic errors previously confirmed in the lab, the minimum percent change was 58%; therefore it was decided to review all results that changed by ± 50% (n = 234) to determine the utility of establishing a delta check of this magnitude. Result review entailed thorough examination of patient medical records, including provider notes, ancillary studies, and other laboratory tests at the time of the delta check results. Based on this review, the etiology of creatinine value change was categorized as laboratory error, physiologic change, or inconclusive. Physiologic change was further classified as secondary to pre-renal, renal, post-renal, dialysis/end stage kidney disease (ESKD), transplant, or mixed (i.e. renal and pre-renal) etiologies.

Results:

Out of the 234 delta checks reviewed, 1.3% (3/234) were determined to reflect 2 instances of true laboratory error that went unrecognized by laboratory staff. In both of these cases, the clinical teams immediately recognized that the results were erroneous and ordered a re-draw. 91.0% (213/234) of the delta checks were determined to reflect a physiologic change in creatinine levels. The remaining 7.7% of delta checks (18/234) were deemed inconclusive. The most common etiology for physiologic change in creatinine was pre-renal at 49.3% (105/213), compared to dialysis/ESKD (22.1%, 47/213), transplant (11.3%, 24/213), mixed (10.8%, 23/213), renal (5.2%, 11/213), and post-renal (1.4%, 3/213).

Conclusion:

This retrospective analysis identified two instances of laboratory error reflected by 3 delta checks (1.3%). The vast majority (91.0%) of creatinine results that changed by ± 50% were due to physiologic etiologies. Our analysis clearly demonstrated that establishment of a ± 50% delta check for creatinine would overwhelmingly flag true biological change and would not be an efficient means for identifying rare laboratory errors. Thus, large-scale, retrospective data analysis with medical record review can serve as a powerful tool to determine the efficacy of current or proposed delta checks.

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Verification of the target values established using robust statistical method

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Background: External quality assessment (EQA) schemes are important for laboratory quality management. In EQA, results are usually assessed against a target value. Therefore, the establishment of reliable target value is the premise of effective assessment. **Methods:** Analytical results were grouped according to the analytical method. Data distributions of the original results were tested using Shapiro-Wilks (n<50) or Kolmogorov-Smirnov Z test (n>50). Outliers in each set of analytical results were deleted using a robust statistical method, which involved establishing a Tukey fence, namely Q_1 -1.5 IQR to Q_3 +1.5 IQR. Data distributions of trimmed analytical results were tested using the above statistical methods. The mean was used as a target value if the trimmed analytical results were normally distributed; otherwise, the median was used. Percent difference between the target value and Roche's calibration value was calculated. **Results:** The original analytical results were not all normally distributed. Outliers were deleted at 0-14.6%. The trimmed analytical results were all normally distributed. The target values are shown in the Table. Percent differences between target values and Roche's calibration values were -0.55-1.48. **Conclusion:** Target values established using a robust statistical method are close to the calibration values provided by Roche.

Analyte, no. of results and outliers, method, calibration value, target value and % difference						
Analyte	No. of results	No. of outliers	Analytical method	Calibration value	Target value	% difference
P	54	0	Molybdate UV	1.70 mmol/L	1.70 mmol/L	0.00
GLU	52	2	HK	11.0 mmol/L	11.0 mmol/L	0.00
UA	58	1	Enzymatic colorimetric test	308 umol/L	307 umol/L	-0.32
TP	59	2	Biuret	54.2 g/L	54.0 g/L	-0.37
ALB	58	1	BCG	37.9 g/L	38.1 g/L	0.53
TC	59	2	CHOD-PAP	4.14 mmol/L	4.19 mmol/L	1.21
TG	58	2	GPO-PAP	1.46 mmol/L	1.46 mmol/L	0.00
ALT	61	2	IFCC w/ or w/o pyridoxal phosphate	96.4 U/L	97.7 U/L	1.35
AST	61	1	IFCC w/o pyridoxal phosphate	97.0 U/L	98.2 U/L	1.24
ALP	58	1	IFCC	203 U/L	206 U/L	1.48
AMY	41	6	IFCC liquid	181 U/L	180 U/L	-0.55
LDH	53	2	IFCC liquid	242 U/L	242 U/L	0.00
FE	37	1	FerroZine	35.4 umol/L	35.6 umol/L	0.56
HBDH	40	1	DGKC	254 U/L	255 U/L	0.39

B-133

A National Survey of Critical Value Reporting Procedures for Chemistry and Haematology Analytes in Clinical Laboratories across Nigeria

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Background: Critical value (CV) reporting is a vital quality indicator of the post-analytical phase of the total testing process. Several international healthcare regulatory agencies have specified requirements for the process of critical value notification (CVN). Despite these requirements and the implications of CVs on patient safety, the practice of CV reporting is not well entrenched across laboratories, particularly, in developing countries, where laboratory medicine is at a budding stage. A national survey on CV reporting for chemistry and haematology analytes was conducted to obtain baseline information on the practice of CVN in laboratories across Nigeria.

Methods: Selected public and private laboratories serving secondary and tertiary healthcare institutions in the six geo-political zones in Nigeria, were enrolled in the study. Questionnaires were distributed by electronic mail and physical dispatch. General information such as the type of laboratory and the level of healthcare serviced, were collected for each laboratory. Specific information regarding the handling of CVs, practice of CVN and the existence of a written policy for CV were also collected. Data analysis was performed using SPSS version 22.0.

Results: The response rate was 46.5% (eighty six laboratories). Most (75.6%) laboratories were government (public) laboratories and 82.6% of the surveyed laboratories serviced tertiary healthcare institutions. Over half (53.5%) of the laboratories did not practice CVN and 52.5% of the laboratories which did practice CVN, did not do so all the time. There were no CV limits or CV lists in 60.0% of the laboratories and no written policy for CV handling in 67.5% of the laboratories. The most frequent analytes on available CV lists were haemoglobin, platelet count, serum potassium, sodium, calcium, glucose, creatinine, and bilirubin. The CV limits for paediatric and adult patients were similar in 57.5% of the laboratories. Telephone call was the means for CVN in 45.0% of the laboratories but only 11.1% of these laboratories had a 'read-back' policy to ensure accurate reception of the notification. All the laboratories practising CVN also repeated the assay of every CV obtained, prior to reporting it, 30.0% however, had no specified number of times to repeat an assay for a CV. In 25.0% of the laboratories, there was no laid-down rule for which of the critical values to report, amongst the repeated assays. More than half (62.5%) of the laboratories had no specifications on the time-frame for which a CVN must occur after a CV is obtained. Only 17.5% of the laboratories had an algorithm in place for situations in which the patient's caregiver is unreachable.

Conclusion: Many laboratories serving higher level healthcare institutions do not practice CVN. Remarkable variability exists amongst the laboratories that do practice CVN with only a few having CV limits and CV lists, and even fewer laboratories having written policies for CV reporting. Repeat-testing of CVs is a unanimous practice amongst the laboratories that practise CVN. There is an urgent need to develop locally applicable guidelines for CVN in order to foster uniform and regular practice of CVN among clinical laboratories in Nigeria.

B-134

Utilization and characteristics of STAT whole blood lactate measurements associated with a newly-implemented sepsis early management program

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BACKGROUND: Elevated lactate (>2 mmol/L) is a condition included among criteria used to diagnose severe sepsis. Identification of severe sepsis leads to initiation of a sepsis protocol, according to specifications of the CMS Core Measure, SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock, implemented in October, 2015. In order to facilitate rapid diagnosis of severe sepsis and timed sample specifications of the Core Measure, STAT whole blood lactate (BL) was made available from the central laboratory for this purpose. Our objectives in this study were to review rates of utilization of BL, and to evaluate turn-around-times and results distributions for BL in comparison to those for conventional STAT serum lactate (SL). METHODS: To meet SEP-1 definition of elevated lactate, the upper limit of our reference interval for lactate was changed system-wide to 2.0 mmol/L (from 2.2 mmol/L). For BL, whole blood samples were delivered to the laboratory as individual samples accompanied by a BL order form. BL was performed using Radiometer 837 analyzers. Elevated BL (>2.0 mmol/L) was reported by telephone. Primary data for ordering locations, results distributions and turn-around-times (TATs) were from LIS reports (Sunquest) for BL and SL (performed by Roche Cobas c500 analyzers) covering a period of 84 days after implementation of BL. RESULTS: Results distributions for BL (n=851 (10.2/day), 548 patients) were slightly right-shifted compared to SL (n=8305 (98.9/day), 3784 patients): medians (BL/SL=1.8/1.6 mmol/L); 95%-iles (BL/SL=6.7/5.7 mmol/L); %positive (>2.0 mmol/L; BL/SL=41.5%/34.2%); %critical (>4.0 mmol/L; BL/SL=14.5%/9.4%). ED orders for BL comprised 42.0% of total BL and 21.6% of total SL. Accrual rates vs. time-of-day for BL followed a pattern reflecting ED admission rates. Turn-around-times (medians, min) were significantly less for BL compared to SL: collect-to-receive (BL/SL=8/16 min); receive-to-report (BL/SL=6/36 min); collect-to-report (BL/SL=15/56 min). Receive-to-report TATs had numerous unexplained outliers (95%-ile=24 min). Among all BL, 184 (21.6%) were first-time identifications of elevated lactate (14.3% of all first-time identifications among BL and SL). Among these, 67 (36.4%) had follow-up lactates either by BL or SL within a 6h interval. In comparison, hospital monitoring of core measures indicated a 91% completion rate for 6h follow-up of initial lactates given diagnosis of severe sepsis (per SEP-1 bundle requirements). Thus, most elevated lactates obtained initially by BL measurement were apparently not associated with a diagnosis of severe sepsis. Last, it was found that a small fraction (5.2%) of BL were submitted from intensive care units (ICUs) from which BL should have instead been performed using available point-of-care testing (POCT). CONCLUSIONS: BL showed significantly reduced turn-around-times compared to SL, meeting administrative objectives in establishment of laboratory-based BL for use in the severe sepsis/septic shock protocol. There was modest preselection for elevated lactate among BL compared to SL. Low follow-up measurement rates for initial elevated lactates obtained by BL indicated that most of these cases were not associated with final diagnosis of severe sepsis. Areas identified for improvement were to minimize outlier receive-to-report intervals for BL, and to limit BL submissions to laboratory from locations where POCT BL is available.

B-135

"Accurate Results for Patient Care:" The Role of Traceability in Laboratory Medicine

D. Armbruster. *Abbott Laboratories, Lake Villa, IL*

Clinical laboratories require global metrological standardization to produce equivalent patient test results across space and time. Standardization is required to use evidence based laboratory medicine (EBLM) practice guidelines and eliminate the need for local or method-specific reference intervals/decision cut-offs with the goal of improving e-healthcare and patient safety. Healthcare providers and patients take for granted all test results are accurate, comparable and interchangeable, and

clinical practice guidelines assume results are independent of assay methodology. Due to lack of standardization, currently all results are not equivalent and assay method-specific reference intervals and medical decision points are required. The European Union's In Vitro Diagnostics Directive (IVDD) mandates metrological traceability for calibrators and trueness controls to promote assay standardization. The Joint Committee for Traceability in Laboratory Medicine (JCTLM), formed in 2002, promotes standardization in the clinical laboratory. It was founded by the BIPM (Bureau International des Poids et Mesures), the IFCC (International Federation for Clinical Biochemistry and Laboratory Medicine), and ILAC (International Laboratory Accreditation Cooperation). JCTLM now has 28 member organizations, including AACC that are committed to traceability in laboratory medicine. JCTLM promotes the use of proven metrological principles to support equivalence of measurements in the clinical laboratory through metrological traceability to appropriate reference materials and methods. Standardization is achieved when all routine assay results for test are traceable, with an unbroken metrological chain of comparisons, to reference materials and methods of a "higher order," with a sufficiently small uncertainty such that results may be validly compared. The JCTLM has developed a database of such higher order reference materials and methods and reference measurement services (http://www.bipm.org/jcltm/). Entry in the database is determined by review by experts using ISO standards and approval by the JCTLM Database Working Group and Executive Committee. In 2015 the database contained listings for 295 materials for 162 measurands, `70 methods for 79 analytes and 130 reference measurement services for 39 analytes. Implementation of traceability requires action by many bodies: national measurement institutes and other organizations that prepare materials and develop methods; reference measurement service laboratories; IVD manufacturers that prepare calibrators/trueness controls for field assays following appropriate traceability chains and provide traceability information to users; clinical laboratories that select and use traceable assays; EQA/PT providers that confirm claimed traceability; and guideline committees that base recommendations on traceable results. To promote these activities the JCTLM formed a Working Group on Traceability: Education and Promotion (WG-TEP) in 2015 to produce and use educational materials demonstrating the value of traceability in laboratory medicine. Its sixteen members represent the JCTLM Executive Committee, the wider international membership, and individuals with skills and experience in creating educational materials. WG-TEP provides key traceability educational material at professional society meetings and maintains a traceability website containing information and resource materials about traceability and standardization in laboratory medicine and links to the

JCTLM database and member organizations. WG-TEP also provides the clinical laboratory industry with recommendations for calibration traceability statements and supporting documentation that provides metrologically appropriate and clear assay standardization descriptions which are the responsibility of IVD manufacturers.

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An Assessment of Why Physicians' Electronically Ordered Add-on Laboratory Tests Are Not Performed in a Large, University Hospital Laboratory

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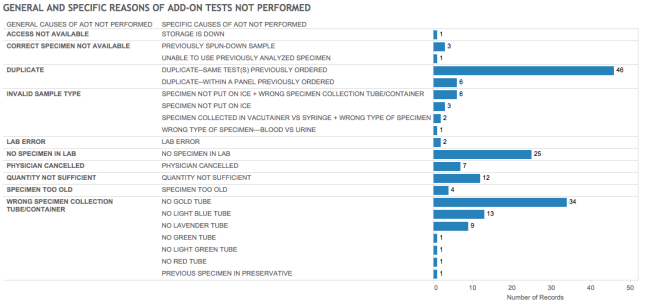
With the universal adoption of the electronic medical records systems in hospitals, physicians often tend to abuse the features that allow for unrestricted electronic laboratory tests orders for so called "add-on" testing. An add-on test is a physician order for a test to be performed on a specimen that has already been collected for other testing purposes. We have observed that having physicians electronically do add-on laboratory orders does not work well since there are many issues involved that may make the add-on ordered test impossible for the laboratory to perform. This leaves the laboratory staff having to contact the physician by telephone to let them know there is a problem. To address this issue, we monitored add-on test orders for a seven day period and observed the following: 1) a total of 1,062 add-on tests were electronically ordered, 2) 883 (83%) of add-on tests were performed and 3) 179 (17%) of add-on tests were not performed. We investigated the major reasons why these add-on tests could not be performed and summarized our findings into 10 major categories which can be broken down into 21 subcategories. As shown in the figure, 34 % (60/179) of add-on tests not performed were specimens collected in the wrong tube/container, 29% (52/179) of tests not performed were duplicate orders, while for 14% (25/179) of add-on tests not performed, no specimen was available in the laboratory. We conclude physician add-on orders require either 1) a sophisticated rules-based assisted expert physician order entry system to alert the physician when an add-on test is possible or 2) a more collaborative approach with the laboratory....such as physicians calling the laboratory and placing the order verbally. Unfortunately, many hospitals including ours do not have the level of IT technology required to do expert system assisted physician add-on order management.



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Clinical Chemistry Education in Medical Students

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Background: Marmara University Medical Faculty currently applies an integrated educational program for medical students enriched with interactive instructional activities based on problem-based sessions and experiential learning. Following the evaluation by "The National Accreditation Council for Undergraduate Medical Education" considering 70 different standards based on the international standards in medical education, the education in our Medical School has been accredited until 2017.

Methods: A 2.5 day introductory education program was implemented within the adaptation to clinical courses module at the beginning of 4th grade, to give the medical students the principles and skills of basic laboratory procedures and introduce them to the principles of evidence based laboratory medicine which is an important part of clinical decision making. In this study, we aimed to evaluate the effectiveness of the clinical chemistry part of this education program. Fourth grade medical students of Marmara University Medical Faculty (n=134) were enrolled in the study. The students were divided into 8 small groups and each group had a lecture on pre-analytic variables, a clinical chemistry laboratory visit, 2 practices (peripheral smear and urine sediment examinations), and a case discussion session focusing on evidence based decision-making according to test results. The course was evaluated at 2 levels: (1) assessment of knowledge transfer by a quiz (10-questions, either multiple choice or correct/incorrect or descriptive type) which was administered at the beginning and end of the course and (2) student satisfaction assessed by a survey.

Results: The median score was 18 for the pre-test and 84 for the post-test over 100 points Improvement was statistically significant for total scores and each question scores (P<0.001). Students' overall feed-back was satisfactory.

course

Q.N.	Question Content	Quiz Time	Median (25th-75th)
1	Differences of anticoagulant types	Pre-test score	0 (0-10)
		Post-test score	10 (10-10)
2	Peripheral blood smear preparation	Pre-test score	4 (4-6)
		Post-test score	8 (6-8)
3	Peripheral blood smear examination	Pre-test score	0 (0-0)
		Post-test score	5 (5-10)
4	Peripheral blood smear faults	Pre-test score	4 (4-6)
		Post-test score	8 (6-10)
5	Pre-analytical errors in clinical laboratory	Pre-test score	0 (0-0)
		Post-test score	10 (10-10)
6	Heel prick blood sampling in neonates	Pre-test score	0 (0-0)
		Post-test score	10 (10-10)
7	Urine sediment preparation	Pre-test score	0 (0-0)
		Post-test score	10 (7-10)
8	Urine sediment examination	Pre-test score	0 (0-0)
		Post-test score	5 (5-10)
9	Urine sediment examination	Pre-test score	0 (0-0)
		Post-test score	10 (10-10)
10	Urine sediment examination	Pre-test score	0 (0-0)
		Post-test score	10 (10-10)
Total Score		Pre-test score	15 (8-25)
		Post-test score	84 (75-88)

Conclusion: Medical student knowledge regarding the foundations of laboratory medicine was improved through this 2.5-day curriculum. Similar courses could be implemented by other medical schools to successfully impart laboratory medicine concepts to medical students.

B-139

Application of a series of robust statistical methods in EQA scheme

Q. Zhou, S. Ren, X. Li, J. Hu, S. Li, Z. Gao. *Beijing Hospital, National Center for Clinical Laboratories, Beijing, China*

Background: Outliers occur constantly in external quality assessment (EQA) scheme to cause the data are not normally distributed. Robust statistical methods should be applied to deal with these data. **Methods:** Analytical results were grouped according to the analytical method. Outliers in each set of analytical results were deleted using a robust statistical method, which involved establishing a Tukey fence, namely Q_1-1.5IQR to Q_3+1.5IQR. The values outside this fence were considered outliers and were removed. The mean was used as a target value if the trimmed analytical results were normally distributed; otherwise, the median was used. Robust between-laboratories z-score (ZB) and within-laboratory z-score (ZW) were calculated using the formulas: ZB = S-median$_{(s)}$/NIQR$_{(s)}$ and ZW = D-median$_{(d)}$/NIQR$_{(d)}$. A robust Youden plot was constructed based on the robust statistical parameters, which were calculated using the formulas: a (major radius) = 2.448NIQR$_{(S)}$ and b (minor radius) = 2.448NIQR$_{(d)}$. Acceptable and unacceptable results fall inside and outside the Youden ellipse, respectively. Questionable results are located on or near the Youden ellipse. **Results:** The robust target values of the 1st and 2nd measurements were P, 1.70 and 1.70 mmol/L; GLU, 11.1 and 11.0 mmol/L; Urea, 16.8 and 16.8 mmol/L; UA, 307 and 307 µmol/L; TP, 53.9 and 54.0 g/L; ALB, 38.1 and 38.3 g/L; TC, 4.19 and 4.19 mmol/L; TG, 1.46 and 1.46 mmol/L; ALT, 98.1 and 97.7 U/L; AST, 98.2 and 98.5 U/L; ALP, 206 and 206 U/L; AMY, 179 and 180 U/L; LDH, 242 and 243 U/L; GGT, 115 and 115 U/L; FE 35.5 and 35.6 µmol/L; and HBDH, 255 and 255 U/L, respectively. The ranges of the robust ZB and ZW absolute values and the robust Youden plots were shown in the Figure. **Conclusions:** It was reasonable to choose robust target value, ZB, and ZW as assessment indexes and the robust Youden plot can reasonably illustrate EQA data.

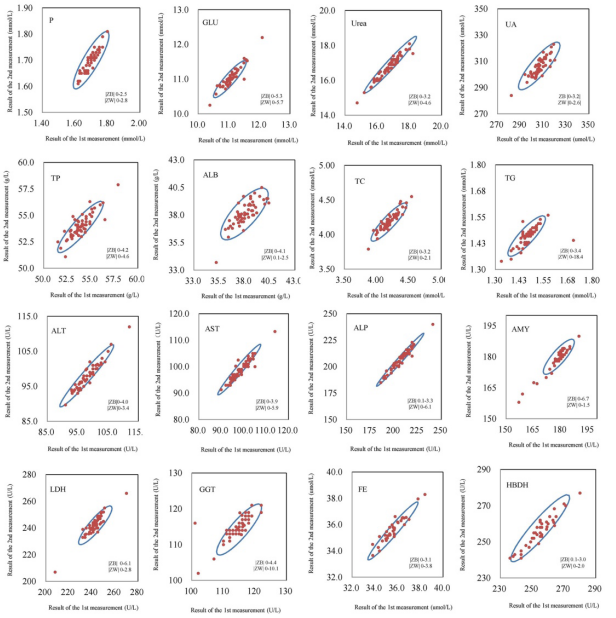

Fig. Robust Youden plots of the measurement results of P, GLU, Urea, UA, TP, ALB, TC, TG, ALT, AST, ALP, AMY, LDH, GGT, FE, and HBDH concentrations

B-140

Analysis of the pre-analytical phase for parathyroid hormone (PTH) measurement in renal patients.

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Background: The parathyroid hormone (PTH) is an important key regulatory hormone in calcium homeostasis and bone mineralization. The balance of calcium levels is achieved through the tight regulation of several mechanisms:intestinal absorption of calcium; calcium and phosphorus mobilization from bone tissue; and renal tubular reabsorption of calcium and phosphorus excretion. Measurement of PTH plasmatic levels is very important for the correct diagnosis of several diseases, including primary or secondary hyperparathyroidism and hypoparathyroidism, and kidney diseases. PTH determination represents a paradigm of quality in laboratory medicine as many variables in the pre-, intra-, and post-analytical phases strongly affect the value of the clinical information. In recent years, clinical laboratories have accepted the evidence that errors in the pre- and post-analytical phases occurred much more frequently than in the analytical phase. **Objective**: To evaluate the frequency of pre-analytical errors related to PTH measurement in clinical samples from renal patients. **Methods**: Data were collected from Hermes Pardini Institute database (Vespasiano, Minas Gerais, Brazil) during the period of 3 months (October to December) in 2015. **Results**: Among 286 analyses, 81 (28%) pre-analytical errors were confirmed, of which 8.74% were problems associated with sample storage. **Conclusion**: The results indicated a significant number of inadequately stored samples, and it is related directly sample collection, generating a delaying in reporting the results. These issues in the pre-analytical phase usually originate from high turnover of laboratory professionals, negligence, and lack of training of good laboratory practices. In spite of the technological improvements in laboratory routine, the pre-analytical phase is still the main responsible for laboratory errors.These errors can be prevented by identifying their causes and by understanding their impacts.

B-146

Sometimes less is more! Managing wisely laboratory tests among hospitalized patients

G. Rashid, E. Weiss, M. Maram. *Meir Medical Center, Kfar-Saba, Israel*

Background: Interest in the subject of choosing of medical tests and treatments wisely is growing. The underlying principle is the desire to use evidence-based medicine (EBM) and the need to decrease excess medicine in general and the unnecessary ordering of repeated tests in particular. Consequences of overuse include patient exposure to infections, pain and stress, as well as extra work for the laboratory staff and unnecessary costs. It is relatively easy to set standards and monitor special treatments and tests. However, it is more difficult to determine standards for routine laboratory tests performed on hospitalized patients.

Objective: Decrease excessive blood tests among in-patients by developing a method to map the extent of repeated routine tests in all departments, and to intervene when necessary.

Methods: Five Internal Medicine departments (similar in patient mix and size) were piloted. We focused on blood count and chemistry tests and developed a computerized report of tests ordered. An index was created to determine the number of repeat tests for each patient and for each test in every department. It is expressed as an index that provides a measure of the number of repeated tests. An intervention was implemented in the department with strikingly excessive orders, data were collected and on-going follow-up was conducted.

Results: One department was reordering tests at a 30% higher rate than the rest of the pilot departments (index 2.0 vs. 1.6). As a result, interventions included appointing a departmental representative, collecting data for six months with regular feed-back to the department along with periodic discussions on the progress and improvement plan. After the intervention, repeat tests ordered by the department decreased to 1.5 (compared to an average 1.6 in other departments).

Conclusions: Awareness of the phenomenon of excessive use of routine laboratory tests led to the development and implementation of a quantitative method to estimate the rate of repeated tests and to compare across departments and institutions. This method allows management to detect variances and encourages departments to establish clear criteria for ordering routine laboratory tests.

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A Process Improvement Project Based on the Updated Guidance for the Management of Myocardial Infarction/Acute Coronary Syndrome: A Significant Reduction in Unnecessary Orderable Testing and Laboratory Costs

T. Nguyen, C. Henemyre-Harris, J. Reese, B. Hemann, K. Brown, M. Austin. *Walter Reed National Military Medical Center, Bethesda, MD*

Background: In 2014, the American College of Cardiology (ACC) and the American Heart Association (AHA) updated guidelines for the evaluation and management of acute coronary syndrome (ACS). Measurement of creatine kinase MB fraction (CK-MB) now carries a Class III recommendation (No benefit or may cause harm) based on A-level evidence (data derived from multiple randomized clinical trials or meta-analyses). The guidelines specify the troponin assay as the preferred diagnostic test for the evaluation of ST and non-ST elevation myocardial infarction and unstable angina.

Objective: In order to align standard practice with consensus guidelines and optimize resource utilization, we collaborated with the Department of Cardiovascular Medicine to remove the CK and CK-MB assays from our Cardiac Panel and develop educational materials to explain the change to providers. CK and CK-MB remain available as individually orderable tests in the Laboratory Information System (CHCS); however, their routine use in the setting of suspected ACS is discouraged.

Methods: A letter reviewed and approved by the Cardiology Department Chief at Walter Reed National Military Medical Center (WRNMMC) and the Army's Cardiology Consultant to the Surgeon General describing the proposed modifications was prospectively sent to providers at all medical treatment facilities (MTFs) and outlying clinics within the National Capital Region (NCR). Once consensus acceptance was received from all MTFs and outlying clinics, a second letter was sent to all NCR client laboratories indicating the changes and effective date (July 1st, 2015). Workload data for CK and CK-MB was collected from July 2015 to January 2016 and compared to the data from July 2014 to January 2015.

Results: We observed a stepwise reduction in CK and CK-MB orders from July 2015 to January 2016. While total tests ordered decreased from 2690 to 1865 for CK-MB (31% reduction) and from 4650 to 3539 for CK (24% reduction) for this 6 month period; January 2016 saw a 78% reduction in CK-MB orders and a 43% reduction in CK orders as compared to January 2015. This change in ordering practice resulted in a savings of $12,000 over a four month period.

Conclusion: We highlight how a collaborative partnership between Cardiology and the Laboratory led to changes in clinical practice that improved adherence to standard of care as well as utilization of laboratory resources in the management of ACS. These findings should encourage laboratories to investigate and implement similar collaborative efforts.

B-149

Pre-analytical nonconformities in immunophenotyping of hematological malignancies

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Flow cytometric immunophenotyping is essential part of the laboratory diagnosis, prognostic classification and treatment effectiveness of hematological diseases.This method has become the preferred to assess the immunophenotypic features of cells present in bone marrow (BM), peripheral blood (PB) and other types of samples suspected of containing neoplastic cells. The list of clinically useful antibodies has progressively increased and this facilitates more precise identification and characterization of specific populations of tumor cells. The quality of the samples and the selection of a suitable panel of antibodies are essential for diagnosis of leukemias and lymphomas. There are some pre-analytical requirements for this test in our laboratory:(I) EDTA-anticoagulated PB or BM samples within 48 hours after withdrawal, (II) the corresponding smear for morphological analysis, (III) clinical information and (IV) hemogram information containing white blood count. In this context, the aim of this study was to assess the pre-analytical nonconformities in immunophenotyping analysis of hematological malignancies in our institution. We retrospectively evaluated 697 immunophenotyping tests conducted at Progenetica Laboratory - Hermes Pardini Institute, between January and July2015.These samples were received from partner laboratories across the country. In our study were identified ten kinds of nonconformities in 44.2% (308) of the tests analyzed.The nonconformities identified and its frequencies were respectively:absence of smear for morphological analysis (23.1%), absence of results of leukocyte differential count blood and smear for morphological analysis (22.1%), absence of clinical information (20.1%), absence of results of leukocyte differential count blood (17.5%), absence of clinical information and results of leukocyte differential count blood (6.5%), samples receivedover48 hours afterwithdrawal (5.5%), absence of clinical information, smearformorphologicalanalysis and results of leukocyte differential count blood (2.6%),inadequate samples (1.3%) and absence of clinical information and smear for morphological analysis (1.3%). As with all diagnostic modalities, an adequate and representative sample is necessary for meaning ful analysis. Three of 17samples received more than 48 hours after with drawal could not be analyzed, due to low viability of the cells in the sample.One of four inadequate samples could not be analyzed due to the presence of clots. The careful correlation of the patient's clinical history and other diagnostic details are necessary to ensure accurate diagnosis. In this study, five of 62 cases without clinical information had inconclusive results. Three of eight cases without clinical information, smear for morphological analysis and leukocyte count also had inconclusive results. These pre-analytical requirements are essential to choose the panel of antibodies. The correct data interpretation and diagnosis is also based on appropriate panel of antibodies. The absence of these requirements only allows selecting a general panel, which explains inconclusive results. The Pre-analytical requirements should be familiar to laboratory personnel and partner laboratories, since many factors may influence the technical preparation and a variety of causes can result in misinterpretations.The knowledge of pre-analytical nonconformities helps avoiding potential sources of errors, ensuring quality in analysis and accurate diagnosis.

B-150

Laboratory labor and cost efficiency improvement with the implementation of six-sigma statistical quality control management

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Introduction: Accurate and reproducible test results are critical as 70% of medical decisions are influenced by laboratory results. Quality control programs are an integral

part of laboratory operation to monitor and ensure accuracy. Six-Sigma metrics applied to quality control programs can help identify waste and redundancy, while verifying analytical performance quality. Adopting a Six Sigma quality control program enable the laboratory to have a standardize method to quantify laboratory quality and improved laboratory efficiencies by eliminating redundant procedures. **Methods**: Sigma metrics were evaluated for 29 chemistry assays on the Abbott's ARCHITECT c8000 chemistry analyzer using the equation: Sigma metrics = (TEa - %Bias) / %CV. The choice of TEa was selected based on the recommendation of the Westgard Verification Program. % Bias and % CV were calculated with QC data collected over a 3 months period. QC optimization of control rules and frequency were based on the Sigma metrics achieved for each of the 29 chemistry assays. Laboratory operation and cost efficiencies were determined after implementing the Six Sigma quality control management program. **Results**: 26 out of 29 chemistry assays (90%) were of world class and excellent performance achieving Sigma metrics >5. The remaining 3 assays were between 3-5 Sigma metrics. Importantly, no assays were <3 Sigma metrics. QC optimization based on the Sigma metrics achieved for each of the results, resulted in reduction of QC frequency from 8x per day to 2x per day for those assays >5 Sigma metrics and 4x per day for those assays between 3-5 Sigma. With the reduction of the QC frequency, this enabled a direct QC material cost reduction of 78% annually for an estimated annual saving of US$5,300. Assay reagent savings of US$36,000 annually, were correspondingly achieved to achieve a total annual operation cost saving of over US$40,000. Importantly, laboratory operation efficiency was dramatically improved with a labor saving reduction of ~78% man hours, from 240 man hour to 52.5 man hour per month.**Conclusion**: By adopting and implementing Six Sigma quality control management, we were able to have a standardize method to quantify our laboratory quality control practice. This provided us with an international benchmark to guide us in optimizing our QC operation that lead to significant labor and cost savings without compromising patient care. Participation in the Westgard Sigma Verification program further validated our laboratory quality control management system while providing excellent quality health care for its patients.

B-151

Change management in continuous quality improvement program implementation

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Introduction: Laboratories are continuously striving to improve their quality standards in order to deliver excellent health care. To fully benefit from any quality improvement program, fast and successful implementation of the program is critical and this would require alignment and buy-in from all levels of the laboratory staffs. Careful change management is an essential component for successfully implementing new practices to the clinical laboratory. **Methods**: To ensure alignment and buy in of laboratory staff during quality improvement changes, a committee comprising laboratory staffs of all levels were formed to evaluate and determine the project(s) to implement. Various programs of consideration included 1. Six Sigma Statistical Quality Control Management; 2. Improvement of timeliness of report inspection; 3. Reduction of sample rejection etc. Careful gap analysis was undertaken to determine the challenges for program implementation. Stepwise incremental program development activities, individual roles and responsibility, timing and milestone goals were established and aligned. **Results**: Based on consensus agreement from the quality improvement committee, the Six Sigma Statistical quality control management program was evaluated to be of most importance and urgency to ensure the laboratory achieved high quality standards to meet patient health care demands more effectively. Furthermore, the program was also considered to be all encompassing, requiring participation of all laboratory staff. Through educational activities, such as quality control expert visits and lectures, it not only enhance and strengthen staffs quality control concept and knowledge such as problem solving capability and communication skills, but also improved team work and spirit as measured by employee engagement surveys. **Conclusion**: By involving and getting buy in and alignment at all levels of the laboratory staff in the choice of program and implementation plan, this ensured fast and successful implementation of the Six Sigma statistical quality control management program as part of the laboratory goal to continuously strive for quality improvement. In addition to breaking old habits and achieving quality improvement, through a world class quality control system validated by the Westgard Sigma Verification program, staff moral, sense of achievement, and engagement were also improved as a result

B-152

Optimalisation of the turnaround time of Borrelia antibodies determination

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Background: Ticks occur very frequently in the Central Europe and much of their population is a carrier of Borrelia burgdorferi causing Lyme borreliosis. Determination of the Borrelia antibodies is therefore a very important examination for possible infection diagnosing and the success of the antibiotic therapy monitoring.

Methods: Testing for Borrelia antibodies classes IgG and IgM was performed by enzyme linked immunosorbent assay (ELISA) using BioRad Evolis processor batchwise twice weekly. The average turnaround time for both of these tests was 96 hours, the median turnaround time was also 96 hours. When confirming the positive results using immunoblot , the response time extended by another 24 hours. In terms of clinical importance of these investigations, it was necessary to shorten the response times significantly. To solve this problem it was chosen to install these methods for the automated immunoassay analyzer Diasorin Liaison XL. Diagnostic kits LIAISON Borrelia IgG and LIAISON Borrelia IgM II were used for the determination of the Borrelia burgdorferi antibodies by indirect chemiluminescent immunoassay (CLIA).

Results: Using this system, the turnaround time for determination of IgG antibodies was reduced to 190 minutes on average with a median of 93 minutes. The turnaround time for IgM antibodies was 186 minutes on average with a median of 90 minutes. The capacity of the analyzer with such determinations was utilized in 44% (22% IgG and 22% IgM). The rest of the analyzer capacity was used for further diagnosis of infectious diseases - CMV, EBV, Rubella, etc. This significant reduction of the response time plays an important role also in the overall operation of the laboratory, because the general part of these tests comes in very narrow time frame - 40% of the samples between the 10 and 11 o'clock, 25% between 8 and 9 am and 20% between 1 and 2 o'clock in the afternoon. There is also a seasonal effect noticeable, the difference between the number of examinations in the summer and winter months is about 20%.

Conclusion: The response time is positively reflected in the perception of the usefulness of this test by the customers of the laboratory, which showed a rise in the number of assays of Borrelia burgdorferi antibodies by an average of 35%.

B-153

Contribution of ESEAP - The Greek Proficiency Testing Scheme for Clinical Laboratories in the improvement of analytical performance of participating laboratories.

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The Greek Proficiency Testing Scheme for Clinical Laboratories (ESEAP) has been operating continuously since 1994. At the beginning the number of participants was about 100 laboratories, but today, the number of participants has reached 320, including almost all public hospital laboratories in Greece an increasing number of diagnostic centers and private laboratories all over Greece and 50 laboratories of the public and private sector in Cyprus. The wide impact and acceptance of our schemes is due to the fact that, they operate in Greek language, cover the most frequently ordered tests in Laboratory Medicine and, although there are very friendly and easy to use, they provide laboratories with an objective assessment of their own performance as well as in relation to that of other laboratories. Furthermore they provide information on the relative performance of the available methods and analyzers, identify factors associated with good and poor performance via the Youden plot and improve the inter-laboratory agreement.

A cycle of the clinical chemistry program involves twelve distributions and covers a two year period. Twenty five analytes are statistically processed on the overall results, regardless of the methodology. After the elimination of outliers (elimination in two passes of all results > or < 2.5SD of the consensus mean value), the "consensus" mean, namely the mean from all individual results is used as target value. At the end of each two-year cycle, the performance of each participant is assessed through a standard scoring and ranking system.

A totally new, web enabled, software was implemented at 2008 which allows participants to send their own results and obtain reports and information about their performance through the Internet. New software features permit further grouping of methods and analyzers, the enhancement of the statistical evaluation of the results, as also as the evaluation of reproducibility of the measurments using 4 samples during each year, (two replicates of the same sample and two other samples, derived from the initial sample by dilution or concentration by p.ex. 10% and 8% respectively,

modifying accordingly the volume of serum to be lyophilized per vial in order to avoid the possibility that participants can detect the replicated samples and to report already known target values. Obviously, two of the samples (the replicates) are evaluated as received and the other 2 after correction with the appropriate factors for the dilution or concentration.

ESEAP has considerably contributed to the improvement of performance for the majority of the laboratories, as the mean CVs for all analytes showed a significant decrease from cycle-1 (1994-1996) to cycle-3 (1998-2000) of the program. Afterwards, and until the latest fully completed cycle (cycle-10 2012-2014) the CVs remained stable. The CV per cycle for each analyte was calculated as average between control A and control B mean CVs over the 12 distributions of each cycle (inter-laboratory CV). This reduction ranges from 1 to 2% (electrolytes), from 2 to 4% (substrates) and from 4 to 8% (enzymes). In this calculation we included only the 100 laboratories that participated continuously in all the above cycles.

B-154

Evaluation of the viability of the decentralization process tests carried out on a large laboratory support for regional technical operational centers

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Background: The Turnaround time (TAT) of a test is used as a laboratory efficiency indicator and the existing high competitiveness in today's clinical laboratory market becomes an extremely important factor when acquiring new customers, being they patients, doctors or laboratories. As conventional ways to reduce the TAT are already present in several laboratories, such as automation at all stages of the process, pre-analytical issues and barcode tube labeling. The Laboratory X, which operates in the private market (patients) and support (laboratories), sought a new way to decrease TAT, by carrying out the examinations in regional technical operational centers (TOC) previously performed only in the headquarters located in western Parana, to verify the possibility of increasing the number of examinations and laboratories attended.

Methods: Thus they were created 3 TOCs: TOC1, TOC2 and TOC3, where the six highest tests in demand (TSH - Thyroid stimulating hormone, VIT25 - Vitamin D - 25 Hydroxy, T4L - free thyroxine, HBGLI - Glycated hemoglobin, FERRI - Ferritin and T4 - thyroxine) were evaluated for 7 different client labs for each TOC, comparing the first 4 months of the years 2014 and 2015.

Results: There was a considerable decrease in the TAT, with an average reduction in hours of TAT for TOC3 of 21:20:57; TOC1 15:40:47 and TOC2 of 12:44:08 (table 1). There was an increase in the number of tests of 582.691, as well as the number of clients that went from 8141 customers in April of 2014 to 8835 in April of 2015.

Conclusion: The test execution process in regional TOCs was highly favorable, and can give the Laboratory X a great competitive advantage in the clinical laboratory market.

Table 1: Difference of TAT in each TOC between the years 2014 and 2015.

TOC	Jan/14	Fev/14	Mar/14	Abr/14	TAT Medium	Difference between TATs
TOC1	25:38:08	33:51:24	25:32:05	22:12:13	26:48:27	15:40:47
TOC2	30:30:59	39:47:52	32:50:51	27:55:04	32:46:12	12:44:08
TOC3	33:31:53	37:28:49	30:51:31	25:38:54	31:52:47	21:20:57
	Jan/15	Fev/15	Mar/15	Abr/15	TAT Medium	
TOC1	14:53:19	12:04:30	9:03:47	8:29:02	11:07:40	
TOC2	18:36:29	16:47:36	18:21:44	26:22:27	20:02:04	
TOC3	11:31:30	11:20:04	10:55:17	8:20:28	10:31:50	

B-155

Automation of a High Volume High Complexity LC-MS/MS Clinical Laboratory

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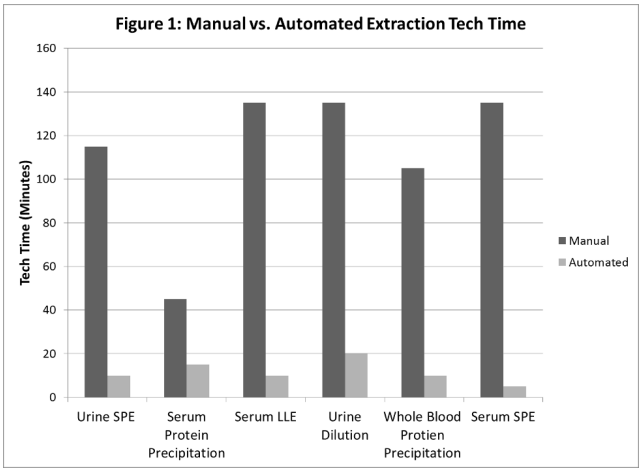
Background: Testing in a high complexity liquid chromatography tandem mass spectrometry (LC-MS/MS) clinical laboratory typically involves a complicated and highly manual workflow. An example of a workflow is as follows: samples received → manual work list created → technologist numbers work list → technologist manually extracts samples → manually enters work list into instrument → samples analyzed → manual review of data → manual entry of results. There are many inherent issues and risks with a highly manual workflow including increased tech time, decreased efficiency and capacity for growth, misidentification and data entry errors, and increased risk of failed runs. **Objective:** The objective of this project was to automate the laboratory through the use of an automated sample preparation instrument (ASI) and electronic interfaces for result upload to the laboratory information system (LIS) in order to reduce the risk of potential errors, increase efficiency, and decrease tech time. **Results:** Several different ASIs were evaluated prior to the selection. Once implemented the workflow of the laboratory is greatly simplified and is as follows: samples received → loaded on to ASI → ASI scans barcodes, creates work list, and extracts samples → Work list electronically transferred to LC-MS/MS instrument → samples analyzed → manual review of data → result electronically transferred to LIS. This greatly simplified workflow has the potential for a ~20% reduction in the number of full time employees (FTE) needed to operate the laboratory. Figure 1 demonstrates the potential tech time savings for a representative six assays. A financial analysis showed that the potential return on investment (ROI) after 5 years is >200%. There is also the potential of increased patient safety and care due to the reduced risk of possible manual errors. **Conclusion:** This significantly improved laboratory workflow potentially has a considerable positive quality and financial impact on an LC-MS/MS laboratory.



B-156

Microbiology Proficiency Testing: Usa and Improvements Based on a National Survey of Laboratory Professionals

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Background: In the U.S., proficiency testing (PT) is required by the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and accrediting agencies as an external performance assessment of clinical laboratory testing. However, PT can have many benefits beyond regulatory requirements. In 2013, the Centers for Disease Control and Prevention, in collaboration with the Association of Public Health Laboratories, evaluated the use of PT and the perception of its value by laboratory professionals through a voluntary survey. A section of the survey contained questions specifically targeted to microbiology PT to assess opportunities for improvement.**Methods:** Survey questions were based upon results from focus groups previously convened to discuss PT uses. Survey participants were recruited from all laboratories in the U.S. certified by CLIA to perform nonwaived testing. A brochure was mailed to the laboratories in July 2013 followed by a reminder postcard in September 2013. Additionally, a one page advertisement was included in the August, September, and October 2013 issues of a professional journal. Only one respondent per laboratory was included in the analysis.**Results:** Of the 679 respondents that answered the question, "Does your laboratory perform microbiology testing?" 401 (59%) responded affirmatively; these were prompted to answer a series of questions about microbiology PT. When asked if the laboratory reported PT results to the same level as reported for patient testing, 86% responded 'yes,' while 12% answered 'yes,' but occasionally report to a lower level, 1% sometimes report PT at a higher level and 1% answered 'no.' Specimen source/type/site, Gram stain results, and patient symptoms, age, and sex, were all considered necessary information to process and analyze PT samples appropriately by a majority of respondents. Additionally, 75% of all respondents agreed that changes should be made to microbiology PT grading to allow for monitoring performance over time

for a particular type of test or examination. When asked to rate the importance of specific proposals to improve PT, a majority of respondents indicated that improving the quality of photographs (55%) and improving the quality of stained slides (61%) were important. Including fewer susceptibility testing challenges (66%), including fewer emerging or less common organisms (67%), and increasing the use of slides or photographs instead of digital images (59%) were not important. Requiring direct antigen testing in mycology (62%) or parasitology (53%), or requiring susceptibility testing in mycology (64%) or virology (64%) were not applicable to most of the respondents. Free text contributions reinforced the need for better quality for Gram stains, listed problems due to preservation/lyophilization of microorganisms, and suggested presumptive identifications be reported without a penalty in cases where confirmation is needed.**Conclusions:** While survey results are not representative of all clinical laboratories in the U.S., it is clear that respondents thought that changes should be made to microbiology PT. Areas of importance included grading, the quality of photographs and slides, and the need to reduce difficulties due to preservation of the samples.

B-157

A Theoretical Basis for Establishing Acceptance Limits for Proficiency Testing Based on Clinical Needs as Reflected in Biological Variability

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Objective We explored the potential to link proficiency testing (PT) acceptance limits (ALs) with goals for total allowable error (TE_A) derived from estimates of biological variation.

Methods Using published data for within-individual coefficient of variation (CV_I), and between-individual CV (CV_G), we calculated the TE_A using a previously published model*, using the achieved factor (f_{AL}) as a variable describing suitability of the TE_A. We examined the current AL's for representative PT analytes required by the Clinical Laboratory Improvement Amendments (CLIA) regulations. We determined the f_{AL} for TE_A goals that are "optimal" (f_{AL}<0.125; Code O in the table), "desirable" (0.125 < f_{AL}<0.25; Code D), "minimal" (0.25 < f_{AL}<0.375; Code M), "marginal" (0. 375 < f_{AL}< 1.0; "R") or "excessive" (f_{AL}>1.0); "E"). We calculated $f_{AL} = CV_B / (AL - k \times CV_A)$ *with* k = 1.65 for 95% CI, one-sided.

Results Few ALs meet optimal clinical needs, but for some analytes current ALs have f_{AL}s in the minimal or desirable ranges. Some analytes have f_{ALs} that are marginal and for these further AL tightening may achieve the minimal error goal (f_{AL}<0.375) or move the AL closer to optimal. For other analytes, the analytical goals may not be achievable with current technology.

Conclusion It is possible to calculate the AL necessary to achieve minimal, desired and optimal TE_A. For some analytes it will be possible to decrease ALs to enhance the ability of PT to identify laboratories that cannot provide testing accuracy necessary for clinical needs; for other analytes different approaches might be needed to determine AL. These findings are consistent with the models for analytical goals proposed by the recent Milan Conference, recommending analytical goals based on: (1) ability to distinguish disease states, (2) the capability of measurement systems, or (3) biological variation.

*Miller et al, Arch Pathol Lab Med. Vol 132:838, 2008.

Suitability of CLIA PT Acceptance Limits

Analyte	CLIA AL	CV_I	CV_G	CV_B	f_{AL}	Code	AL for f_{AL} <0.375
ALT	20%	19.4	41.6	45.9	0.09	O	
Alk.Phos.	30%	6.5	26.1	26.9	0.92	R	15%
Chol., Tot.	10%	6.0	15.3	16.4	0.31	M	
Cortisol	25%	15.2	38.1	41.0	0.30	M	
IgG	25%	4.5	16.5	17.1	1.24	E	10%
Iron, Total	20%	26.5	23.2	35.2	-0.05	O	
Leuk. Cnt	15%	11.4	21.3	24.2	0.23	D	
Magnes.	25%	3.6	6.4	7.3	3.00	E	5%
Protein, T.	10%	2.8	4.7	5.4	1.42	E	4%
Trigs	25%	19.9	32.7	38.3	0.22	D	
Uric Acid	17%	8.6	17.5	19.5	0.51	R	14%

OPTIMAL, O f_{AL} < 0.125
DESIRABLE, D 0.125 < f_{AL} < 0.25
MINIMAL, M 0.25 < f_{AL} < 0.375
MARGINAL, R 0.375 < f_{AL} < 1.0 ALs should be reduced
EXCESSIVE, E f_{AL} > 1.0 current technology may not support ALs tight enough to meet clinical needs

B-158

Glycine's affinity to a cation-exchange resin offers potential treatment for glycine encephalopathy

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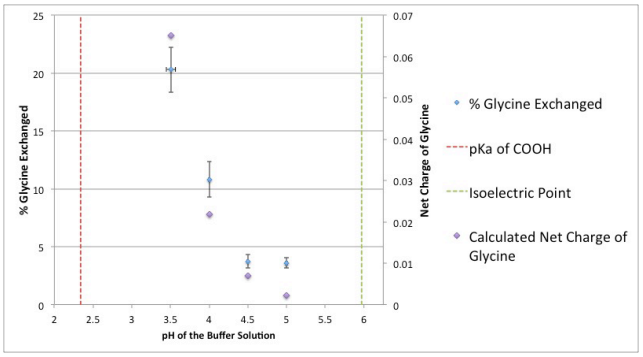
Background: Glycine encephalopathy(~ 1 in 60,000 births) is a rare autosomal recessive disorder characterized by high cerebrospinal fluid and plasma glycine concentrations. Glycine accumulation leads to NMDA receptor hyperactivity, resulting in hypotonia, apnea and death in neonates, and mental retardation and seizures in infants. The only existing therapy is the sodium benzoate, which is toxic and poorly penetrates the CSF. Plasmapheresis using a cation exchange resin may reduce circulating glycine, depending upon the affinity of the glycine-resin interaction. Glycine's anionic carboxylic acid (COOH) moiety reduces its affinity to cation resins, but neutralization of COOH by lowering the pH may increase affinity and improve glycine's removal.

Objective: To determine whether varying pH alters glycine's affinity to cation-exchange resins as a possible removal method.

Methods: We used potassium hydrogen phthalate solutions to alter pH of a glycine solution before passing it through 2mL of cation-exchange resin (Sigma-Aldrich 50WX8 hydrogen) embedded with a sulfonic acid functional group. Glycine removal was calculated after 5 passes through the resin at each pH with similar eluent volumes. pH was titrated to values between 3.50 to 5.25, between the pKa of the COOH group in glycine and the isoelectric point (5.97) to induce protonation of glycine. Affinity was quantified as percent glycine exchanged from solution. The theoretical net charge of glycine in each pH environment was additionally calculated.

Results: Decreasing pH resulted in a significant increase in glycine's affinity to the resin (ANOVA, $p < 0.05$). Highest affinity to the resin occurred at pH 3.50 with 20.30±1.96% of glycine exchanged (Figure). Calculated charge of glycine correlated to the affinity to the resin by Pearson correlation (R^2=0.98).

Conclusion: Protonation of glycine in low pH increases affinity to cation exchange resins. At physiological pH (7.4), extracorporeal exchange resins within an acidic environment (pH ~4) may be used to treat glycine encephalopathy.



B-159

Comparing Instrument Performance using Bio-Rad Mission: Control Software

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Objective: Evaluate and compare performance of different clinical diagnostic instruments using Bio-Rad Mission: Control software.

Relevance: Clinical diagnostic instrument performance is critical to producing reliable patient results that enhance patient care and reduce patient risk. We investigate the value of Mission: Control software to evaluate and compare instrument performance and help assess the need for new instruments in our laboratory.

Method: We are interested in two assays; 25-OH Vitamin D and HbA1c.

25-OH Vitamin D: We compared our current laboratory instrument to a new instrument being considered for acquisition. Our 25-OH Vitamin D allowable total error limits are ±15%, we use a 1:3s/2:2s/R:4s QC rule with 2 QC concentration levels, and we average 61 patient examinations between QC events. We used manufacturer's information for means and SDs for the new instrument.

HbA1c: We recently changed instruments after moving to a new buying group. We wished to compare our previous instrument's performance to the new instrument. We used an allowable total error of 15%, 1:3s/2:2s/R:4s multirule with 2 QC concentration levels, and we average approximately 200 patient examinations between QC events.

Results: Mission: Control software was used to estimate the worst-case expected number of unreliable final patient results, max E(Nuf), and average sigma values. Assuming no bias in the measurement procedures, the max E(Nuf) for our instruments is higher compared to the new Instruments.

Comparing Instruments on 25-OH Vitamin D Assay		
	Current Instrument	**New Instrument**
Max E(N_{uf})	137.7	<1
Average Sigma	1.7	5.1
Comparing Instruments on HbA1c Assay		
	Previous Instrument	**New Instrument**
Max E(N_{uf})	2.4	1.2
Average Sigma	4.3	4.6

Conclusion: The Bio-Rad Mission: Control software helped us evaluate and compare the performance of different instruments. We used this analysis for our business plan to support the need for a new instrument. However, budget constraints prevented the purchase of the new instrument for 25-OH Vitamin D. Our move to the new instrument for HbA1c was justified as it turned out to be a less expensive alternative with better performance characteristics.

B-160

Defining Performance Metrics and Workload Capacity in a High Throughput Immunological Cellular Function Testing Clinical Laboratory

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Rationale: To remain competitive in today's crowded clinical reference laboratory business environment, productivity and turnaround times (TAT) that are the most noticeable signs of laboratory service and performance must be measured. Here we describe the development and implementation of novel key performance indicators (KPI) for our lymphocyte proliferation testing (LPT) laboratory that have helped us measure and predict laboratory staffing needs and meet turnaround time expectations, thereby improving our laboratory's productivity, efficiency and overall quality of testing.

Methods: To assess process, we defined average capacity per performing technician for a number of testing processes based on historical average test volume, ergonomic considerations, key performance benchmarks for the various steps of the assay, published TAT, and laboratory needs, amongst other things. We then implemented manual input mechanisms outside of our Laboratory Information System (LIS) to measure test volume and productivity in the laboratory for individual steps in the testing process. The very manual nature of the LPT test is a limiting factor. The test takes 14 days to complete and consists of 82 individual non-interfaced steps. In the 14 day LPT testing process our leading indicator for TAT is a step after cellular proliferation has occurred, but before measurement of proliferation can begin called harvesting. We chose to measure this harvesting process as our KPI to most accurately predict the TAT and resulting of the LPT test, because it occurs after day 7 but before day 13, giving us a 6 day window of opportunity to make improvements to meet TAT. Metrics for the various assay processes were then charted and measured against incoming sample volumes to predict TAT and future staffing needs.

Results: Over the 18 months that these measurement tools were implemented, we noticed a dramatic decrease in the laboratory LPT testing TAT. Before implementation, the TAT was a weekly average of 18 days, 4 over our contractual agreement to our clients. After implementation, our performance metrics and the definition of our new KPI we were able to allocate resources to compensate workloads and improve TAT back to a monthly average of 9 days for January of 2016.

Conclusion: Laboratories that do not have automated and customizable reporting metrics would benefit from creating their own. In a competitive and quality driven clinical testing environment, it is necessary to define and monitor of KPIs as they apply to the individualized test. In the LPT Laboratory at National Jewish Health, we improved our processes by redefining them and what they needed to succeed. Measuring the manual and previously unmeasured harvesting process as a KPI and then adjusting staffing and delegation of tasks accordingly improved patient care through improved TATs on clinical testing.

B-161

Improving Quality Patient Care by Strengthening Relations

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Rationale: Translating quality between nursing staff and the clinical laboratory is very important. The two areas need to work hand in hand to ensure smooth transition of samples and patient information. Appropriate collection, handling, and analyzing patient samples correctly the first time and every time should be the goal of every clinical environment. The most common issues between nursing staff and clinical laboratory staff involve poor communication, and lack of understanding of both sides about their processes and requirements. Realizing this, we reached out to our nursing staff and implemented a program between the two groups with an ultimate vision to improve communication through mutual respect and understanding that will foster the partnerships necessary to provide safe and high-quality patient care and testing to optimize the patient experience.

Methods: We created a proactive communication program between an established clinical laboratory and a new infusion clinic that was increasing not only in the number of patients served but in samples that required STAT handling as well. Meetings minutes were kept and followed up on over a 6 month period. We also analyzed sample volume, turnaround time (TAT), and critical reporting to make sure we were meeting the needs of the clinic. From these meetings and communications we made a number of policy and procedure changes that improved quality patient care and offered operational efficiencies across both areas.

Results: The program created discussion of specimen collection techniques and decrease rejection, as well as a better understanding of specimen results in relation to patient treatments. In addition, down time processes and procedures were improved to increase communication to the clinic staff which ultimately reduced patient testing TAT by allowing the clinics to better schedule around laboratory activities.

Conclusion: The program improved efficiencies and created improvements that would not be realized without good understanding of different workflow processes. Understanding the needs of the lab and of the clinical staff can better create a synergetic mindset for improving pre-analytical, analytical, and better patient outcomes. In the end, a proactive communication program seeks to accomplish the task of successfully facing a complex challenge that will allow all those included to feel and support a sense of shared power and collective competence, which will

improve and grow the organization. People in organizations want and need to work together effectively and productively. Individuals long to be part of a bigger picture that connects them to a larger purpose. That purpose at National Jewish Health (NJH) is "to heal, to discover and to educate as a preeminent health care institution". This change initiative will help to grow the mission of NJH by bettering communication and understanding throughout the organization by starting in the clinical laboratory and expanding collaboration from one area to another. This will benefit everyone by bringing us one step closer to quality patient care.

B-162

Intactness of medical nonsterile gloves against alcohol disinfectants

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Background: Every morning from 8 am to 10 am, the blood collection room in the outpatients department of our hospital becomes overly crowded. Patients should wait on long lines for blood collection. Healthcare workers wear gloves for their own protection, and wash hands (or apply alcohol disinfectants in pressing times) and change gloves between patients for patient safety. The current regulation prohibits alcohol disinfection when gloves are worn, since sanitary intactness of gloves may not be guaranteed by alcohol. However, when viewed as a time saver, alcohol disinfection with gloves between patient blood collections can shorten waiting times of patients.

Methods: Four kinds of medical gloves were used: 1) 3 types of powder-free non-sterile latex medical examination gloves, Top glove (Top Glove, Malaysia), Dowoo, (Siam Sempermed Corp., Thailand), and Maxter (Maxter glove manufacturing, Malaysia), and 2) 1 type of nitril gloves, DERMAGRIP Nitrile extended cuff examination gloves (WRP Asian Pacific, Malaysia). For disinfection, 2 kinds of ethanol 62% gel, Clesis hand sanitizer gel (Liebecos, Korea) and 3M Hand Instant Sanitizer(3M Korea, Korea), and an ethanol 83% disposable skin cleaner, Clean Swab A (Meditop, Korea), were used. For two types of latex gloves, and one type of nitril gloves, ethanol 62% gel was applied, rubbed and dried for 30 times. For another latex gloves brand, we used disposable ethanol 83%, skin cleaner. Five pairs of gloves for each brand of medical gloves, in total 40 gloves, were tested. Using Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Acinetobacter baumannii, bacterial suspensions were prepared to match 0.5 McFarland turbidity standard. Glass slides were smeared with each inoculum and dried for 30 minites at room temperature. Glove fingertips were placed on the smeared surface for 1 minute. Fingertips were pressed into BAP and incubated for bacterial growth. **Results**: All the gloves were found intact after 30 times of rub-and-dry action with alcohol disinfectants. No significant bacterial growth was recognized on glove fingertips after ethanol disinfection. **Conclusion:** Gloves were found intact after 30 times of application of alcohol disinfection. Since blood collection for each adult patient takes less than 2 minutes, we recommend the use of alcohol disinfected gloves after 30 minutes or 15 patients if intact. The test results can apply only to adult outpatients in highly busy times.

B-163

Test utilization of serum free light chain assay in Northern Alberta

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Background: Inappropriate use of laboratory tests wastes valuable healthcare resources and places additional burden on the laboratory. Serum free light chain (sFLC) analysis is used as a prognostic indicator for the risk of progression from monoclonal gammopathies of undetermined significance (MGUS) to multiple myeloma (MM), and to detect and monitor monoclonal light chain diseases. Light chain escape is a recently described phenomenon which results from a shift in myeloma cell secretion of intact immunoglobulin to FLC only due to chronic and extensive treatments. Patients with light chain escape are especially vulnerable to renal impairment due to high level of FLC, and thus close monitoring of sFLC will be required to allow early detection of renal complications. The purpose of this study is to review sFLC assay utilization to determine if its use is appropriate in the context of current medical guidelines.

Methods: We completed a retrospective analysis of sFLC tests performed at DynaLIFEDX, Edmonton, Alberta, Canada from January 2014 to December 2015. De-identified data containing patient age, gender, interpretative results and ordering physician was extracted from the Laboratory Information System. Criteria to assess test utilization appropriateness include age, frequency, and the ordering physician specialty. Measurement of sFLC was performed in the Siemens Advia 1800 analyzer with reagents from BindingSite.

Results: The total number of sFLC assays requested increased by 41% from 2014 to 2015. A total of 10827 sFLC assays were performed in 2884 patients (57% male) in the study period of 24 months. There was a total of 307 sFLC assays performed for patients 40 years or under, with 41% of these tests having abnormal results as defined by free kappa/ free lambda ratio outside of the reference intervals (0.26 to 1.65). For patients older than 40 years where the majority of tests were performed (10522 tests), 63% of these tests had abnormal sFLC results. To determine the origin of the test orders, a list of top 20 physicians who ordered the most sFLC were generated. 87% of the test orders were from oncologists, while the remaining 13% were from internists, nephrologists, neurologists and family physicians. For monitoring the disease, 18% of the repeated sFLC tests were performed within 26 days, with the majority from oncologists.

Conclusion: Physician awareness of the Light chain escape phenomenon has led to a surge in sFLC testing in Northern Alberta. This study identified that approximately 1 in 5 serial sFLC tests were requested at intervals less than one month.

B-164

Most prevalent suspected diagnosis in primary care laboratory tests orders

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Background: The aim is to show the completeness of the request form regarding patient clinical question along years, and the most prevalent from primary care.

Methods: The laboratory located at a public University Hospital serves a population of 234 551 inhabitants, including nine different primary care centers (PCC). At least once a year, one meeting between laboratory professionals and General Practitioners (GPs) is held, to discuss the current strategies to improve laboratory service, and a median of 3 contacts each year through email.

Laboratory requests are made through Computerized Patient Order Entry that offers the GPs a field to be fulfilled regarding the reason for the laboratory request through International Classification of Diseases, Ninth Revision, Clinical Modification codes.

A retrospective observational cross-sectional study was conducted from January 1st 2009 to December 31th 2015. We counted the requests with clinical question and the number of every patient clinical question that was fulfilled in the request form and available in laboratory information system patient demographic data in absolute numbers and percentage (when percentage in 2015 was above 1%). The rest were grouped into a category called *other diagnosis*.

Results: The requests with patient clinical question increased over time (40% in year 2009)**,** achieving more than 80% in year 2015. Table shows annually the total annual number of requests from primary care and those with patient clinical information in the request through the 7 year period. It also shows the percentage of every diagnosis every year. Disorders of lipid metabolism, essential hypertension and diabetes mellitus were the most prevalent diagnosis.

Conclusions: The number of requests with patient clinical question augmented through a seven year period. Education and communication with GPs and new technologies could have contributed to this improvement along years.

	2009	2010	2011	2012	2013	2014	2015
TOTAL REQUESTS	89450	87056	91676	87424	94922	97438	49183
REQUESTS WITH CLINICAL QUESTION (%)	31296 (35.0%)	62028 (71.3%)	69018 (75.3%)	67556 (77.3%)	74701 (78.7%)	79057 (81.1%)	39914 (81.2%)
CIE-CODE (*)							
272	3,9%	7,7%	7,7%	7,9%	9,6%	9,8%	9,3%
401	2,7%	5,2%	5,2%	5,6%	6,2%	6,0%	6,2%
250	1,8%	3,7%	3,8%	4,1%	5,1%	5,4%	5,6%
595	1,0%	2,2%	2,3%	2,3%	2,7%	3,4%	3,0%
780	2,0%	3,8%	2,6%	2,5%	2,5%	2,7%	2,8%
244	0,7%	1,5%	1,6%	1,9%	2,3%	2,5%	2,7%
280	0,6%	1,1%	1,1%	1,3%	1,4%	1,5%	1,7%
790	0,5%	1,0%	1,1%	1,2%	1,3%	1,5%	1,6%
300	1,1%	2,0%	1,9%	1,9%	1,6%	1,6%	1,6%
285	0,5%	1,0%	1,2%	1,3%	1,5%	1,6%	1,6%
V72	0,3%	0,6%	0,8%	1,1%	1,1%	1,3%	1,5%
599	0,3%	0,6%	0,8%	1,3%	1,4%	1,6%	1,4%
536	0,4%	0,9%	1,1%	1,5%	1,2%	1,4%	1,3%
789	0,4%	1,1%	1,2%	1,3%	1,2%	1,3%	1,3%
719	0,5%	1,2%	1,2%	1,2%	1,2%	1,1%	1,2%
724	0,7%	1,3%	1,4%	1,4%	1,2%	1,1%	1,1%
788	0,4%	0,8%	0,9%	0,9%	1,1%	1,1%	1,1%
Rest of codes	17,1%	35,6%	39,1%	38,6%	36,1%	36,2%	36,4%

*** 272=Disorders of lipid metabolism; 401=Essential hypertension; 250=Diabetes mellitus; 595=Cystitis; 780=General symptoms; 244= Acquired hypothyroidism; 280=Iron deficiency anemias; 790=Nonspecific findings on examination of blood (Abnormality of red blood cells,Elevated sedimentation rate, Abnormal glucose, Excessive blood level of alcohol, Nonspecific elevation of levels of transaminase or lactic acid dehydrogenase [LDH], Other abnormal blood chemistry, Bacteremia, Viremia, Other nonspecific findings on examination of blood); 300=Anxiety, dissociative and somatoform disorders; 285=Other and unspecified anemias; V72=Special investigations and examinations (Examination of eyes and vision, Examination of ears and hearing, Dental examination, Gynecological examination, Pregnancy examination or test, Radiological examination, not elsewhere classified, Laboratory examination, Diagnostic skin and sensitization tests, Other specified examinations, Unspecified examination); 599=Other disorders of urethra and urinary tract; 536=Disorders of function of stomach; 789=Other symptoms involving abdomen and pelvis; 719=Other and unspecified disorders of joint; 724=Other and unspecified disorders of back; 788=Symptoms involving urinary system**

B-165

Extra technician tasks and turnaround time in a Stat Laboratory

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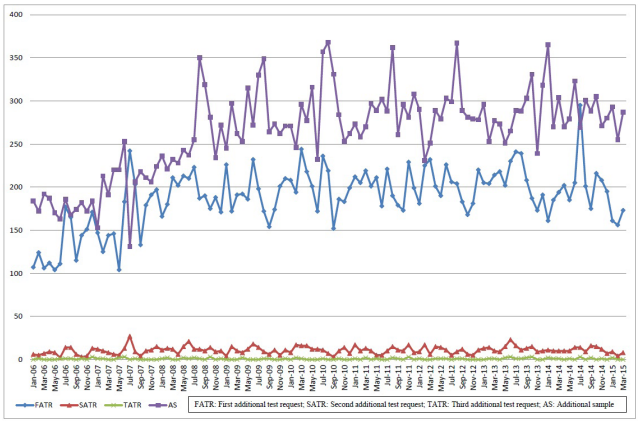
Background: The aim was to identify the main extra additional technician tasks carried out in a stat laboratory (SL) and its quantification and analysis over a ten year period through turnaround time (TAT) and test workload comparison.

Methods: In a meeting to identify and list the different extra additional tasks, to be collected its incidence in a daily basis, were decided as extra additional activities when a first, a second or a third additional test is requested. Also, we considered as extra additional task when an out of time sample is received. Technician would register in the Laboratory Information System (LIS), a specific "quality test" for each one of the four additional activities. The registers were collected automatically by the LIS using a data warehouse program. Every extra additional task was counted in absolute number in a monthly basis and referred to 1000 tests requested. Extra additional tasks, TAT results and tests workload in summer was compared to the rest of the year.

Results: In the 111 months studied, there were 51385 extra additional tasks. The monthly median was 475 extra additional tasks: 10.2 per 1000 tests requested. The main activity was "sample out of time" (271 per month), followed by "first additional test request" (191). The Figure shows in a monthly basis, the number of the four different extra additional activities along the period of study. In the summer period the workload and number of extra additional tasks were significantly higher. In spite of seasonal variations in workload and additional technician tasks, the TAT did not show this variation, complying always with our 30 minutes indicator target.

Conclusion: It is important to have the knowledge of the real SL workload, including extra additional tasks to improve the service provided to the ED patients.



B-166

The experience of setting up an advanced digital temperature monitoring system in the clinical laboratory and the application of log data

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Background: Accurate and reliable monitoring of temperature, humidity is crucial for the clinical laboratory to ensure that samples, materials and reagents are stored properly and compliance to laboratory quality control. It is recommended that the monitoring should be done continuously for 24 hours/every day. When a temperature control system fails, it is essential for appropriate personnel to be alerted immediately and actions should be taken properly to make sure the integrity of samples and reagents stored in the refrigerators/freezers. **Methods:** There are 451 sites located in four different buildings in which the temperature need to be monitored in our laboratory. We transformed the temperature monitoring system from manual recording, weekly and monthly reviewing and paper based archives to digital system that can record data automatically and data can be reviewed on line regularly since 2013. The continuous temperature log data collections from calibrated probes are compressed to one data point every five minutes and digital signals are transmitted to server by cable. Numeric data are stored in the structural database. **Results:** Besides all temperature data are kept in a manageable file structure that can be reviewed anytime and anywhere through web browser with authority control, alarms are notified through multi routes, including broadcast to GSM, e-mail, and alarm lights. The characteristics of these systems that are less mentioned previously but are much more important for the integrity of collected data are as follows: 1. mechanisms for detecting expected or unexpected shout down of the data collecting workstation, power cuts at any single probe, nodes or switches, disconnection of network or out of service of the database servers, 2. mechanisms for detecting any fails of the alarm system mentioned previously by dual separated system , 3. second backup of alarm system by Remote Computer Alarm Programs beside the work bench of the staffs who are in charge of the monitoring of temperature control equipments, 4. all the alarms of the temperature control equipments are logged automatically and the actions

taken and follow up can be documented by the linking of laboratory's document system. **Conclusion:** With the automatic digital laboratory temperature monitoring system, estimated more than fifteen thousand A4 sized papers and 540 working hours are saved from 2013 to 2015. The malfunction log of these equipments can be calculated routinely and the information from temperature log data can be extracted through data mining process by decision tree analysis. With the predicted results, the laboratory's managers/directors can evaluate the performance of the temperature control equipments in the basis of evidence and achieve prior risk management to prevent unexpected fails of the temperature control in the laboratory.

B-167

Reducing false quality control failure rate with implementation of six-sigma statistical quality control management program reduces laboratory operational cost.

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Introduction: The clinical laboratory is urged to produce high quality, timeliness results at a low cost. Laboratory Quality Control program has been used to detect analytical errors. Often to avoid missing any error, there is a tendency of the laboratory to maximize error detection with the selection of the QC rules with fairly high probability of error detection (P_{ed}) but this is often accompanied by a high probability of false rejection (P_{fr}) resulting in high false rejection rate. This will results in unnecessary use of resources, effort and time in performing troubleshooting for the false QC failure and results in high costs of failure. Aim of this study is to determine whether adopting a Six Sigma quality control management program can reduce false QC rejection rate and costs of failure of the laboratory, without affecting detection of errors. **Methods**: Sigma metrics were evaluated for 27 serum and urine chemistry assays across two units of Abbott's ARCHITECT c8000 chemistry analyzer using the equation: Sigma metrics = (TEa - %Bias) / %CV. % Bias and % CV were calculated with QC data collected over a six months period with the choice of TEa based on the recommendation of the Westgard Verification Program. QC optimization of control rules and frequency were based on the Sigma metrics achieved for each of the 22 assays. False QC failure rate and the amount of resources used on troubleshooting the false QC failure rate were evaluated before and after implementing the Six Sigma quality control management program. **Results**: QC rules optimization were achieved based on the assay's Sigma metrics performance whereby 22 of 27 assays (81%) were of world class and excellent performance achieving Sigma metrics >5 with the remaining 5 assays at >4 Sigma metrics. Changing from the standard 1-2s QC rules practice to QC rules optimized by Sigma metrics resulted in the reduction of 80% false QC failure rate. As a result of the reduction of the false QC failure rejection, the laboratory achieved an estimated annual operation efficiency saving of approximately 650 man hour (reduction from 820 man-hour to 170 man-hour) and direct estimated annual operating cost saving of approximately 18% comprising of reagent, control materials and labor cost saving, equating to MYR 45,000. **Conclusion**: By adopting and implementing Six Sigma quality control management, we were able to improve laboratory operation efficiency by reduction of false QC rejection rate, which in turn enable direct cost saving benefit without compromising the detection of any errors and enable us to continuously provide speedy, high quality service at low cost.

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Increased demand in Primary Care in Spain. A Big Data analysis

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BACKGROUND: To compare Primary Care Requesting patterns between two different years in Spain, using appropriateness indicators, to try to ascertain tests demanding behaviours along years.

METHODS: Every Spanish citizen possesses the Individual Health Care Card, which let access to public health services as a healthcare user throughout the National Health System. Every Autonomous Community (17 in Spain) is divided into a number of Health Departments. Every Department covers a geographic area and its population and is composed by several primary care centers and usually a unique Hospital. The laboratory located at the hospital attends the needs of every Health Department inhabitant.

A call for data was posted via email. Spanish laboratories willing to participate in the study were invited to fill out an enrollment form and submit their results online. The dissemination of the questionnaire was addressed to the participants of previous studies of the REDCONLAB group that recommended to other laboratories to join the current edition. Numbers of 50 tests requested by all of the general practitioners for the year 2014 from laboratories at different hospitals from diverse departments across Spain were used. Each participating laboratory was required to be able to obtain patient data from local Laboratory Information Systems Patient's databases and also to provide data of the organization. The same study had previously been done in 2012.

After collecting the data, test-utilization rates were calculated by standardization with the population attended by each laboratory. Rates were expressed as tests per 1000 inhabitants. We considered inhabitants the residents in each public Health Departments. The differences in indicator results in both years were calculated by way of the U Mann-Whitney test analysis. A two-sided $p \leq 0.05$ rule was utilized as the criterion for rejecting the null hypothesis of no difference

RESULTS: In the 2012 study, 76 laboratories, on a voluntary basis, participated, corresponding to a catchment area of 17,679,195 inhabitants from 13 different communities throughout Spain (38% of the Spanish population) and 110 laboratories participated in the 2014 study, corresponding to 27,798,262 inhabitants from 16 different communities (59% of the Spanish population).

Significant increases in year 2014 were found in alanine aminotransferase, transglutaminase antibodies, calcium corrected for albumin, cholesterol, creatinine, folate, glucose, HDL-cholesterol, glycated hemoglobin, complete blood count, potassium, sodium, thyrotropin, triglycerides, urinalysis, vitamin B_{12} and 25-OH-vitamin D.

CONCLUSION: Overall, Primary Care requests in Spain have increased significantly in the most demanded tests in two years period. From the Laboratory is possible the use of management tools as Big Data, for the analysis of data with special characteristics of volume, variety, velocity, variability and veracity to get the knowledge regarding test demand in large geographical areas

B-169

Verify the Utility of a Simplified Model to Evaluate the Analytical Performance of Creatinine in the Medical Decision Points

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Background: Given that commercial materials of internal control do not generally cover all the concentrations that represent Medical Decision Points (MDPs), it is relevant to evaluate the analytical performance of the tests at these points. This work shows a simplified model (Model-2) of estimation of the analytical performance in the MDPs for creatinine in serum expressed like sigma metric using the results obtained from verification tests, and comparing them to a more robust model (Model-1).

Methods: A homogenous system was used in the analytical platform Architect ci8200. The method used for the determination of creatinine was kinetic alkaline-picrate. The theoretical MDPs (0.60, 1.60, 6.00mg/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 (Allowable Total Error) was selected from CLIA 88' (0.3mg/dL and 15%), and it was calculated with the formula Sigma = [ETa(%) - Bias(%)] / CV(%). Model-1: the bias that represents the systematic error of measurement was estimated as the absolute percentage difference 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 36 external quality control surveys which ranged from 0.56 to 11.30mg/dL. The CV(%) that 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 a pool of samples from patients with 16 different creatinine concentrations daily during a minimum of 30 days, the creatinine concentrations ranged from 0,052 to 6.65mg/dL. Model-2: the bias was estimated by using the linear regression from the linear verification test, and the precision in the MDPs was estimated from the results from the precision verification (EP15-A2) and the limit of quantification. **Results:** Model-1: the slope of the Deming linear regression was 1.013 (CI 95%: 1.002 to 1.024) and the y-intercept 0.0081 (CI 95%: -0.0411 to 0.0574). The estimated MDPs obtained from the Deming regression were 0.62mg/dL, 1.63mg/dL and 6.09mg/dL, the bias being of 3.3%, 1.9% and 1.5% respectively. The estimated CV(%) in the MDP

of 0.60mg/dL was of 2.17%, in 1.6mg/dL of 1.74% and in 6.0mg/dL of 1.29%. The sigma performance obtained in the MDP of 0.60mg/dL was of 21.5, in 1.60mg/dL of 9.7 and in 6.00mg/dL of 10.5. Model-2: the linear regression obtained from the linear verification was y=0.929x+0.075 and the estimated MDPs were 0.63mg/dL, 1.56mg/dL and 5.65mg/dL, the bias being of 5.0%, 2.5% and 5.8% respectively. The estimated CV(%) in the MDP of 0.60mg/dL was of 4.5%, in 1.6mg/dL of 1.98% and in 6.0mg/dL of 0.87%. The sigma performance obtained in the MDP of 0.60mg/dL was of 10, in 1.60mg/dL of 8.2 and in 6.00mg/dL of 10.6. **Conclusion:** The utility of the simplified model to estimate the sigma performance in the MDPs was verified.

B-170

An Audit Of Critical Result Reporting In A New Regional Hospital

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Background: Accurate and timely transmission of critical results to the appropriate caregiver ensures patient safety, and is one of the criteria that regulatory bodies worldwide requires clinical laboratories to meet for licensing and accreditation purposes. Our new regional hospital, Ng Teng Fong General Hospital, began operations in phases from July 2015. Our objective is to perform an audit of critical result reporting from July to December 2015, to appreciate our new patient profiles, and to ensure our protocols and service levels meet international standards.

Methods: Critical results triggered from July to December 2015 were obtained from our Laboratory Information System. The following were analyzed: total number of tests reported, number of critical results, the most common critical results, and the laboratory sections and time of day with the most number of critical results (categorized as 8am - 4pm, 4pm - 12am, 12am - 8am). Pertaining to notification, information on response time, number of failed responders (defined as TAT more than 60 minutes) and main reasons for failure were studied.

Results: The total number of critical results reported each month showed a steady increase from 63,692 in July to 141,288 in December. This correlated with the increasing number of patient beds being opened in phases. The proportion of critical results over all tests was similar ranging from 0.54% to 0.67%. The top 5 critical results triggered were positive blood culture (21%), followed by platelets (10.9%), sodium (10.7%), glucose (9%) and potassium (9%). As a section, biochemistry had the most number of critical results (54%), followed by microbiology (27%) and hematology (19%). The 8am - 4pm period had the highest number of critical results (49%), followed by 4pm - 12am period (26%) and 12am - 8am period (25%). Most of the critical results were electronically communicated to the requesting physician via Healthcare Messaging System (HMS) within 11 - 30 minutes (53%), followed by within 10 minutes (35%), between 31 - 60 minutes (11%) and beyond 60 minutes (1%). The proportion of failed responders, defined as more than 60 minutes, ranged from 0.6% to 1.4%. Main reason was delayed closure of the case by the call center operator. Our further investigation revealed no compromise in patient safety as appropriate management plans were already in place based on prior clinical suspicions.

Conclusion: Majority of critical results are communicated to the appropriate clinician without delay via automated notification systems, thus helping save time and manpower. Coupled with the information above, more effective manpower allocation can be achieved, which hopefully translates into improved quality and efficiency of laboratory processes, and ultimately patient care. Frequent monitoring and review of critical results management processes and feedback to all stakeholders should be a good standard of practice that all clinical laboratories adopt.

B-173

Laboratory Utilization Analysis as a Clinical Service: A Pilot Study Using Dashboards with an Intensive Care Unit

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Background: The laboratory utilization literature suggests that both overutilization and underutilization are significant problems. Past work also demonstrates that some physicians are not comfortable using some laboratory tests, have not received adequate training on concepts of laboratory medicine, and are not aware of the costs for even common laboratory tests. Rather than test a single intervention to improve laboratory utilization, we piloted a collaborative process with an intensive care unit to assess needs and jointly develop solutions to improve appropriate test use.

Methods: The first step in the process was an analysis of laboratory utilization patterns for a pilot ICU, which included test volumes, frequencies of testing for individual tests, and direct cost and charge information. We also developed an interactive utilization dashboard that displays testing frequency and proportion of tests duplicated within 24 hours by specific test for individual patients, in addition to summary views of general utilization. We then met with senior physicians and administrative leadership to discuss general patterns of utilization and identify areas for improvement, and provided clinicians access to dashboards to drill down on outliers and determine appropriateness of testing. Based on their feedback, we came to consensus on which tests were the best candidates for improvement and identified interventions with target goals.

Results: Point of care testing (POCT) was the highest volume test category in the pilot unit. POCT utilization was driven by lack of awareness of the optimal uses of POCT and a lack of standard ordersets to guide ordering of routine tests. Residents in particular were not aware that POCT results can be less reliable than central laboratory testing for some analytes and are costlier, nor were they aware of the rapid turnaround times for blood gases performed in the central laboratory. After discussion and review of dashboard data, there was agreement that at least 50% of the POCT performed could either be shifted to blood gases, other equivalent testing, or eliminated altogether. Awareness of the issue decreased the overall rate of utilization from a baseline of 0.98 tests/patient/day over 12 months (n=1539 patients) to 0.55 tests/patient/day over 4.5 months (n=617 patients). The effect was expected to be transient so the unit also created an orderset to better standardize ordering and placed POCT testing below blood gases and other equivalent tests. This change further decreased POCT use to 0.39 tests/patient/day over a 2-month period (n=368 patients), or a 60% decrease in daily utilization from the original baseline. Even after accounting for the increase in blood gas utilization, these changes are projected to decrease yearly direct costs by $60,000 for the pilot unit alone. Furthermore, after instituting the orderset, utilization of other labs besides POCT and blood gases decreased by 12%, from 7.7 tests/patient/day to 6.7 tests/patient/day.

Conclusions: Utilization of laboratory testing is highly variable between practice settings, so implementing systemic changes to improve utilization can be challenging. We demonstrate that a process targeted by clinical unit that includes data analysis and partnership with clinicians improves laboratory utilization.

B-174

Comparative Study of Six Sigma Assay Performance on VITROS Systems

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Objective: Evaluate long term manufacturing release data to determine process capability within a tightly controlled laboratory and compare those results to external laboratory data using the six sigma statistic, where a sigma greater than 4 indicates good performance.

Methodology: Perform a retrospective analysis of manufacturing data from 3 years of precision and uniformity testing on a single level of QC material, across 10 different VITROS® Systems to quantify the total error (%bias and %CV) relative to total allowable error (TEa). CLIA proficiency testing limits[1] were used as the total allowable error (TEa) criteria; for those not graded or where a definitive unit or percentage was not given (example: +/- 3sd), the TEa was based on biological variation.[2] Percent bias was estimated using the rolling average (defined as the average difference in measured values between reagent lots) divided by the QC fluid target value X 100. The SD across reagent lot data collected was used to determine the %CV; (fluid target mean/SD) X 100. The total error was determined by subtracting the %bias from the TEa expressed as a percentage and divided by the CV% [(%TEa - %bias)/%CV]. A separate analysis was performed using within-lab QC data collected using e-Connectivity® Technology from two facilities, with 2 VITROS® 5600 Integrated Systems each, that utilize the Bio-Rad quality control materials. The within-lab grand mean was calculated to estimate %bias within each lab and the %CV was established by calculating the SD over a minimum of 30 days of stable operation divided by the within-lab grand mean X 100. The sigma for each assay was calculated for each QC level in use.

Results: Long term manufacturing data demonstrated sigma levels of 6 or better for the 17 assays evaluated. Data pulled electronically from the two external laboratories across two levels of assayed control materials demonstrated > 6 sigma on both levels, all analyzers, for AST, ALKP, GGT, Crea, Gluc, K, Cl, Ca, Chol, Trig, HDL, and LDL. The remaining assays were >5 sigma (Urea, TP, Alb, TropI, TSH). **Conclusions:** Choice of TEa as well as the concentration or activity level assessed will impact the sigma calculated, as will the timeframe for data collection. Evaluation of manufacturing release data indicate that all assays assessed exceeded 6 sigma using CLIA limits or, in the absence of distinct limits, limits for biological variation. External laboratories achieved >6 sigma for 70% of the assays - across all analyzers and QC levels. The remaining 30% demonstrated >5 sigma. Manufacturing release

data are collected under tightly controlled conditions, limiting variation that may be more prevalent in external laboratories. While sigma values were higher under these conditions, the external laboratories demonstrated excellent performance, both within and between analyzers.

[1] Federal Register February 28, 1992;57(40):7002-186.

[2] Ricos C, Alvarez V, Cava F, Garcia-Lario JV, Hernandez A, Jimenez CV, Minchinela J, Perich C, Simon M. "Current databases on biologic variation: pros, cons and progress." Scand J Clin Lab Invest 1999;59:491-500. Database updated in 2014.

B-175

Frequency that laboratory tests influence medical decisions

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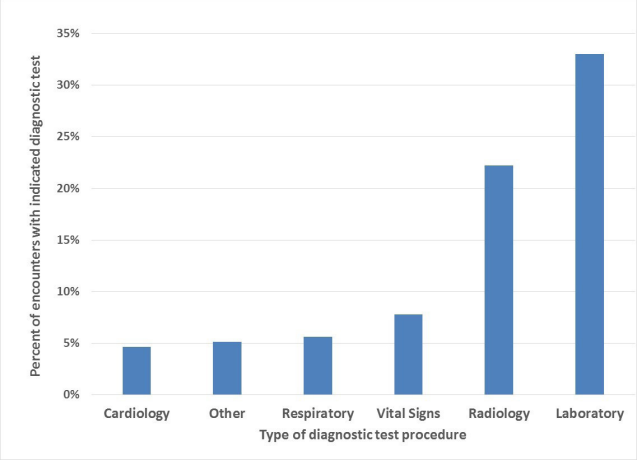
Background: Among the variables that influence medical decisions, laboratory tests are considered to be among the most important and frequently utilized. The influence of laboratory tests on medical decisions have been difficult to estimate. The goal of this study was to estimate the number of patient encounters that had an associated laboratory test.

Methods: We extracted information for 71,201 patient encounters from one-week intervals each quarter of a year from our comprehensive academic medical center electronic medical record. We determined for which encounters laboratory and other orders existed.

Results: Of the encounters examined, 33% had one or more laboratory tests ordered. The figure shows the frequency that different types of diagnostic procedures were ordered. Note that a single patient encounter may have more than one type of diagnostic procedure. For inpatient, emergency department and outpatient populations, ≥87%, 50% and 29%, respectively, had one or more laboratory tests ordered. The influence of laboratory tests on inpatients was dependent on the length of stay with 1, 2 or >2 days stay having laboratory orders 87%, 96% or 98% of the time, respectively.

Conclusion: Overall 33% of patient encounters had laboratory tests ordered. Meaningful differences in laboratory utilization were observed with almost all inpatient, half of emergency department and nearly one-third of outpatient visits informed by laboratory tests.



B-176

Notification for recollection in a large clinical laboratory: is there a need to review the process?

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Background: Assay interferences may occur in variable degrees with many laboratory tests; therefore the reliability of a specific result may need a call for recollection. The notification process for that purpose should be well designed and effective, to guarantee proper medical intervention. The aim of this study was to access the dimension and efficiency of the established process for outpatient call for recollections. **Methods**: To understand the actual performance of the recollection call process demanded by "highly altered results", we evaluated LIS data from June to November of 2015, from a large clinical laboratory, where about 6 million laboratory tests are performed monthly. Medical staff, remotely based outside the central lab, daily access a list of necessary recollection calls of outpatients through LIS feature. Patient contact is performed within 24 hours after demand input on the LIS from central lab. Primary contact is tried by telephone; if not achieved, a telegram is sent. The 5 tests with highest recollection demand rates were selected for performance analysis of contact efficacy and results on the new sample, compared to the primary result. **Results**: Laboratory quality processes resulted in 11,202 calls for recollection demanded by "highly altered test result". Telephone notification succeeded in 91.5% of recollection calls, and 947 telegrams were sent. The 5 most prevalent tests were serum vitamin C (VitC) (3,382; 30.2%), serum aluminum (Al) (288; 2.6%), serum selenium (Se) (185; 1.7%), serum copper (Cu) (173; 1.5%), and serum vitamin B6 (VitB6) (84; 0.75%). The rate of no show for recollection was 63.8%, 74.0%, 59.5%, 64.7% and 67.9%, respectively. Among patients that returned, the result of the new sample remained in the same range of previous result in 78.9%, 22.6%, 65.3%, 72.1% and 48.1%, respectively. Results of the new sample fell in normal ranges and in the opposite result range on 19.5 and 1.6% for VitC, 49.3% and 28.0% for Al, 16.0% and 18.6% for Se, 13.1% and 14.7% for Cu and 7.4% and 44.4% for VitB6. **Discussion**: Even with a consistent mechanism of notification, the majority of patients did not return for recollection. In our current model of recall, we do not know if the patient was effectively reached when telegram is needed, due to possible errors in registered address. Phone call is the main form of contact, but the use of other medias could possibly increase the rate of return. Still, among patients that return for recollection, the same result is maintained for the majority of cases of VitC, Se, Cu and VitB6, but the minor rate of normalization reflects the importance of the repetition for its clinical implications. On the other hand, Al results in the new sample were found normal more often after repetition than for the other analytes, showing how patient's return can prevent unnecessary treatments. **Conclusion**: This process review shows that patient's compliance with recollection is important and rates of no show must be reduced. Therefore, the investment in new media such as SMS, email alert, and app developments for smartphones could be appropriate in large clinical laboratories.

B-177

Implementation and Performance Characteristics of a Weekly Patient Pooled Quality Control Specimen in a Networked Healthcare System.

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Background: Traditional quality assurance programs usually consist of daily quality control (QC) runs, quarterly proficiency testing, and at times, periodic with-in site instrument comparisons. These programs tend to use third party control materials that serve as surrogates for patient serum and can miss potential issues related to the sample matrices. This poster defines an implemented protocol for using pooled patient specimens as supplemental QC within a hospital network and includes specimen preparation, test ordering, data capture and interpretation, and corrective action communications when necessary. The quality assurance program also highlights the advantage of standardized equipment and the performance characteristics of these assays over time.

Methods: A team of 4 people from the laboratory identified the steps needed to move a pooled patient specimen, and the results, around 4 hospital sites comprising 6 instruments in total, without introducing additional work for the technologist at each site. To minimize manual test ordering at each site, a protocol was developed, generating site specific labels with preordered lab tests, to be performed when the specimen was received. Upon arrival, the technologist incorporated the specimen into the routine workload. The laboratory results automatically downloaded from the instrument and into the LIS, Sunquest v. 7.1. Data was retrieved from the LIS and populated in an excel worksheet and interpreted. Weekly, summarized, emails were sent out to the chemistry departments. Cumulative variances were also calculated and tracked over time for trending. All chemistry or immunoassay testing was performed on the Abbott ARCHITECT c4000, ci4100, or c8200 systems per the manufacturer and laboratory procedures.

Results: Implementation of the protocol requires no more than 3 key resources , avoiding additional steps at off-site labs. Procedural steps for ordering tests at the core lab, generates specific bar codes for each specimen that is unique to the site. Weekly email communication by a supervisor has led to more proactive involvement by lab leadership, with specific directives each week for specific assays. Weekly monitoring for approximately one year indicates very little variability across the 32 assays monitored.

Conclusion: This semi-automated quality control strategy for utilizing a pooled patient specimen for quality performance has been successfully implemented across 5 sites, with sample prep and data analysis occurring at the core lab. As a result, the

weekly quality metric has led to earlier interventions through email communication to each site. In addition, involving a supervisor to summarize the findings each week has also facilitated more collaborative communication with the techs and overall knowledge of how the systems are performing. Matrix matched patient controls can help identify assay or instrument errors that may have been masked by third party materials. Minimizing the steps needed by the off-site labs has contributed to the overall success of the program. Finally, the small variances observed week to week illustrate the advantages of having standardized high quality equipment and assays.

B-179

Does essential human resource to mix primary blood tubes before to assay HbA1c by turbidimetric inhibition immunoassay?

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Background: Pre-analytical phase is considered the most vulnerable phase in laboratory diagnostics. Presently, accurate mixing of primary blood tubes to assay HbA1c is claimed to be important and recommended by laboratory managers. This procedure directly impact on laboratory costs since need expressive human resource. We aim to evaluate whether it is really necessary to mix the primary blood tubes immediately before to assay HbA1c by turbidimetric inhibition immunoassay.

Methods: Blood from 20 diabetes patients were collected directly into K2EDTA evacuated tubes. The collection of all diagnostic blood specimens were performed by a single, expert phlebotomist, following the international standard from Clinical Laboratory Standard Institute. All diagnostic blood specimens were kept in vertical, closure-up position, and hand carried by our laboratory personnel in an appropriate biohazard container at room temperature from the phlebotomy service to the core laboratory. The mean transport time was 7 min. All specimens were manually mixed by inversion ten times, as recommended - front of the cobas c501 (Roche Diagnostics) - then HbA1c were immediately assayed using properly reagent Tina-quant Hemoglobin A1c Gen.3 (Roche Diagnostics). Subsequent the same blood specimens were left in upright position at room temperature, without mixing afterwards, and re-assayed at 2, and 4 hours after blood collection. The instrument was calibrated against appropriate proprietary reference standard material and verified with third-party control material (independent from calibrator material). Differences between samples were assessed by Wilcoxon ranked-pairs test. The level of statistical significance was set at $P < 0.05$.

Results: Main results are showed in Table 1.

Table 1. Impact of no-mix blood tubes before to assay HbA1c by turbidimetric inhibition immunoassay.

Parameter	Basal	2h	4h
HbA1c (%)	8.34 [6.74-9.62]	8.30 [6.78-9.51] P=0.556	8.40 [6.77-9.63] P=0.435

Values expressed as median [interquartile range].
P values represents significance by Wilcoxon ranked-pairs test.

Conclusion: We considered unnecessary to mix primary blood tubes before to assay HbA1c by turbidimetric inhibition immunoassay, since no statistical significant differences were observed between results from sample immediately mixed, and sample no-mixed till 4 hours after blood collection. We also strongly encourage all laboratory managers to perform similar verification to save both laboratory costs and human resource.

B-182

To Add-on or not to Add-on - Analysis of the Add-on testing in the context of TAT and volume for 2 major clinical hospitals

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Background: Request for additional testing to existing specimens is frequently encountered in the clinical setting. Add-ons can theoretically reduce unnecessary blood collection and save costs. Despite these advantages, the processing of add-on requests is challenging for many laboratories and creates substantial issues for workflow and processing. To better understand add-on trends the authors retrospectively evaluated ordering trends to identify possible areas for improvement. Data from the LIS was used analyze add—on volume, TAT, for both ED and non-ED locations.

Methods: The authors retrieved add-on data over a period of six months retrieved from Beaker LIS. The data was then sectioned into ED and non-ED locations. The daily add-on volume for the Santa Clara Valley Medical Center (SCVMC) averages around 300-400 different test add-on requests peaking 20-30 order an hour. The order shows up on the pending log and is followed up by the MLA. Then the specimen has to be located and linked to the specimen if enough sample is left and then added on the appropriate analyzer. This process takes about 4-5 minutes for each specimen.

Results: The authors made a detailed TAT and volume analysis showing 54% of the add-on volume during the dayshift, 39% during the evening shift and 7% night shift. The emergency department accounts for about 40% of the total add-on volume with an evenly distribution of the order volume. The most frequent chemistry add-on tests are liver function tests (7.1%), magnesium (5.4%) and basic metabolic panel (4.3%). The observed TAT for STAT troponins was drastically prolonged when ordered as add-on. There about 11% of all STAT troponin add-ons required more than 60 minutes between order and add-on by the MLA, which is above the cut-off of 60 minutes between order to result.

Conclusion: Frequently, physicians added different tests on the same specimen with just minutes apart. While this might be due to an interrupted order pattern, this increases the workload for the lab. Add-ons are not included by the auto-cancel policy implemented in the EMR. That leads to unnecessary test duplication on the same specimen. This investigation noticed that often multiple different provider request the same add-on tests on the same specimen. It also became very apparent that the information system department has a big problem with pulling a comprehensive and accurate report. The observed reporting problems include add-on ordering provider vs ordering provider of the primary tests, add-on ordering test vs primary tests, add-on ordering time and add-on time.