Wednesday, August 1, 2018

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

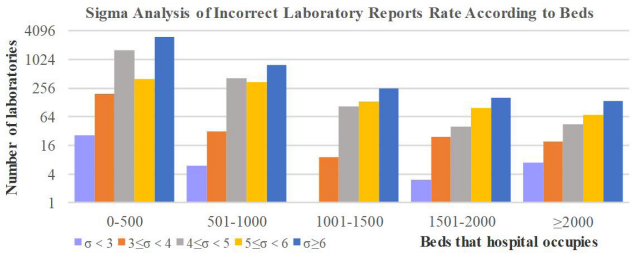
Management

B-162

National Survey on Sigma Analysis of Appropriateness of Laboratory Reports in 2017 in China

Y. Huang, W. Wang, F. He, K. Zhong, S. Yuan, Y. Du, Z. Wang. *National Center for Clinical Laboratories,Beijing Hospital, National Center of Gerontology, Beijing, China*

Background: Appropriateness of laboratory reports is a part of post-examinational process. Three quality indicators (QIs) about it have been developed in China, including incorrect laboratory reports rate, critical values notification rate and timely critical values notification rate. This study aimed at analyzing sigma level of these three QIs. **Methods:** 9039 clinical laboratories from 31 provinces enrolled in external quality assessment programs for QIs of clinical laboratories in 2017. General information and related data were asked to be submitted via net platform established by National Center for Clinical Laboratories (NCCL). The results were evaluated with sigma scales (σ) and percentage. Mann-Whitney Test and Kruskal-Wallis Test were used to perform the group comparison. **Results:** 7633(84.5%), 7169 (79.3%) and 6974(77.2%) laboratories submitted data of three QIs, respectively. Among laboratories provided data about incorrect laboratory reports rate, 6319 laboratories reported beds their hospital occupied. As caculated, most labs had three QIs at σ≥6, even more than 6000 labs had critical values notification rate at world class level. For incorrect laboratory reports rate, even though a large number of laboratories got the lowest defects per million opportunity, there were still a certain number of laboratories got unacceptable sigma level for each group. **Conclusions:** Although overall sigma level of these three QIs in 2017 in China was satisfied, but there were some problems if data were grouped by different methods like beds that hospital occupied. Therefore, there is still space for labs to improve the quality of testing reports.



B-163

Strategies for the implementation of the ISO 15189 standard in clinical laboratories in Mexico

S. Quintana-Ponce. *Universidad Autónoma de Guerrero, Chilpancingo, Gro., Mexico*

The ISO 15189 accreditation is a specific international standard for clinical laboratories (CL), which allows demonstrating quality and technical competence. In Mexico this accreditation is voluntary, placing this country in second place in Latin America and the Caribbean, in terms of the number of laboratories accredited by this standard. However, these laboratories only represent 1.97% of the total LC in Mexico, so it is convenient to analyze the strategies used by the currently accredited laboratories, with the intention of disposing elements that facilitate the implementation and accreditation to other laboratories. Mexico has a mandatory standard for the operation of CL that does not require accreditation; however, ISO 15189 accreditation is available as a voluntary standard since 2005, by the national accreditation body called the Mexican Accreditation Entity. The objective of this research was to establish strategies for the implementation and accreditation of Quality Management Systems (QMS) under the ISO 15189 standard in CL in Mexico, identifying the main problems detected in the implementation, the strategies used and alternative proposals to increase the number of accredited laboratories.For the methodology, it was considered a quantitative, descriptive, cross-sectional investigation, using the survey as a technique and the questionnaire as an instrument, which was previously validated according to the criteria of Rivas (2004). A probabilistic sampling without replacement was used, with a confidence level of 90%, for a finite population of accredited laboratories, involving a representative sample of 44 CL and 3 accredited blood banks (BB). The sample size was determined by looking for it to be statistically representative of the universe that was constituted of 106 CL and 6 BB accredited at the time of the investigation.The information was tabulated using the statistical program STATA version 14, elaborating contingency tables. To analyze the relationship between variables, the Pearson Chi^2 test was used. To estimate the association between variables we used Cramer's V, Kendall's tau-b and Goobman's and Kruskalll's Gamma.As a result of the analysis of the information, it was identified that: 1. The knowledge and commitment of the personnel, 2. The previous experience in QMS and 3. The counting in the country with free technical documents to meet technical requirements considered critical such as validation of methods, traceability and measurement uncertainty, are key elements for CL accreditation. The results obtained also allowed to verify that the accreditation is accessible to any Mexican laboratory, regardless of its size or complexity, being convenient to train the personnel in QMS.In conclusion: the commitment of the personnel, the training of the human resource, the availability and use of free technical guides facilitate the ISO 15189 accreditation.

B-164

Summary and Analysis of Blood Culture Contamination Rate in Clinical Laboratories in China from 2015 to 2017

S. He, W. Wang, F. He, K. Zhong, S. Yuan, Z. Wang. *National Center for Clinical Laboratories, Beijing Hospital, National Center of Gerontology, Beijing, China*

Background: Blood culture is a long-term test carried out by clinical microbiology laboratory, the positive results of which have great significance. Blood culture contamination rate is one of the 15 quality indicators (QI) of examination procedures published by National Health and Family Planning Commission. In the research, we collect and process the data obtained from clinical laboratories around the country in 2015, 2016 and 2017 to observe the status of blood culture contamination rate. **Methods:** By using the software developed by National Center for Clinical Laboratories (NCCL), we can get the data of blood culture contamination rate from 2015 to 2017. The proportion of clinical laboratories is classified according to the different level of blood culture contamination rate and we also look into the contamination rate by hospitals with different beds to identify the corresponding status in hospitals of different rank. Microsoft office Excel 2007 is applied to finish the calculation. **Results:** There are 3065, 4487, and 4826 laboratories taking part in this survey from 2015 to 2017, as illustrated in the table below. In the left column we can figure out that blood culture contamination rate is mainly distributed in 0 to 0.25, which are 48.32%, 48.21% and 47.70%, separately, while the ratios in other rows are small and decentralized, indicating a good control in blood culture contamination rate. Hospitals with more than 2000 beds get the lowest blood culture contamination rate on the basis of mean value, compared with hospitals possessing a smaller number of beds. **Conclusions:** To sum up, the quality control of blood culture contamination rate in Chinese clinical laboratories is relatively good, but there are still some cases having an unsatisfactory quality control in contamination rate. Therefore, hospitals and clinical laboratories should work together to find the causes behind and make their best effort to achieve a better practice.

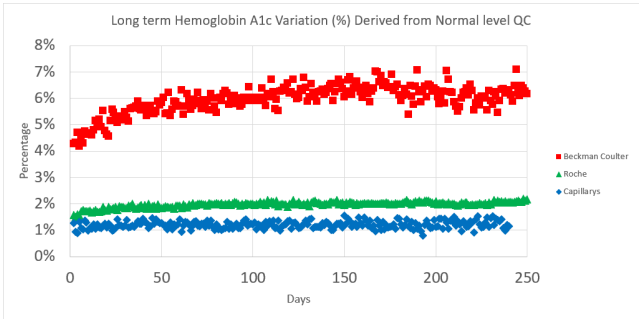
Year	Basic situation			Situation of hospitals with different beds				
	Classification (blood Culture contamination rate) (%)	Laboratories Number	Percentage (%)	Classification (number of beds)	mean	P25	P50	P75
2015	0-0.25	1481	48.32	0-500	2.52	0	0	2.31
	0.25-1	350	11.42	501-1000	2.29	0	1.09	2.86
	1-1.75	347	11.32	1001-1500	2.79	0.38	1.21	2.86
	1.75-2.5	207	6.75	1501-2000	2.00	0.54	1.25	2.93
	2.5-3.25	163	5.32	>2000	1.69	0.43	1.15	2.30
	3.25-10	517	16.87					
2016	0-0.25	2163	48.21	0-500	3.25	0	0	2.50
	0.25-1	540	12.03	501-1000	2.20	0	0.95	2.57
	1-1.75	484	10.79	1001-1500	2.60	0.23	1.06	2.45
	1.75-2.5	360	8.02	1501-2000	1.80	0.34	1.08	2.08
	2.5-3.25	243	5.41	>2000	1.75	0.41	1.25	2.42
	3.25-10	697	15.53					
2017	0-0.25	2302	47.70	0-500	2.72	0	0	2.00
	0.25-1	604	12.52	501-1000	2.08	0	0.78	2.17
	1-1.75	546	11.31	1001-1500	2.28	0.26	1.00	2.11
	1.75-2.5	310	6.42	1501-2000	2.62	0.34	0.96	1.79
	2.5-3.25	236	4.89	>2000	1.37	0.24	0.94	2.12
	3.25-10	828	17.16					

B-165

Long term variation in the quality control measurements of three contemporary hemoglobin A1c assays easily demonstrates effects of biased testing: a new tool in the laboratorian's QC armamentarium

G. S. Cembrowski[1], J. Mei[2], M. S. Cembrowski[3], R. Guerin[4], E. Xu[2], T. Higgins[1], M. Cervinski[5]. *[1]University of Alberta, Edmonton, AB, Canada, [2]University of Manitoba, Winnipeg, MB, Canada, [3]Howard Hughes Medical Institute, Janelia, Ashburn, VA, [4]CSSS, Chicoutimi, QC, Canada, [5]The Geisel School of Medicine at Dartmouth, Hanover, NH*

Introduction: We determine the long term (LT) variation of quality control (QC) specimens and apply this variation to the interpretation of the analysis of patient specimens. Repeated QC measurements can be considered analogous to the repeated measurement of a single patient specimen over months or years. For hemoglobin A1c (HbA1c) interpretations, a measurement of a prior specimen is compared to a measurement of a new specimen. In our model, the variation of all possible QC pairs is calculated; QC results are grouped with subsequent QC results as long as the time interval between the two QCs is the same. The standard deviation of the differences (SDD) of the groups of QC pairs provides an average variation for each time interval. Graphs of the LT QC SDD easily illustrate the effect of reagent lot variation or closely spaced biased analytical runs. **Materials and Methods:** QC data were obtained from a Quebec laboratory for Beckman Coulter Synchron DxC®immunoassay and the Capillarys 2 Flex Piercing® (C2FP), and from a New Hampshire hospital, the Roche Tinia Quant Gen III, Cobas 8000, c502. and Cobas 6000, c501. We generated graphs of the LT QC SDD variation for the three methods for the available QC levels. **Results:** The Figure compares the LT QC SDD of the three assay's normal level A1c analysis. The traditional QC chart of the Beckman data (not shown) demonstrates sporadic intermediate term biases. **Discussion:** The LT graphs demonstrate the superiority of the Roche and Capillarys assays (we maintain that HbA1c imprecision should not exceed 3%). With reference to the Beckman assay, even QC results separated by 10 to 20 days begin to demonstrate high variation compared to prior results. We recommend that suppliers of quality control product begin to provide such long term variation analyses for all of their analytes.

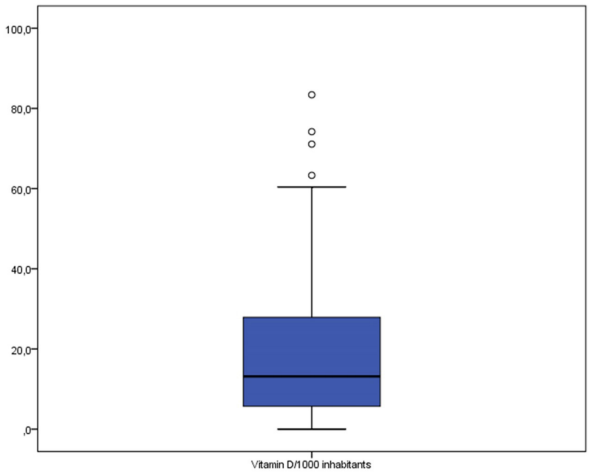


B-166

Vitamin D request in Primary Care. Is it Really Pandemic?

M. Salinas[1], C. Hernando de Larramendi[2], M. Lopez-Garrigos[1], E. Flores[1], C. Leiva-Salinas[3]. *[1]Hospital Universitario San Juan, San Juan, Spain, [2]Fundación Ignacio Larramendi, Madrid, Spain, [3]University of Missouri Health, Columbia, MO*

Background: The request of 25[OH]D by general practitioners (GPs) in Spain doubled in a recent period of two years. Such over-screening might result in unnecessary prescriptions of supplemental vitamin D. Our goal was to study the current request of 25[OH]D in Primary Care to evaluate its evolution over-time, and a potential over-request correction. **Methods:** Clinical laboratories from the Redconlab working group were invited to report the number of 25-hydroxyvitamin D (25(OH)D) tests requested by GPs during the year 2016 and number of individuals covered by their health departmentes. The number of 25(OH)D requested per 1000 inhabitants and the index of variability (90th percentile/10th percentile) were calculated. Economic cost taking into account prices reported by the participants were also calculated **Results:** Seventy-seven laboratories participated corresponding to 19222006 inhabitants (41.3% of the Spanish population). The number of 25(OH)D requested was 426406, that corresponded to an expense of 2166142.5 euros. That would mean 5244897.1 euros if extrapolated to the entire Spanish population. 13.2 tests per 1000 inhabitants were requested (Figure), with a variability index of 61. **Conclusion:** 25(OH)D request was even higher than that observed in the two previous Redconlab editions, as was the variability index, suggesting increasing differences between geographical areas. The total expenses were significant for a test with such specific conditions for its request. From the laboratory, and in consensus with GPs, it is necessary to design interventions for an optimal request of a test that is not recommended for routine screening.



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Factors Affecting The Interests Of Medical Students To The Study Of Laboratory Medicine/Pathology At The University Of Calabar Medical School

l. ekpe[1], E. Ekpe[2], A. Omotoso[1]. *[1]university of calabar teaching hospital, calabar, Nigeria, [2]university of calabar, calabar, Nigeria*

Good medical practice and management of patients begins with making the right diagnosis. This leads to the right treatment of a disease entity. Laboratory medicine/pathology has to do with the study of diseases and their diagnoses. Adequate exposure of medical students to laboratory medicine will enhance their ability to become good clinicians. The interest of students to a particular subject may be influenced by different external and personal factors. This study aimed at investigating the factors affecting the interest of medical students to the study of laboratory medicine at the University of Calabar medical school. A total of 139 students involving two sets of medical students in their fourth year of study were randomly selected for this study. A 17-item questionnaire was used for data collection The study showed that gender, socio-economic class, number of hours spent on reading, good academic background, a positive attitude, and good subject perception enhanced interest in the study of laboratory medicine; while poor learning environment, low level of exposure, poor understanding of the subject had negative effects on medical students.

KEYWORDS: Medicine, Calabar, students, pathology, university, interest

B-168

Establishment and implementation of an improvement plan using lean six sigma to minimize variation in the ordered lab request

R. Rashwan. *Medical Research Institute, Alexandria, Egypt*

Background:
Laboratory total testing process (TTP) encompasses internal and external laboratory activities that require interaction between laboratory personal and other specialists. The TTP can be divided into five phases; pre pre-analytic, pre analytic, analytic, post-analytic and post post-analytic phases. Test ordering is a part of the pre pre-analytical lab phase which is high error prone. Many of the tests ordered are unnecessary where excess tests ordering represent as much as 25–40% of all tests. Owing to the scarce data worldwide concerning the application of Six Sigma in pre pre-analytical lab phase, and the fact that it was not applied on the tests ordering process before, it was noteworthy to work on.
Aim of the work:
The present study targeted the pre pre-analytical lab phase aiming at establishing and implementing an improvement plan using Lean Six Sigma methodology (DMAIC) to minimize variation in the ordered lab requests.
Method:
The Define phase of the current improvement project, started by selecting the department with the highest work load. The Hepatology department represented 18.83% of the total number of lab tests ordered at the MRI hospital. Stakeholder analysis was the first tool performed in order to better understand the identified problem. The Project Charter was the last step in the Define phase. It included the business case, the current and desired Sigma levels, and the estimated savings achieved from the current project.
The Measure phase started by making the Flow Chart of the lab request tests ordering process Brainstorming sessions were then held in order to identify the possible root causes for the problem of the variation in ordering lab requests.
Results:
The Analyze phase started by prioritizing the root causes of the problem using a prioritization matrix. Pareto chart was used to identify the vital few causes that are responsible for nearly 80% of the problem of variation in lab tests request ordering process. The identified four main causes are; the ordering of unindicated tests as (ALT/AST ordered together), lack of awareness of evidence based medicine (EBM) basics, ordering certain tests in frequency that is not complying with biological variation (BV) as (Urea and Creatinine), and awareness of BV concept. The Sigma level for ALT/AST ordering process was calculated to be 0.66 and that of Urea and Creatinine was 1.23.
The Improve phase aimed mainly at creating solutions for the root causes selected during the Analyze phase. The Sigma level of ALT/AST tests ordering process became 1.2 Sigma which represents 45% improvement. The combined ordering of ALT and AST after improvement was significantly lower when compared to ordering of ALT and AST before improvement (P = 0.035). The Sigma level of Urea and Creatinine became 2.16 Sigma which represents 43.1% improvement.
Conclusion:
- Educational sessions and conjoint meetings between physicians and laboratorians are essential for any possible improvement initiatives.
- A simple change in the lab request form could be an important source of improvement and a cost reduction tool in the pre pre-analytical lab phase.

B-169

Demand management and optimisation, using precious laboratory resources wisely

T. L. Ellison, T. Morris, M. Mutabagani, C. Ellison, S. Althawadi. *King Faisal Hospital, Riyadh, Saudi Arabia*

In 2017 we performed 19.5 million tests across the department of Pathology and Laboratory Medicine, serving the needs of a large tertiary referral hospital specialising in transplantation and oncology. With a 7% year on year increase in testing volume (average for the last 5 years, and 11.2% from 2016 to 2017) with fixed budgets, it was timely to review testing demand and to design strategies to maximise our precious resources; to ensure that we used them wisely. We have a duty to challenge and ensure that the right tests are performed on the right patients at the right time to drive optimal outcomes. Our objective was to explore the impact (financial and work volume) of time restricting tests that add no clinical value. To that end, a literature review was undertaken to explore international experience with lock-out frequencies (minimal re-test intervals). Using this guidance we engaged with clinical colleagues and agreed to pilot an approach to demand management with common tests that were high volume, high cost or perceived to be over used within our institution. We identified an initial list of common tests, over-subscribed in our institution, to lock-out that the literature supports added no clinical value. This locked-out group of tests reduced by an overall average of 6.6% versus the previous year, and saved 2.05 million Saudi Arabian Riyal (SAR) during a 6 month period. Given that we were growing at +7% year over year (preceding 5 year average), this means that the testing volume reduced by approx. 13% in real terms for all tests in this pilot study. There was a demonstrable reduction in work volume with associated cost avoidance; but more importantly this reduced the number of blood samples being collected from patients that added no clinical value. Due to the success of the pilot we continued to develop and add more tests to the lock-out list by implementing minimal re-test interval rules in the computer system to manage demand and ensure that we use our precious resources wisely.

B-170

Biological Variation of Serum Glycated Albumin in Chinese Healthy Population

Y. Zeng[1], H. Huang[2], L. Yang[1], X. Guo[1], Y. DU[1]. *[1]Medical Laboratory Technology, West China Clinical Medical College, Sichuan University, Chengdu, China, [2]West China Hospital of Sichuan University, Chengdu, China*

Background: European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working groups challenged existing biological variation (BV) and established a checklist for critical appraisal of studies of BV to establish a reliable and valid BV database. The BA data of glycated albumin (GA) was from a literature and needed to improve. This study aimed to estimate BV, individual index(II), reference change value(RCV) of GA in Chinese healthy population under the standard operating protocol.
Methods: Nineteen healthy subjects (males 9, females 10, aged between 21-35 years old) in Chengdu,a city in southwest China were enrolled in this study. Blood samples were obtained from the same phlebotomist every two weeks at the same time, for 3 months with a total of 5 times. Serum were separated and stored at -80 °C. All samples were thawed at room temperature uniformly. GA was measured in Roche Modular-P800 automatic biochemical analyzer in duplicate in the same analytical batch. The data were analyzed using CV-ANOVA test. BV, II and RCV of GA were calculated ultimately.
Results: For all subjects, males and females, the analytical variation (CV_A) of GA were 1.62%, 1.73%, 1.66%. The within-subject biological variation(CV_I) were 1.25%, 1.22%, 1.38%. The between-subject biological variation(CV_G) were 6.44%, 5.04%, 3.86%. II were 0.19, 0.24, 0.36 and RCV were 5.68%, 5.87%, 5.97%, respectively.
Conclusion: BV of GA estimated under the standard operating protocol were obviously lower than the data reported in the online database as expected (CV_I:1.25% VS. 5.2% and CV_G: 6.44% VS. 10.3%). The low II indicated the diagnostic effectiveness of population-based reference interval of GA was limited.

B-171

National Survey on Internal Quality Control Practice for Biochemistry Tests of Cerebrospinal Fluid in Clinical Laboratories in China

S. He, W. Wang, F. He, K. Zhong, S. Yuan, Z. Wang. *National Center for Clinical Laboratories, Beijing Hospital, National Center of Gerontology, Beijing, China*

Background: The biochemistry tests of cerebrospinal fluid (CSF) is important for the diagnosis of central nervous system disorders. In this survey, the internal quality control (IQC) data of clinical laboratories in China is analysed so as to have a knowledge of the current situation of impression level of measurement procedures in Chinese clinical laboratories in 2017. **Methods**:The data and clinical laboratories information including albumin(Alb), total protein(TP) , chloridion(Cl), glucose(Glu), lactic dehydrogenase(LDH), lactic acid(Lac), IgA, IgG and IgM are obtained via the external quality control (EQA) software developed by National Center for Clinical Laboratories(NCCL) in 2017. By comparing cumulative CVs with 1/3TEa or1/4TEa which is the quality standards published by NCCL for Chinese clinical laboratories and doing some mathematical calculation, we can get the proportion of laboratories meeting quality requirements. Computation is finished with the use of Microsoft office Excel 2007. **Results**:As shown in the following table, there are 85, 277, 311, 323, 134, 30, 52, 29 and 67 laboratories submit their data on the corresponding CSF biochemistry test items in 2017. Most biochemistry tests of cerebrospinal fluid carried out by clinical laboratories get a good IQC evaluation judging from the table. We can find that no matter which quality requirement is applied, 1/3TEa or 1/4TEa, the LDH always have the best IQC practice in clinical laboratories among these tests. However, the results of Alb and TP are not satisfactory with the proportion lower than 50%. What is noteworthy is that for IgA, IgG and IgM, the number of participant clinical laboratories is very small, from 29 to 52, thus, the result is unrepresentative. **Conclusion:** The bulk of biochemistry tests of CSF have a relatively good IQC practice, but for the specific items such as Alb and TP with unsatisfactory impression level, clinical laboratory should do maximum possible efforts to make suitable IQC plans to improve them.

Analytes	Number of participant laboratories	Cumulative CVs		Proportion of laboratories meeting quality requirements	
		Median of CVs (%)	IQR of CVs (%)	1/3 TEa	1/4 TEa
Alb	85	3.42	3.00	42.35%(36/85)	29.41%(25/85)
TP	277	4.04	3.85	34.66%(96/277)	20.22%(56/277)
Cl	311	1.43	0.86	58.52%(182/311)	30.55%(95/311)
Glu	323	2.00	1.37	75.23%(243/323)	59.13%(191/323)
LDH	134	2.50	1.74	86.57%(116/134)	77.61%(104/134)
IgA	30	4.79	3.51	73.33%(22/30)	60.00%(18/30)
IgG	52	4.19	2.06	82.69%(43/52)	73.08%(38/52)
IgM	29	4.80	2.23	72.41%(21/29)	68.97%(20/29)
Lac	67	2.69	2.23	80.60%(54/67)	76.12%(51/67)

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Evaluation of insulin measurements performance through external quality assessment surveys from 2015 to 2017 in China

Q. Long, T. Zhang, J. Wang, W. Zhou, J. Zeng, H. Zhao, Y. Yan, R. Ma, C. Zhang. *National Center for Clinical Laboratories, Beijing Hospital, National Center of Gerontology, Beijing Engineering Research Center of Laboratory Medicine, beijing, China*

Background: Insulin is an important anabolic hormone which is tested to assist in differentiating type 1 or type 2 diabetes and identifying insulin resistance. Due to its important role in diagnosing and monitoring diabetics, the quality assurance of insulin measurement is of great significance for clinical laboratories. **Methods:** Results from External Quality Assessment (EQA) program for insulin is carried out by the National Center for Clinical Laboratories(NCCL) in china from 2015 to 2017. Five levels of samples of which the homogeneity and stability were assessed referring to ISO 13528 were shipped to participant laboratories biannually.Data from participants were analyzed in different instrument group through robust statistics based on ISO 13528. The target value was determined by the robust median in each group. The performance criteria was target value±25% and comparability criteria was intergroup CV<8.33%(1/3 total error). intergroup CV and all-method CV were used to evaluate insulin measurement performance. **Results:** The number of laboratories increased gradually from 1091 to 1341 while pass rate maintained above 90% from 2015 to 2017. The all-method CV was higher in 2016 (A:20.49%-22.31%)than other years(A:12.58%-16.56%)in the low level samples.(Fig.1) The intergroup CV of low and high level were 13.11%-19.45%(D)and 10.67%-23.27%(E) respectively which were all above 8.33%. (Fig.1) **Conclusion:** The insulin measurement has been well-performed from 2015 to 2017, despite all-method CV of low level was higher in 2016 than other years. The results of different instrument group were not comparable which are probably caused by matrix effects. Therefore, it is essential to adopt commutable samples and improve standardization of insulin measurement for further efforts.

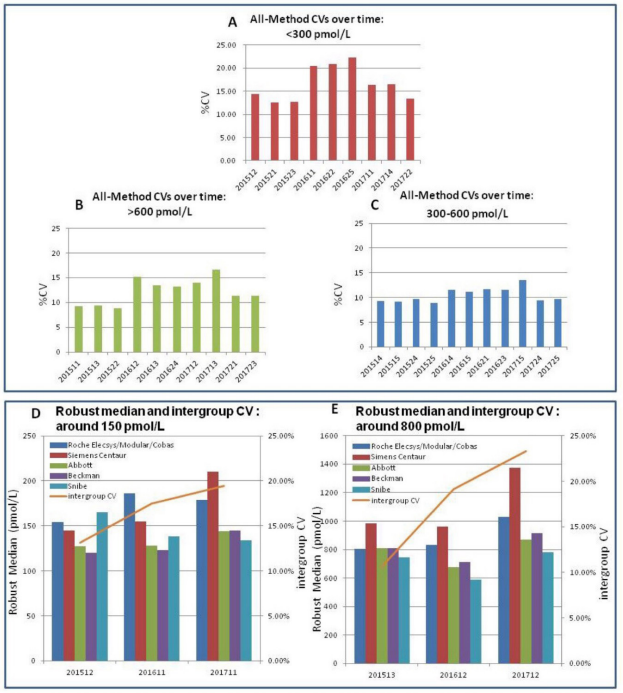

Figure 1: A,B and C show robust CV for all-method from 2015-2017 with assigned insulin values of (A)<300 pmol/L,(B)300-600 pmol/l,(C)>600 pmol/L; D and E display robust median of each group and intergroup CV from 2015-2017 with 2 level :(D) around 150 pmol/L,(E) around 800 pmol/L, the X-axis displays the material lot in each level through 3 years.

B-173

Imprecision investigation and analysis of internal quality control of five hepatic function tests in clinical laboratories of China

M. Duan, W. Wang, F. He, K. Zhong, S. Yuan, Z. Wang. *National Center for Clinical Laboratories, Beijing Hospital, National Center of Gerontology, P. R., Beijing, China*

Background: This study aimed to investigate the imprecision of the five most important analytes in diagnosing and monitoring diseases associated with hepatic dysfunction, including alanine aminotransferase (ALT), aspartate aminotransferase (AST), albumin (Alb), total bilirubin (TBIL) and direct bilirubin (DBIL). **Methods:** Internal quality control (IQC) data and related information of ALT, AST, Alb, TBIL and DBIL were collected by on-line questionnaire respectively in February, May and August of 2017. Cumulative coefficient of variations (CVs) were analyzed and the percentages of laboratories meeting the quality requirement were calculated in SPSS, which were calculated according to three levels of specifications for imprecision derived from within-subject biologic variation including the minimum, desirable and optimal specification. Chi-square ($\chi 2$) test was used to compare the pass rates among different analytes in 2017. **Results:** There are 1755, 1720, 1718, 1683 and 1583 laboratories submitting their

IQC data for ALT, AST, Alb, TBIL and DBIL, respectively. The percentages of laboratories meeting different imprecision specifications are shown in table below. For ALT, TBIL and DBIL, more than 80% participants obtained a satisfied Cumulative CVs no matter which imprecision specification applied. The acceptable rates of AST varied largely with different allowable imprecision. Alb had the best imprecision performance among all analytes, and even compared with the minimum criteria, the pass rate was only 60.7%. The percentages of laboratories whose cumulative CVs met three imprecision criteria for Alb were far less than the other four analytes (all P<0.01).

Analytes	Number of participant laboratories	Concentration of control materials		Cumulative CVs (%)		Percentages of laboratories meeting quality specification (%)		
		Median	IQC	Median	IQC	Minimum	Desirable	Optimal
ALT	1755	39.2	41.7	3.6	2.5	99.3 (1742/1755)	98.5 (1729/1755)	84.2 (1487/1755)
AST	1720	43.0	55.2	3.2	2.4	95.7 (1647/1720)	88.7 (1526/1720)	44.2 (726/1720)
Alb	1718	39.2	9.5	2.1	1.5	60.7 (1042/1718)	30.6 (525/1718)	3.4 (58/1718)
TBIL	1683	26.5	27.9	3.3	2.7	99.5 (1674/1683)	97.9 (1649/1683)	84.8 (1427/1683)
DBIL	1583	17.0	8.1	3.9	3.0	99.7 (1579/1583)	99.1 (1568/1583)	91.7 (1451/1583)

Conclusion: Although most of hepatic function tests acquired satisfactory imprecision performance and good IQC practice in 2017, only a few laboratories can pass the imprecision requirement for Alb. Therefore, clinical laboratories should pay more attention to the IQC of Alb to provide more accurate test results to patients.

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One of these things is not like the other, or is it? Why laboratory informatics should lean heavily on lessons learned in disparate industries to create novel solutions.

A. Vangeloff. *Yahara Software, Madison, OH*

BACKGROUND: (study objectives, hypothesis, or a description of the problem) Often when trying to solve a problem, we find ourselves looking in familiar places for the answer. But when it comes to data and Informatics surface similarities aren't enough. Familiar methods such as HL7 and other health informatics go-tos have drawbacks that confine data entry to certain formats and prevent access to important non-standardized data sets stored in different formats. This technological set of road blocks can keep data in silos and prevent complete and accurate reporting as well as hinder case management efforts. METHODS: (study design and appropriate statistical analysis) A novel software framework built in C# with a WPS and React front end was modified from its original purpose to track trucking data to collect and store surveillance data from around the globe. This flexible software allowed for ingestion and normalization of various data types, creating a case management system that allow disparate data to be presented in normalized formats. In addition, because it was build for the trucking industry originally, the system was designed to adapt to large amounts of data that came from different locations, at different times, in different formats. RESULTS: (specific results in summary form) The software solution was adapted from its original purpose in trucking to intake surveillance and healthcare data from disparate sources (CSV, REDCap, XML, PDF, .JPEG, .PNG, and others), extract the data for input into SQL tables, combine the data into a case management system, and display data in a unified report format. The collected reports were then used to determine the cause of death in infant mortality cases globally. CONCLUSIONS: (description of the main outcome of the study) This project demonstrates how seemingly different problems -preventing childhood mortality and tracking trucks across the US - were solved using the same technical philosophy. We offer advice on how approaching technical puzzles from a different angle can lead to successful software projects as well as discuss the expertise, time, and budget needed to implement methods such as these.

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Implementing procedure for laboratory critical values communication at the Hillel Yaffe Medical Center

M. Shapira, N. Dugma, O. Honig, S. Zeevi, E. Nadir, N. Goldschmid. *Hillel Yaffe Medical Center, HADERA, Israel*

Objective: Laboratory critical values should be communicated immediately by telephone, throughout hospital departments. Oral communication is prone to errors, and therefore the "Read Back" procedure, is necessary. An interdisciplinary task force developed and implemented a structured procedure to maintain and improve communication between laboratory and clinical staff to improve patient safety. **Methods:** The team approved the laboratory critical values and wrote a procedure that included definition of critical steps in the process, staff role, and a reviewed form for process documentation. Laboratory and risk management members were assigned as process implementers. Critical values reports were produced by the laboratory and the team conducted tracers in the departments for matching data documentation. During departmental review, an immediate feedback and staff training was conducted by the team. Data analysis was performed monthly and transferred to the department heads emphasizing weaknesses and barriers. Longitudinal learning was achieved by staff meetings and publication of adverse events regarding critical values communication. **Results:** Data analysis showed a significant improvement in adherence to the "read back" procedure during the project period. In the ED a complete documentation was only 50% at the beginning and rose to 95%. Constant monitoring was required to maintain a high performance level. There were significant differences among the departments, depending on the management involvement in the process. **Conclusion:** Transferring critical information orally is necessary to ensure patient safety. The complex process requires a correct implementation and ongoing monitoring in order to ensure its proper execution.

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Calculating the cost of poor quality: a multi-facility study

J. Dawson[1], C. Nickel[2], R. Benavides[3], C. Duclon[4], P. Eschliman[5], K. Miller[6], L. Thomas[7], A. Daley[8]. *[1]Human Longevity Clinical Laboratories, San Diego, CA, [2]Bryan Medical Center, Lincoln, NE, [3]Baylor University Medical Center, Dallas, TX, [4]Froedtert & Medical College of Wisconsin, Milwaukee, WI, [5]St. Luke's Hospital-South, Overland Park, KS, [6]Washington Regional Medical Center, Fayetteville, AR, [7]American Esoteric Laboratories, Memphis, TN, [8]Daley Consulting, LLC, Mesa, AZ*

Background: The Cost of Poor Quality (COPQ) concept was first described by Joseph Juran in 1951. COPQ can be defined as the cost of not doing something right the first time or "the costs associated with providing poor quality products or services". Although it is widely accepted that poor quality costs organizations significant amounts of money, postulated at 20% of sales for an average company, there is not much published work on COPQ in the context of the clinical laboratory. Another obstacle for application and adoption of the COPQ concept is that there is no standardized and widely accepted methodology to calculate COPQ. The COPQ concept is useful in demonstrating the financial value provided to a clinical laboratory or hospital by its quality program through cost avoidance and cost savings realized through elimination of root causes of nonconforming events. Without the intervention provided through the nonconforming event management system and quality improvement initiatives provided by the quality program, the laboratory and/or hospital would continue to experience financial losses for these events, in addition to potential patient safety risks. This study sought to develop a standardized tool incorporating feedback from leaders from multiple facilities in different geographical locations across the United States and across a variety of types and sizes of laboratories. **Methods:** A standardized COPQ worksheet, referred to as the COPQ Calculator, was developed and tested by seven leaders from multiple facilities across the US. Feedback was incorporated and the resulting COPQ Calculator was then deployed at the same seven facilities for a study on seven types of nonconforming events commonly encountered in the clinical laboratory: Specimen Mislabels, Instrument Downtime, Test Reruns, Proficiency Testing Failures, Corrected Reports, Product Recalls, and Turnaround Time Delays. The group met August 16th, 2017 in Indianapolis, Indiana for a full day to discuss use of the COPQ calculator and to calibrate their COPQ calculations. **Results:** All contributors to this study successfully utilized the tool to collect COPQ data for the seven types of nonconformities for the duration of the study. Data was collected from 6/27/2017 to 2/21/2018 and included COPQ calculations for 160 nonconforming events. Microsoft Excel was utilized to analyze the data. This poster presents COPQ ranges for each type of

event, as well as the median and average COPQ figures for each event type. **Conclusion:** This study succeeded in providing a free widely available, interactive tool for laboratory professionals to calculate COPQ as well as to provide COPQ figures for common event types that laboratory professionals can reference when articulating COPQ in their facilities. Understanding, articulation and examples of the COPQ concept in the clinical lab will help laboratories to gain financial investment and executive buy in for their quality programs. The COPQ data from the 160 nonconformities captured will be published and available for laboratorians to reference in order to articulate the financial implications of nonconformities, demonstrate cost avoidance and/or cost savings through quality initiatives and to aid in securing additional investment in quality for their laboratories.

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Internal Quality Control Analysis for Urinary Total Protein and Urinary Microalbumin from 2014 to 2017 in China

Y. Huang, W. Wang, F. He, K. Zhong, S. Yuan, Y. Du, Z. Wang. *National Center for Clinical Laboratories,Beijing Hospital, National Center of Gerontology, Beijing, China*

Background: Quantitative analyzing of twenty four-hour urinary protein has an impact on diagnosis of renal diseases, while urinary microalbumin (mALB) is the preferred analyte for the early diagnosis and monitoring of diabetic nephropathy. This study investigated the internal quality control (IQC) practice of these two analytes from 2014 to 2017, to have a general picture of variation tendency. **Methods:** IQC programs for these two analytes were organized by NCCL in China, in April for each year. Information including cumulative coefficient of variation (Cumulative CVs) were collected via an on-line questionnaire. For urinary total protein, the percentages of laboratories meeting quality requirement were calculated according to three kinds of allowable imprecision specifications based on biological variation including the minimum, desirable and optimal performance specification. Since there is no biological variation data of urinary microalbumin, 1/3 allowable total error (TEa) and 1/4TEa defined by NCCL from 2014 to 2017, were taken as quality requirement. Chi-square ($\chi 2$) test was used to compare the pass rates among different years. All data were calculated by SPSS 20.0. **Results:** There were 147/110, 174/137,205/166 and 243/201 laboratories submitted their results of urinary total protein and urinary microalbumin, respectively. Only 146/108 laboratories continuously submitted of these two analyte. The percentage of laboratories meeting different quality specifications were shown in table. Although there was no statistical significance of each accepting rate from 2014 to 2017, the percentage of laboratories satisfying each specification were increased year by year, roughly. By 2017, over 90% of laboratories had cumulative CVs meet optimum performance specification of urinary total protein, while more than 80% of labs satisfied 1/4TEa. **Conclusion:** In general, IQC practice of urinary total protein and urinary microalbumin was satisfied. Even so, more efforts should be taken to continuously improve the IQC practice of urinary total protein and urinary microalbumin.

Analyte	Statistics		2014	2015	2016	2017	P value
Urinary total protein	Cumulative CVs	Median (%)	4.57	4.45	4.50	4.33	—
		IQR (%)	3.84	2.99	2.50	3.27	—
	Allowable imprecision specifications based on biological variation	Optimum performance (%)	78.08	89.73	90.41	91.78	0.940
		Desirable Performance (%)	86.99	97.95	97.95	100.00	0.785
		Minimum Performance (%)	89.04	99.32	98.63	100.00	0.847
Urinary micro-albumin	Cumulative CVs	Median (%)	5.09	4.99	4.19	4.95	—
		IQR (%)	2.88	4.07	4.24	3.33	—
	Quality requirement	1/3TEa(%)	81.48	91.67	91.67	92.59	0.924
		1/4TEa(%)	69.44	77.78	83.33	80.56	0.940

B-178

Improving efficiency in ionic calcium measurements in the an emergency public clinical laboratory using good practices in the equipment management

M. E. Mendes, F. G. C. Campos, R. C. D. Novais, L. M. O. Lavorato, N. M. Sumita. *Central Laboratory Division of Hospital das Clinicas da Faculdade de Medicina da Universidade de Sao Paulo, Sao Paulo, Brazil*

Background: The challenge of any large clinical laboratory is to keep the facilities and equipment available, with maximum reliability, within the best possible operating condition and using in maintenance management, which will enable the performance in the processes efficiency to support strategic decisions. This study aims to evaluate the impact of the equipment management (GE) on the efficiency of the ionic calcium measurement of a public, hospital and tertiary emergency laboratory, through the turnaround time (TAT). **Methods:** The study was performed between March / 2016 and April / 2017 in the emergency laboratory of a tertiary public hospital. For the measurements of serum ionic calcium was used the methodology Selective Electrode Ion (ICA-1) in ABL 800 Flex analyzer (Radiometer - Copenhagen). GE was structured using tools such as planning, FMEA, the PDCA cycle, the concepts of total productive maintenance, kaizen, 8S program, training and qualification of operators, employees as sector multipliers, computerized equipment management software, well detailed documentary, safe operation and set of performance indicators per equipment. The following indicators were studied and comparing with TAT: mean time between failures (MTBF), mean time to repair (MTTR), number of preventive and corrective maintenances, and percentage of availability. The Minitab v.15.0 software was used in the statistical analysis. This included: mean, standard deviation, median, normality test, trend analysis, Pearson correlation analysis. **Results:** The risks were assessed through the FMEA and action plans were implemented. The correct execution of the planning and the application of the mentioned tools allowed improvements. The investments in education were positive, resulting in an increase in the training mean from 1 to 2hr / employee / m. The implementation of the concepts of total productive maintenance with its eight pillars generated greater commitment of the operator with the equipment. There was a correlation between training hours and TAT reduction (r = 0.92).The relationship with the technical assistance team of the supplier was consolidated and promoting a faster service with a reduction in the MTTR of 75% (from 6 to 1,5 hr). The mean time between failures (from 32 days to 180 days) and the percentage of availability increased (from to 92% to 99.9%), a smaller number of stops of unscheduled equipment (n=2). The trends analysis confirmed this data. The number of complaints from the medical staff for delays in the delivery of reports decreased (from 33 to 1/ month).**Conclusion:** This approach adopted allowed increasing the efficiency in the serum ionic calcium dosages, reducing the non-scheduled stops and providing greater availability of the analyzer. It has contributed to increase the useful life of the equipment, bringing flexibility to production, knowledge of the machines by the operators, enabling innovation and cultural change.

B-179

Harmonization of the chemistry area in a network of clinical laboratories through the sigma metric and the comparison with percentiles

A. Porras[1], A. Montenegro[2], M. Leon[3], K. Solorzano[3], K. Solorzano[3], J. Vargas[3], J. Vargas[3]. *[1]Quik, BOGOTA, Colombia, [2]QUIK, BOGOTA, Colombia, [3]Colsanitas, BOGOTA, Colombia*

Background
Achieving the harmonization and standardization of results in clinical laboratories is one of the challenges of laboratory medicine. Many organizations in the world have been created to pursue this goal. The Colsanitas Clinical Laboratories process an average of 873,141 tests per month, among 60 laboratories with 6 in emergency services, 12 for outpatient care, and one Referred laboratory center.
Objective
This work shows the harmonization result for 36 analytes of Blood Chemistry in a network of 15 laboratories with 21 measurement systems, during 2017.
Method
Pursuing harmonizable results, has been used several analytical quality assurance tools such: Definition of analytical performance limits as TEa, from different sources (BV, RilliBak and state of the art per percentiles), integrated QC graphs (Levy-Jennings and TE), monthly reports of Interlaboratory comparison, analytical sigma Metric of TE, SigET, Comparison by percentiles, "Performance-Per-Percentiles-PER3", statistical control rules and validation of analytical runs with sigma metric criteria, certification processes contribut-

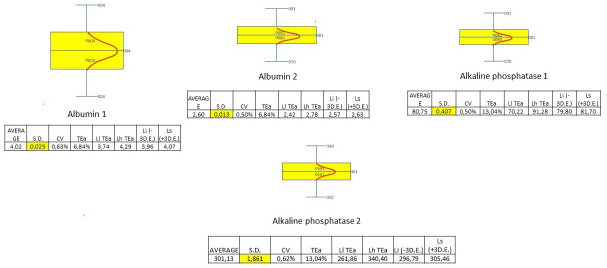
ing to improve the organizational procedures (training and continuing education)

Results

26 of the 38 analytes had a CV≤ 1%. The 96.75% had a ≥ 1.96δ, and the 63% ≥ 5δ . The 95% of the analytes were within the demanding analytical performance limits established by the laboratory network. The 49.4% of the tests were within the best performances of its peer group ($P_{10} \geq \leq P_{30}$), compared with an international network with Roche Cobas systems.

Conclusions

The use of tools as sigma metric, certification processes, contribute to the achievement of the harmonization of the results. It´s possible to keep continuously and consistently harmonized results with a high level of quality (High sigma metric) and stay consistently among the best performances in the world.



B-180

Sigma metrics for assessing the analytical quality of clinical chemistry assays: A comparison of two approaches

X. Guo[1], T. Zhang[2], X. Cheng[1]. *[1]Peking Union Medical College Hospital, Chinese Academic Medical Science and Peking Union Medical Col, Beijing, China, [2]National Center for Clinical Laboratories, Beijing Hospital, National Center of Gerontology, Beijing, China*

Introduction: Two approaches were compared for the calculation of coefficient of variation (CV) and bias, and their effect on sigma calculation, when different allowable total error (TEa) values were used to determine the optimal method for Six Sigma quality management in the clinical laboratory. **Methods:** Sigma metrics for routine clinical chemistry testing using three systems were determined in June 2017 in the laboratory of Peking Union Medical College Hospital. Imprecision (CV%) and bias (bias%) were calculated for ten routine clinical chemistry tests using a proficiency testing (PT)- or an internal quality control (IQC)-based approach. TEa from the Clinical Laboratory Improvement Amendments of 1988 and the Chinese Ministry of Health Clinical Laboratory Center Industry Standard (WS/T403-2012) were used with the formula: Sigma = (TEa − bias)/CV to calculate the Sigma metrics ($\sigma_{CLIA,}$ $\sigma_{WS/T}$) for each assay for comparative analysis. **Results:** For the PT-based approach, eight assays on the Beckman AU5800 system, seven assays on the Roche C8000 system and six assays on the Siemens Dimension system showed σ_{CLIA} > 3. For the IQC-based approach, ten, nine and seven assays showed σ_{CLIA} > 3 on Beckman AU5800, Roche C8000, and Siemens Dimension, respectively . Some differences in σ were therefore observed between the two calculation methods and the different TEa values. **Conclusion:** Both methods of calculating σ can be used for Six Sigma quality management. In practice, laboratories should evaluate Sigma multiple times when optimizing a quality control schedule. **Figure 1** Comparison of σ_{CLIA} values calculated using two methods for the same test item. Note: 201721-201725 represent the lot number of proficiency testing materials, and 45751 and 45752 represent the lot number of Bio-Rad chemistry quality control materials. The short-dashed horizontal lines indicate the 3σ level line.

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Application of Sigma-metrics for assessing the analytical performance of clinical chemistry tests

J. LEE[1], L. LAM[1], D. CHUNG[2]. *[1]Ng Teng Fong General Hospital, Singapore, Singapore, [2]Abbott Diagnostics, Singapore, Singapore*

Background:

The core laboratory in Ng Teng Fong General Hospital, Singapore uses two ARCHITECT c16000 analyzers and one ARCHITECT c8000 analyzer connected to an integrated ACCELERATOR a3600 track system (Abbott Diagnostics, Chicago, IL, USA) for its clinical chemistry testing service. There is a need to objectively and quantitatively assess our laboratory's performance on 42 routine chemistry tests so as to provide a quality benchmark for the service provided to our clinicians.

Methods:

Using quality control materials and interlaboratory comparison data, bias and imprecision were calculated. Quality specifications were extracted from published sources for Total Error Allowable (TEa) such as CLIA, CAP and the Ricos Biological Variation database. A normalized method decision chart was generated and an average Sigma-metric was calculated for each test to assess the laboratory's performance.

Results:

The bias and imprecision were generally well within 30% of TEa, across the different instruments as well as concentration levels covered by the QC material. Of the 42 tests evaluated, 33 were operating at 6 Sigma (World Class performance), 6 were operating at 5 Sigma (Excellent performance), 1 was operating at 4 Sigma (Good performance), 2 were operating at 3 Sigma (Moderate performance), and none were operating at or below 2 Sigma (Poor performance).

Conclusions:

The Sigma-metric analysis showed that our laboratory has excellent performance, with 39 out of 42 (92.9%) tests operating at 5 Sigma and above and no tests below 3 Sigma. This high level of quality means that we can be confident that our laboratory

service is providing high quality results. This also means that we can seek greater workflow efficiencies and cost savings in our laboratory with a more optimized quality control strategy in the future.

B-182

The CDC's Laboratory Medicine Best Practices Initiative (LMBPTM): Systematic Reviews for Evidence-Based Laboratory Medicine Quality Improvement

L. Williams, M. Rubinstein. *CDC, Atlanta, GA*

Objective: The CDC's Division of Laboratory Systems sponsors the Laboratory Medicine Best Practices (LMBP™) initiative, with a vision of evidence-based laboratory medicine quality improvement in support of health care and patient outcomes. The LMBP™ initiative uses a multi-stakeholder, six-step process termed the A-6 cycle.[1] This process has produced important best practice recommendations through a systematic review process that considers laboratory medicine quality improvement and quality assessment studies. Here we describe some of these achievements for increased awareness of the LMBP™ initiative. **Methods**: LMBP™ systematic reviews are done using the A-6 method developed by the CDC LMBP™ team, in collaboration with an external LMBP™ Workgroup, topic-specific expert panelists, and professional organizations (e.g. the American Society for Microbiology, and the American Association for Clinical Chemistry). Nationally important laboratory medicine quality gaps are identified, and relevant evidence is quality scored and synthesized for evidence summaries and practice recommendations. Evidence summaries include ratings on the strength of evidence as substantial, moderate, suggestive, or insufficient, and results from meta-analysis, with judgments on consistency of practice intervention effect across studies. Evidences for which the overall strength is substantial or moderate are used to develop recommendations. LMBP™ solicits topic suggestions for systematic reviews through their mailbox: LMBP@cdc.gov, and is refining a process for stakeholders to submit quality improvement/assessment data to the Initiative. **Results**: Since 2012, ten systematic reviews have been published, and 2 reviews are currently accepted for publication.[2] Six new reviews are in progress, while four reviews previously published are currently being updated with new evidence. **Conclusion**: The LMBP™ A-6 cycle is increasingly gaining success, defined as production of evidence-based findings with practical utility to laboratory professionals, completion of evaluations of recommendations in new settings, and strengthening laboratory services to achieve local quality goals with increased likelihood of improved health outcomes. To better achieve success, additional networks and stakeholder involvement are continuously sought in order to increase the relevance of LMBP topics, obtain unpublished quality improvement/assessment data, provide assistance in the process of evidence-based practice recommendation development and dissemination, and evaluate processes and outcomes of best practice implementation in various settings.

1. Christenson RH, Snyder SR, Shaw CS, et al. Laboratory medicine best practices: systematic evidence review and evaluation methods for quality improvement. Clin Chem. Jun 2011; 57(6):816-825.
2. Published systematic reviews and findings at https://wwwn.cdc.gov/labbestpractices/.

B-183

Creation of a Successful Professional Development Program for Women in a Major Medical School Pathology Department

A. Gronowski, C. D. Burnham. *Washington University, St. Louis, MO*

Introduction: According to 2015 AAMC data, the percentage of full professor faculty who are women in US medical schools is 22% and the percent full professor women within pathology departments is 26%. To improve promotion and retention of women in pathology, professional development for faculty and trainees at major medical schools is important. The percentage of women faculty at the full professor level at Washington University School of Medicine (WUSM) is below AAMC average at 19% and within Pathology is 13%. Hence, professional development for women within the Pathology Department of WUSM is particularly important. **Goals:** Our goal was to create a women's professional development program within the Department of Pathology at Washington University School of Medicine. **Methods:** The **"**Women of AP/CP", a forum for women faculty, residents, and fellows was created in November 2012. The forum meets at the University from 4:00-5:00 once per month and includes various topics, articles, books and invited speakers that cover a broad range of professional development subjects. After five years of activity, the success of the forum was assessed by surveying past attendees. A survey was created using Surveymonkey.com and sent to 65 women who had been invited to the forum over the five year period. Responses were received from 26/65 (40%) of women surveyed. **Results:** Junior faculty constituted 42% of attendees, with fellows (35%), residents (27%), mid-career (23%) and senior faculty (4%) attending in descending frequency. 100% of responders indicated that they found the content valuable to their professional development. Virtually all attendees agreed that including both faculty and trainees enhanced their experience, with only one faculty indicating they felt inclusion of trainees diminished the experience. 95% of respondents found the time of day for the program (4 to 5 pm) to be appropriate. The content topics rated as most useful were "Increased awareness of issues facing women in science" (95%), "Increased knowledge of faculty development programs and resources" (89%) and "Increased awareness of unconscious bias" (74%). A panel discussion with high profile successful women was the highest rated guest speaker event. "Career development strategies" was the highest rated topic covered. "Women Don't Ask" and "Ask for It" by Linda Babcock & Sara Laschever were tied for the highest rated books reviewed, and "Speaking out about gender imbalance in invited speakers improves diversity" (Klein R *et al*. *Nature Immunology* 2016;18:475-77) was the highest rated article covered in the forum. A session on promotion by the department chairman was rated highly. Questions such as "most valuable session" and "suggestions for future sessions" were also addressed. **Conclusion:** Here we describe the formation of a successful professional development program for women within a pathology department at a major medical school. The most valuable topics covered in this forum included unconscious bias and negotiation skills for women. This format could easily be replicated in any academic department. Knowledge of what topics women found most valuable can help direct the content and enhance successful outcomes of these types of professional development programs.

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Application of Sigma-metric Run Size Nomogram to Establish Multistage Bracketed SQC of 8 Enzymes

Y. Zeng[1], H. Huang[2], L. Yang[1], X. Guo[1], Y. Du[1]. *[1]Medical Laboratory Technology, West China Clinical Medical College, Chengdu, China, [2]Department of Laboratory Medicine, West China Hospital, Chengdu, China*

Background: Bracketed statistical quality control(SQC) was proposed in 2016 CLSI (C24-Ed4)document, for the purpose of reducing patient risks. Recently, Westgard has drawn a sigma-metric run size Nomogram, which can visually recommend quality control(QC) rules and QC frequency of different sigma test items, and came up with multistage bracketed SQC. In this study, we intended to evaluate the sigma performance of 8 enzymes and apply multistage bracketed SQC. **Methods:** (1) Sigma Performance Calculation: Calculate sigma levels using formula:*sigma=(TEa%-Bias%)/CV%,* where TEa is from the updated quality specification of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) biological variation data issued in 2017, bias is obtained through external quality assessment (EQA), and CV is the coefficient of variation of internal QC data for consecutive 6 months. (2) Multistage bracketed SQC: Estimate the daily workload of each test item in our laboratory, and design the expected reporting QC intervals. According to the sigma-metric run size Nomogram drawn by Westgard, determine "start-up" and "monitor" QC rules of ALT, AST, GGT, ALP, LDH, CK, AMY, LIP based on different sigma performance. Design SQC schedules and apply them in our laboratory. **Results:** The sigma performance of 8 enzymes were 4.33, 4.89, 4.70, 2.76, 1.83, 9.72, 6.14, 3.35, respectively. For ALT, ALP, LDH and LIP with sigma less than 4.50, MR N4 QC rules were recommended in the whole QC schedule; For AST and GGT with daily workload of 1500-2000 and sigma closed to 5, MR N4 in the "startup" stage and 1_{3S} N2 in the "monitor" process were recommended. For CK and AMY with sigma more than 6, 1_{3S} N2 were suggested in the whole QC events. **Conclusion:** Multistage bracketed SQC is mainly determined by sigma performance, setting personalized multistage QC rules and frequency, which can monitor risks in the assay process and reduce patient harms. Nevertheless, utilization of tests with low sigma is costly and the best is to improve their sigma levels in the laboratory.

B-185

Investigation and Analysis of Imprecision of Four Years' G6PD in Neonatal Screening in Clinical Laboratories in China

H. Sun, W. Wang, F. He, K. Zhong, S. Yuan, Z. Wang. *National Center for Clinical Laboratories, National Center of Gerontology, Beijing Hospital, Beijing, China*

Background: Glucose-6-phosphate dehydrogenase (G6PD) is an important constituent of neonatal genetic metabolic disease screening, G6PD deficiency is one of the major causes of neonatal hemolytic disease. The aim of this study was

to investigate and analyze the imprecision of internal quality control (IQC) of G6PD in neonatal from 2014 to 2017, in order to have an integral understanding of its imprecision level of measurement in Chinese clinical laboratories. **Method**: The laboratories' cumulative coefficient of variation (CVs) and relevant data of four years' G6PD were collected from the external quality assessment (EQA) software. Microsoft Excel 2010 and SPSS 20.0 were used to analyze the data. The one third and one fourth of allowable total error (10% and 7.5%) as well as quality specification based on biological variation including the minimal (5.5%), desirable (3.7%), optimal (1.8%) allowable imprecision were used to evaluate whether laboratories could satisfy the quality requirement and to calculate the percentages. **Results**: From 2014 to 2017, there were 69, 85, 101, 120 laboratories submitted their data, respectively. The results are shown in the table below. The majority of participant laboratories obtained satisfied CV when 1/3TEa was used (63.77% to 75.83%). About half of laboratories obtained satisfied CV when 1/4TEa was used (44.93% to 55.83%). The percentages of laboratories meeting quality requirements increased gradually from 2014 to 2017 no matter 1/3TEa or 1/4TEa was used. However, only a few laboratories could meet quality requirement when using the quality specification based on biological variation (<40%). **Conclusion**: Although the imprecision of G6PD's testing in China has been improved from 2014 to 2017, the overall level of measurement was not very good. Laboratory managers should highlight and monitor cumulative CVs of G6PD continuously. Meanwhile, it is suggested that more laboratories in China should participate in IQC program of G6PD, and make effort to improve the quality of measurement.

Item	Year	Number of participant laboratories	Cumulative CVs (%)		Percentages of laboratories meeting quality requirements (%)				
			Median	IQR	1/3TEa	1/4TEa	minimal	desirable	optimal
G6PD	2014	69	6.50	5.09	63.77	44.93	31.88	20.29	5.80
	2015	85	5.58	4.09	64.71	54.12	38.82	15.29	3.53
	2016	101	5.55	4.41	69.31	54.46	39.60	21.78	5.94
	2017	120	6.02	4.24	75.83	55.83	35.83	20.83	5.83

B-186

National survey on quality indicators related to the acceptability of samples in China

M. Duan, W. Wang, F. He, K. Zhong, S. Yuan, Z. Wang. *National Center for Clinical Laboratories, Beijing Hospital, National Center of Gerontology, P. R., Beijing, China*

Background: The quality of samples is crucial to ensure the accuracy of the test result. There are six quality indicators (QIs) related to the acceptability of samples applied in clinical laboratories of China, including incorrect sample type, incorrect sample container, incorrect fill level, anticoagulant sample clotted, haemolysed sample and unreceived sample. The aim of this survey is to investigate the status of the six QIs in clinical laboratories of China. **Methods:** A survey on 18 QIs was performed in 32 provincial clinical testing center all over China in 2017. Data of the six QIs were collected via Clinet-EQA reporting system established by National Center for Clinical Laboratories. The results were evaluated with sigma scale(σ) and percentage. **Results:** There were 7703, 7711, 7708, 7346, 7657 and 7620 laboratories summitting their data for the six QIs, respectively. The medians of the six QIs were 0.013%, 0.010%, 0.031%, 0.076%, 0.055% and 0.000%, and the medians of sigma value were 5.2, 5.2, 4.9, 4.7 ,4.8 and 6 in sequence. The detailed distribution was shown in the table below.

Evaluation index	Classification	Incorrect sample type		Incorrect sample container		Incorrect fill level		Anticoagulant sample clotted		Haemolysed sample		Unreceived sample	
		Number	Proportion (%)	Number	Proportion (%)	Number	Proportion (%)	Number	Proportion (%)	Number	Proportion (%)	Number	Proportion (%)
Percentage (%)	0-0.05	5148	66.83	5846	75.82	4566	59.24	3058	41.62	3698	48.30	7363	96.63
	0.05-0.25	1723	22.37	1472	19.09	2143	27.80	2767	37.67	2585	33.76	200	2.62
	0.25-0.45	412	5.35	229	2.97	442	5.73	705	9.60	645	8.42	30	0.39
	0.45-0.65	154	2.00	64	0.83	222	2.88	300	4.08	284	3.71	11	0.14
	0.65-0.85	84	1.09	32	0.41	90	1.17	149	2.03	147	1.92	7	0.09
	0.85-5	182	2.36	68	0.88	245	3.18	367	5.00	298	3.89	9	0.13
σ scale	0-3	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	3-4	281	3.65	109	1.41	361	4.68	546	7.43	482	6.29	17	0.22
	4-5	3053	39.63	2783	36.09	3871	50.22	4453	60.62	4486	58.59	448	5.88
	5-6	1287	16.71	1738	22.54	1237	16.05	445	6.06	1163	15.19	705	9.25
	6	3082	40.01	3081	39.96	2239	29.05	1902	25.89	1526	19.93	6450	84.65

Conclusion: The six QIs related to the acceptability of samples have played an important role in ensuring the quality of samples. Although the overall performance of the six QIs in 2017 is quite satisfactory, clinical laboratories should insist on monitoring the QIs and take more effective measures to reduce unacceptable samples.

B-187

Laboratory Assessments: Management Of Non Conformities In 'Management Requirements, Clause 4' - Single Hospital Experience.

C. V. Hingnekar, S. V. Khobrekar, A. K. D'Cruz. *Tata Memorial Hospital, Mumbai, India*

Objective: To review the nonconformities (NC) reported on the management requirements clauses of ISO 15189, its occurrence and impact on improving the quality of laboratory services. **Background:** Most of the accreditation bodies assess and provide recognition to the quality and competence of medical laboratories based on ISO 15189 standards. The laboratories take appropriate corrective measures for the closure of reported non conformities resulting in compliance towards the accreditation standards. **Methodology:** Nonconformities reported during on-site assessments by the external assessment team from 2007 to 2017 were retrieved and tabulated based on the Main and Sub clauses of Management Requirements - Clause 4. Data was analyzed according to the number and nature of NCs reported and presented in the form of Number (count) and percentage by clause and sub-clause. It was reviewed for the frequency of occurrence, type and its impact on the Quality Management System (QMS). **Results:** The highest number of NCs was reported in Document control (21.1%); QMS and Evaluation and audits (13.2%) each; Organization and management responsibilities (10.5%) and 7.9% in Resolution of complaints and Control of records each. NCs under rest of the clauses were below 5.3%. Of the total number of 38 NCs, it was observed that there were equal number of (19) Major and Minor type. **Discussion:** The accountability, coordination and execution of quality related activities across the laboratories were enhanced through defining roles of deputies and laboratory Director. The in-house external assessors' induction into the internal audit programme added value to the audits. Sample acceptance criteria and TAT defined with clinician's concurrence were among many other quality indicators that were adopted for continual improvement. The implementation of vendor evaluation system controlled the external services and supplies, providing continuous monitoring of vendor services quality. A mechanism was evolved through biomedical unit for monitoring of equipment. Safety devices such as eye wash stations were installed, staff education were addressed through regular CMEs. Version controls, review processes, identification of obsolete documents and uniformity in documents and records were achieved through structured formats and master files. The above changes undertaken to achieve compliance have impacted in enhancing the Laboratory leadership, internal audits, continuous education, safety, quality indicators, Document control and purchase procedures. **Conclusion:** It is evident from the above study that the NCs have reduced significantly over the decade. The number of NCs reported in 2008 (10) were reduced to four in 2017. This indicates that the assessments ensure quality and are a path for continuous and overall improvement of laboratory services. Ho and Ho (2012) in their study have similar observations indicating improvement through compliance with ISO 15189. Ref: Ho B, Ho E. (2012) - The most common nonconformities encountered during the assessments of medical laboratories in Hong Kong using ISO 15189 as accreditation criteria, Biochem Med (Zagreb). 2012;22(2):247-57. PMCID: PMC4062334

B-188

Identifying Barriers in the Dissemination and Adoption of Clinical Laboratory Practice Guidelines (LPGs) and Improving the LPG Lifecycle

D. E. Sterry[1], J. R. Petisce[2], P. A. Mann[3], R. J. Molinaro[4], L. A. Wyer[5], P. Allweiss[6], J. R. Astles[6], L. V. Kalman[6], I. M. Lubin[6], J. L. Reinhardt[7]. *[1]Clinical and Laboratory Standards Institute, Wayne, PA, [2]Becton Dickinson, Billerica, MA, [3]University of Texas Medical Branch, Galveston, TX, [4]Siemens Healthcare Diagnostics, Inc., Newark, DE, [5]Sentara Healthcare, Norfolk, VA, [6]Centers for Disease Control and Prevention, Atlanta, GA, [7]National Institutes of Health, Bethesda, MD*

Background: The Centers for Disease Control and Prevention (CDC) and the Clinical and Laboratory Standards Institute (CLSI) launched a study in 2013 to identify strategies to increase the dissemination and adoption of CLSI's laboratory practice guidelines (LPGs). CLSI selected two guidelines for this study, POCT12-A3, *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities*, and POCT13-A3, *Glucose Monitoring in Settings Without Laboratory Support*, because they are related to diabetes control, an important public health issue. **Methods:** A Web-based survey was distributed to gather opinions about the selected LPGs' content, adoption, and implementation. The survey was designed around Cabana's framework (Cabana, et al. *JAMA*. 1999;282(15):1458-1465) concerning why clinical practice guidelines are not always followed. The survey assessed the following barriers: lack of awareness, external barriers, lack of outcome expectancy, and guideline-related issues. The survey was distributed to approximately 15,377 potential users of POCT12 and 14,250 potential users of POCT13 contacted through relevant professional organizations, mailing lists, and the Clinical Laboratory Improvement Amendments (CLIA) database. Additionally, the project team used the National Academy of Medicine (NAM) standards for clinical practice guidelines and the AGREE II tool to evaluate CLSI's LPG lifecycle and suggest improvements for the development and delivery of CLSI's LPGs. **Results:** 879 usable survey responses were obtained; yielding a 3% response rate; thus, potential response bias must be considered. Data reported here primarily pertain to POCT12, because few respondents were familiar with POCT13. Most respondents from the typical CLSI target audience were aware of CLSI, while responses from the non-laboratory-based respondents showed a lack of awareness. Responses from both audiences demonstrated a lack of awareness of these glucose testing LPGs. Additional reasons for not using these CLSI LPGs were external barriers (lack of educational materials/tools to facilitate implementation, added expense for the laboratory, staffing burden, and purchase price), lack of outcome expectancy (no perceived improvement to the current procedure), and guideline-related issues (LPGs are not easy to use and not written at a targeted end-user reading level that facilitates staff training, and the recommendations are not practical to implement). Evaluation using the NAM guidelines and AGREE II tool resulted in 15 recommendations for improving three key areas of CLSI's LPG lifecycle: committee formation, project idea generation and approval processes, and the document systematic review and revision process. Metrics were developed for CLSI to measure the success of the recommended process improvements to be implemented during the final year of the project. **Conclusion:** CLSI can increase uptake and use of LPGs by supporting products that facilitate the implementation of LPGs, developing LPGs that are more easily understood, and enhancing communication with the intended audience of its LPGs. These actions should help to overcome some of the barriers identified by the survey responses. Additionally, CLSI should consider restructuring LPG pricing. The identified lifecycle process improvements should enhance the quality and timely delivery of LPGs.

B-189

Impact of cross-sex hormone therapy on common laboratory tests in transmen and transwomen

J. A. SoRelle, R. Jiao, E. Gao, P. Day, P. Pagels, N. Gimpel, K. Patel. *University of Texas Southwestern Medical Center, Dallas, TX*

Background: Reference intervals describe variation in healthy individuals so that pathologic values can be distinguished from normal physiologic values. For transgender individuals taking cross-sex hormone therapy, changes in physiology is expected, but the effect on laboratory tests is scarcely studied and cannot be easily predicted. Laboratory values that are out of range could initiate unnecessary diagnostic work up and alternatively, abnormal values may go unrecognized. **Objective:** This study aimed to determine alterations in common laboratory tests in a large, diverse population of transgender patients transitioning with CSHT. **Methods:** Retrospective data from a community transgender clinic and large county hospital was performed from 2007 to 2017. Lab values for complete blood count, complete metabolic panel, and lipids were recorded. We compared laboratory parameters of female to male transgender (FTM) and female transgender (MTF) patients on CSHT for > 6 months (median 21 months) to values of transgender patients assigned male (M) or female (F) at birth not taking CSHT. We excluded patients with recent illness, liver or kidney disease, non-fasting status (glucose >200 mg/dL or triglycerides >400 mg/dL), or non-compliance with CSHT. **Results:** We identified 264 unique patients (156 transwomen and 108 transmen) that met the inclusion criteria. 89 FTM and 133 MTF patients on hormone therapy were identified. Further, 87 transgender patients assigned male (M) at birth and 62 transgender patients assigned female (F) at birth not taking CSHT were identified for comparison. Transgender men: Transgender men (FTM) taking intramuscular testosterone for CSHT were found to have increased RBC, Hgb, Hct, creatinine, and ALT, while albumin and BUN decreased compared to F patients not taking hormone therapy ($p<0.005$). High-density lipoprotein values decreased significantly while triglyceride values increased on the lipid assessment ($p<0.005$). Although these patients were on hormones for various time periods, we showed that these changes were dynamic for the first 6 months, after which the values remained stable. Interestingly, a subset of patients (19%) had Hgb values $\geq$ 16.5 g/dL and/or hematocrit values $\geq$ 49% (Male reference interval: 40-54%, Female reference interval: 36-46%), values which might prompt consideration of polycythemia vera in cisgender men. Transgender women: Transgender women (MTF) taking either intramuscular or oral estradiol displayed decreased RBC, Hgb, Hct, creatinine, ALT, albumin, total protein, calcium, alkaline phosphatase, total bilirubin, and sodium, while glucose, and platelets were increased compared to M patients ($P<0.005$). Notably, no lipid parameters were significantly changed. **Conclusion:** Our results demonstrate substantial differences in several lab indices for FTM and MTF patients. These findings have important implications for interpreting lab tests. For instance, altered hematocrit or creatinine could prompt unnecessary work up for polycythemia vera and kidney injury or could prevent proper diagnosis of anemia or kidney disease. Alterations in lipid profiles in the context of testosterone can have potential implications in the assessment of cardiovascular risk. These findings underscore the need for transgender specific reference intervals for laboratory testing.

B-190

Comparison of rates of nearly simultaneous, identical central laboratory testing associated with blood gas/electrolyte/metabolite point of care testing in two adult intensive care units

J. Mei[1], E. Xu[2], M. Kattar[3], T. Curic[4], G. S. Cembrowski[3], N. Gibney[5], H. Sadrzadeh[4]. *[1]University of Manitoba, Edmonton, AB, Canada, [2]University of Manitoba, Winnipeg, MB, Canada, [3]University of Alberta, Edmonton, AB, Canada, [4]Calgary Laboratory Services, Calgary, AB, Canada, [5]Department of Medicine, University of Alberta, Edmonton, AB, Canada*

Background: The GEM 4000™ (Instrumentation Laboratory, Waltham MA.) and ABL 800 (Radiometer, Copenhagen, DE) are point-of-care analyzers, primarily used in critical care settings to measure blood gases, glucose, and electrolytes. Previous studies have shown that the GEM 4000 produces borderline low sigma tests results compared to the ABL 800. While physicians using a low sigma analyzer have recourse to retesting with point of care testing, they might simply send blood to the central laboratory. In this study, we compared the number and costs of replicate tests sent to the central laboratory within 30 minutes of running the point of care test panel. **Methods:** Laboratory databases were mined for measurements of glucose and electrolytes using either twin GEM 4000™ instruments or twin Radiometer 800 ABL blood gas analyzers at either the Foothills Hospital adult ICU in Calgary, Alberta or the General Systems adult ICU at University Hospital in Edmonton, Alberta, respectively, between 2013-2016. We counted any concurrent testing (within $\pm$ 30 minutes) performed by the central laboratory Roche Cobas 8000™ or the Beckman DXc chemistry systems in Calgary and Edmonton, respectively. In Alberta, individual electrolytes and glucoses have been costed at $5.00 per test. **Results:** Each patient with GEM 4000 testing averaged 6.1 central laboratory sodiums, compared to the average patient with ABL 800 testing who averaged 2.5 sodiums. For Na, Cl, bicarbonate and potassium, the rate of central laboratory testing for the GEM patients was roughly 2.2 to 2.4 times that of the ABL 800. The yearly total cost for repeated central laboratory Na, Cl, bicarbonate, potassium and glucose testing was $120,000 for the GEM patients and $45,500 for the ABL 800 patients. **Conclusions:** One of the hidden costs of using a low sigma analyzer may be the increased costs of redundant central laboratory testing. In addition to this extra testing which is presumably associated with the use of a low sigma analyzer, other less tangible factors should be considered when selecting an ABG analyzer including the cost of diagnostic error.

B-191

Impact of biochemistry critical values communication in outpatient outcomes

L. Macías, N. Rico, A. Merino, J. Bedini. *Core Laboratory. Biomedical Diagnosis Centre. Hospital Clínic, Barcelona, Spain*

Background: The effectiveness in the report process of critical values (CV) is considered an essential quality indicator in clinical laboratory to ensure patient's safety. In our Laboratory, there is a specific protocol for CV management, which sets up the communication pathway to properly inform these results to clinicians.The aim of this study is to evaluate the impact of communicating CV on outpatient's care. **Methods:** When a CV appears, date, time, laboratory results and person notified are recorded. Our biochemistry CV alert list is collected in the Table 1. We retrospectively evaluated the CV records and the consequent clinical actions undertaken from outpatient serum samples between January 2017 and October 2017. **Results:** A total of 100 CV corresponding to 89 outpatients were registered (Table 1). Regarding to actions triggered, patients were admitted into the Emergency Department (ED) in 41 CV events; visited in Day Hospital the same day of the phlebotomy in 16 and managed safely in their homes in three CV events. A total of 42 CV events corresponded to hypoglycemia, most of them seen in diabetic patients and only in two a medical action was registered. Therefore, in 57 from 60 CV (95%), their notification resulted in treatment initiated.

Table 1- Number of critical values, number of outpatients and number and frequency of events triggered in patient's clinical evaluation.

Test	Critical values (n)	Patients (n)	Events in which patients were visited in Day Hospital or ED n (%)
Potassium > 6,5 mmol/L	34	29	32 (94.1)
Potassium < 2,5 mmol/L	3	3	3 (100)
Glucose < 50 mg/dL	42	40	2 (4,8)
Calcium < 6,5 mg/dL	14	12	13 (92.9)
Calcium > 13 mg/dL	5	3	5 (100)
Sodium < 120 mmol/L	2	2	2 (100)
Total	100	89	57

ED, Emergency Department.

Conclusions: Although hypoglycemia was the most frequent CV event, its notification had a low impact on patients care. These results lead us to raise whether decrease the critical limit or not to notify this CV in case of diabetic patients. For the rest of CV studied, their notification resulted in treatment initiated in 95% of the outpatients affected. This data proves the relevance of informing life-threatening results for the safety of outpatients, in which ongoing health care is not provided.

B-192

Apply learning analytics to teaching clinical chemistry via an online digital learning platform

Y. Yang. *The Hong Kong Polytechnic University, Kowloon, Hong Kong*

Background: Digital learning tools are widely adopted in current academic teaching. In addition to serving as effective platform for distributing materials, initiating surveys, and gathering teaching feedbacks, a well-designed learning module can also be used to study and understand the students' learning activity, study pattern, and their associated outcomes by tracking their log-ins and accesses to the course contents on the platform. **Objective:** The study is aimed to apply learning analytics to the teaching of two undergraduate level clinical chemistry courses: a lecture-based theory course and a laboratory-based practical one. The study tracks the pattern of the students' learning activity via its online learning module Blackboard Learn™ and compares their learning behaviors between the two different knowledge delivery methods. **Method:** The two courses are taught on a weekly schedule in the 17/18 Spring semester to 52 undergraduate medical laboratory science students. The students are instructed to study the course contents through the online platform Blackboard in addition to attending lectures and laboratory sessions. The content includes lecture notes, additional reading, and self-practice clinical cases. To track the students' learning patterns, we track and record their accesses to different components of the course contents, class announcement, and student surveys. To establish their study pattern, the date and time of their log-ins and number of downloads and on-line viewings have been analyzed in both the theory and practical courses. **Results:** The data were analyzed at week 6 of the semester, and all the students (n=52) had logged onto the learning platform for both courses. The average number of accumulative accesses to the course content for each student is 25 times for the laboratory course and 20 times for the lecture component. There are varying degrees of content access among the student group, with the highest over 80 times for some students, whereas the lowest less than 10. The standard deviations (SD) for the access clicks are 13 and 14 for the laboratory and lecture course respectively. When analyzed against the date and time, the content viewing from the students frequently peaks (60-70 accesses/day for the laboratory course, 40-70/day for the theory course) the day before the relevant lecture or the laboratory session takes place, even though the course content is normally made available 7 days prior to the session. Similarly, the number of log-ons also increases significantly before the submission deadline of each coursework assignment. The content access can be attributed to each participating student to establish an individualized study pattern. As the overall access for the practical course is higher than the tutorial theory course, the same study behaviors apply to most of the students too. There is a strong positive correlation (r^2=0.68, k=0.84) between the numbers of overall access times for the laboratory course and the theory course. **Conclusion:** The learning pattern of students can be reflected by their accesses to the online learning platform. Its correlation with teaching outcomes (grades and teaching evaluations) can be further explored to improve knowledge delivery and engage students participation.

B-193

Anchoring Method Performance Evaluations with the Sigma Calculation De-emphasizes the Question: Is the Assay Fit for Purpose?: How much better are 10 sigma than 5 sigma (or 5 versus 2) assays?

A. Budhai[1], W. Skoropadyk[2], M. Cervinski[3], I. Surtina-Azarov[4], H. Sadrzadeh[5], G. S. Cembrowski[6]. *[1]Department of Pathology, New York Medical College, Valhalla, NY, [2]Interior Health, Kelowna, BC, Canada, [3]The Geisel School of Medicine at Dartmouth, Hanover, NH, [4]Northern Alberta Institute of Technology, Edmonton, AB, Canada, [5]Calgary Laboratory Services, Calgary, AB, Canada, [6]University of Alberta, Edmonton, AB, Canada*

Introduction: In a recent paper, we compared the sigmas of two point of care blood gas/electrolyte analyzers. While one analyzer's sigmas were significantly lower, we were hard pressed to coherently express, based on sigma, one analyzer's analytical advantages over the other. This poster presents our investigations in exploring the putative advantages of a higher sigma. **Materials and Methods:** We used estimates of the biologic variation (BV) and analytical variation (AV) of the two analyzers (Table) to determined sigma. As clinicians primarily classify normal and abnormal based on institutional reference intervals, for both analyzers, we simulated, charted and compared serial patient data that were close to the upper and lower reference limits. We identified problematic analytes using Cotlove's and Harris'criteria: those analytes whose AV contributes more than 12% to the overall patient variation. **Results:** The Table shows the AV contribution to the total patient variation. With the exception of iCa, the simulated serial patient data generated for both analyzers are very similar when evaluated with typical reference limits. **Discussion:** The concentrations provided by the two analyzers are very similar from the view of a clinician. With the exception of iCa, nearly identical clinician diagnoses and therapeutic decisions would arise from either system. For iCa, the AV in the low sigma analyzer doubles the patient variation and obscures or even invalidates iCa interpretation. We propose that tests with a sigma value as low as 2 can be used for point-of-care, as they meet the 12% cutoff, and can be readily rerun if their values are unexpected. Tests with sigma as low as 2 produce acceptable results, and beyond the value of 5, sigma does little to denote quality in this setting. Clinicians using tests with sigma under 2 should be made aware of this AV issue.

Test	Patient BV	Inst1 AV	Inst2 AV	Inst1 Sigma	Inst2 Sigma	Inst1, AVcontrib	Inst2, AVcontrib
pH	0.02	0.001	0.010	20.0	2.0	0.1%	11.8%
K, mmol/L	0.2	0.02	0.04	10.0	5.0	0.5%	2.0%
pO2, mmHg	15.0	1.5	5.0	10.0	3.0	0.5%	5.4%
pCO2, mmHg	2.0	0.35	1.3	5.7	1.5	1.5%	19.3%
Glucose, mmol/L	0.5	0.1	0.4	5.0	1.3	2.0%	28.1%
HCO3, mmol/L	0.8	0.2	0.6	4.0	1.3	3.1%	25.0%
iCa, mmol/L	0.015	0.004	0.030	3.8	0.5	3.5%	123.6%
Cl, mmol/L	1.0	0.4	0.5	2.5	2.0	7.7%	11.8%
Na, mmol/L	0.5	0.5	0.8	1.0	0.7	41.4%	80.3%

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Four years microbiological laboratory activity summary of high volume Central Laboratory of Turkey

S. Aksaray[1], S. Daldaban Dincer[2], U. Oral Zeytinli[2]. *[1]Haydarpaşa Numune Hospital, İstanbul, Turkey, [2]Association of Public Hospitals Northern Anatolian Region of Istanbul, İstanbul, Turkey*

Background: Cost reduction is the primary driving force of the healthcare reform; to survive, laboratories must adapt. The other benefits targeted are to use the recent technologies to decrease turnaround times, standardize the interpretation and reporting for cultures while reducing the staff needs. Therefore a Central Laboratory was designed for maintaining high quality services and cost effectiveness of consolidating separate Clinical Microbiology Laboratories in 11 hospitals (totally 3614 beds capacity) in Istanbul in 2014. This Central Laboratory has been serving to 13 hospitals (4972 beds capacity) since 2017. Nowadays approximately 430.000 samples are accepted and 2.400.000 tests are run per month in the Central Laboratory. In this study, we evaluated the laboratory based reflection of increasing work volume within three years on a test basis.**Methods:** The Central Laboratory test numbers (urine culture, antibiotic susceptibility tests, ELISA, serologic and PCR tests) between 2014 to 2017, were retrospectively evaluated from the received data with Automated Laboratory Information System (Ventura,Turkey) and statistically analysed.**Results:**Between the years 2014 to 2017, the total numbers of hospital bed capacity Central Laboratory served, has increased 37%. There are no changes in the number and the capacity of the devices. The number of; manual serologic testing has increased 33%, antibiotic susceptibility test has increased 32%, PCR has increased 30%, urine culture has increased 27% and the number of patients to be studied has increased 17%. The number of laboratory technician in the Central Laboratory decreased 12% and the number of Laboratory specialist increased 30% within the same time period. **Conclusion:** Despite the increased number of patients, and the decreased number of laboratory staff over the years, thanks to rational laboratory management in the Central Laboratory, the number of devices has remained same. Despite the increase in served bed capacity, number of tests we run, has not increased proportionally. Effective laboratory usage rules and hospital automation systems; such as the prevention of panel test requests, the organization of test request pages, visual warnings to the clinicians regarding the test request frequency, and the intermittent trainings to the clinicians has helped us to achieve this successful result.

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Performance comparisons among homogeneity and two kind heterogeneity systems used in laboratories

W. Luo, J. Zhang, J. Zeng, T. Zhang, W. Zhou, H. Zhao, Y. Yan, R. Ma, C. Hu, J. Wang, W. Chen, C. Zhang. *national center for clinical laboratories, Beijing, China*

Background: Measurement systems adopting instruments, reagents and calibrators manufactured by the same manufacturers are called homogeneity systems, and those that don't meet the requirement are heterogeneity systems. Currently the ratio of homogeneity to heterogeneity systems used by laboratories across China is about 1:1. Owing to a more open market, cost-effectiveness and convenience, more laboratories may tend to choose heterogeneity systems in the future. We here compared the performance of heterogeneity systems with homogeneity systems. **Method:** Part of National category 1 serum uric acid external quality assessment(EQA) data in 2017 were extracted, in this EQA program commutable materials with target value (416.6μmol/L) assigned by reference measurement procedures were repeatedly measured by all participants. After removing outliers by 3SD, there were 75 homogeneity systems (8 Abbott, 55 Beckman,12 Siemens) and 126 heterogeneity systems classified into two categories that systems adopting reagents and calibrators from the same manufacturers were classified as group 1 and systems adopting instruments, reagents and calibrators all from different manufactures were group 2 (group 1: 8 Abbott, 20 Beckman, 31 Hitachi, 10 Siemens; group 2: 3 Abbott, 22 Beckman, 22 Hitachi, 10 Siemens). Bias and inter-lab CVs were compared with biological variation data (bias<4.87%, CV<4.30%) as criteria for evaluation. **Result:** As shown in Fig1, for all 4 mainly used instruments, all homogeneity systems showed desirable bias within biological variation criteria and better inter-lab CVs compared with heterogeneity systems, but both homogeneity and heterogeneity systems were within CLIA88 requirement (17% bias). All systems showed inter-lab CVs within biological variation criteria, meanwhile, group 1 heterogeneity systems showed slightly better inter-lab CVs and better bias except Hitachi than Group 2. **Conclusion:** Homogeneity systems showed better performance than heterogeneity systems, and group 1 heterogeneity systems showed no obvious better performance than group 2.

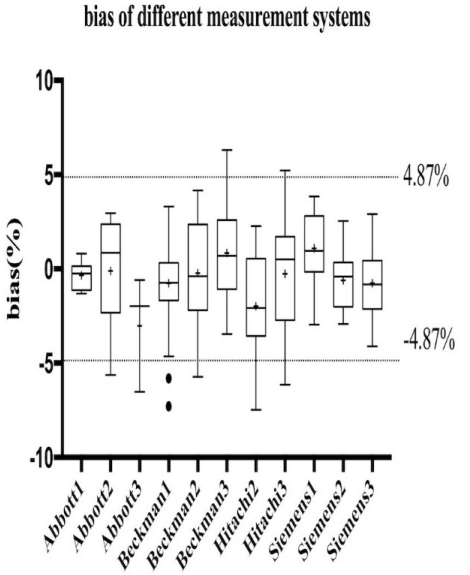

Fig1. code 1,2,3 separately represent homogeneity systems, group 1 heterogeneity systems and group 2 heterogeneity systems.

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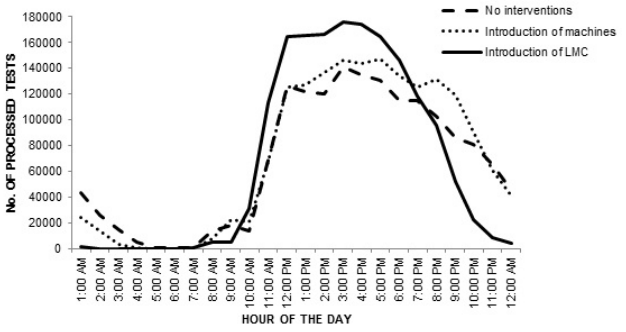
Toward clinical laboratory productivity gains: machines or lean manufacturing?

K. S. Oliveira, J. R. S. Oliveira, I. B. W. Escalante, L. A. Silva, R. H. Jácomo, L. F. A. Nery, G. R. Martins. *Laboratório Sabin, Brasília, Brazil*

Background: Here, we evaluate the impacts of additional machines introduction and the lean manufacturing concepts (LMC) application into a pulled biochemistry and immunohormones production line of a large clinical laboratory located in Brazil's center-west. **Methods:** The analyzed laboratory sector consisted of integrated biochemical/immunologic unit composed of 10 ADVIA Centaur XP®, 04 ADVIA Chemistry 2400® and 04 IMMULITE 2000® coupled into the 70 meters Siemens Aptio®, approximately. The studied period was from January to June 2017 and was divided into three identical time frames: January and February (no interventions), March and April (introduction of machines), and May and June (introduction of LMC). On March, 2 ADVIA Centaur XP® and 2 IMMULITE 2000® were introduced. In May, LMC was introduced. LMC included in loco process flow mapping, time-motion study, and production capacity analysis. Measured variables were: the maximum tests processed per hour and turnaround time (TAT), related to productivity, and employee overtime, blood redraws, report corrections, related to defects. Calculations considered the variable average normalized by the number of blood tests performed on each analyzed period. **Results:** Compared to the no interventions period, the introduction of machines reduced: the TAT in 5%; the blood redraw in 16%; and the employee overtime in 22%. On the other hand, the maximum tests processed per hour increased in 1% and report correction in 25%. Compared to the introduction of machines period, the introduction of LMC reduced: the TAT in 25%; the employee overtime in 33%; the blood redraws in 17%; and report correction in 74%. In addition, the maximum tests processed per hour increased in 21%.



Conclusions: Increasing the number of machines brought more considerable gains to the variables related to the defects, but not productivity. Conversely, the LMC brought significant benefits to both productivity and defects variables (which are the crucial points of the Lean Manufacturing philosophy).

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Utilization of Laboratory Testing Algorithm for Celiac Disease in a Pediatric Hospital

M. Ali[1], D. J. Danner[2], F. Douglas[1], S. Devaraj[3]. *[1]Department of Pathology & Immunology, Baylor College of Medicine, Division of Clinical Chemistry, Texas Children's Hospital, Houston, TX, [2]Department of Pathology & Immunology, Baylor College of Medicine, Houston, TX, [3]Department of Pathology & Immunology, Baylor College of Medicine, Division of Clinical Chemistry,Texas Children's Hospital, Houston, TX*

Background-Increasing prevalence of celiac disease (CD), primarily in the pediatric population, results in lifelong treatment and complications in a growing number of individuals. At Texas Children's, during our annual review of our send out tests, we found numerous celiac tests were ordered from a wide range of non-specialty health care providers. The Celiac Disease Foundation and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) implemented guidelines for assisting health care professionals by using a screening approach and standardizing clinical practice. Biopsy remains the gold standard for diagnosis of celiac disease but is associated with high cost, turn-around time, and risk. Herein, our main goal was to improve celiac disease test utilization, so we implemented an in-house celiac disease screening cascade and reflexed it to a comprehensive celiac testing panel if an abnormal screen result was obtained. **Methods-** We carefully analyzed all orders for comprehensive celiac testing (which includes genotyping) from July 2016 to September 2017 in the central laboratory at Texas Children's Hospital. We also examined the proportion of ordering providers that were gastroenterologist versus non- gastroenterologist health care providers. We initiated a screening cascade for celiac disease screening. Then, we conducted pathology review of all comprehensive celiac testing orders and made a recommendation based on patient's history to either send to comprehensive celiac testing or to change the standing order as an add-on to the in-house celiac screen. After the appropriate test was ordered, results were re-evaluated. **Results-**The total volume of celiac test orders for approximately 14 months period is 60 orders (n=60). The ordering physicians were gastroenterologist in 4 of the cases and a non-gastroenterologist in 56 cases. Out of 60 cases, there were only 3 of 60 cases that were approved for send out for comprehensive celiac testing, and 52 of 60 cases were altered to celiac screen from comprehensive testing. Subsequently, 5 out of 60 cases were tested further due to incorrect ordering. Only 1 of the 52 celiac screen were positive and reflexed to the comprehensive panel. Remaining 51 out of 52 resulted as negative celiac screen. Over 14 months, this strategy resulted in direct cost savings of approximately $117,550. We were also able to improve turnaround time for effective management and treatment of these patients. **Conclusion-** Our data reflects utility of celiac disease test utilization; by effectively implementing strategies to modify physicians ordering pattern and by advocating celiac reflexive cascade, we were able to improve celiac disease test utilization, reduced cost of testing and improve turnaround time for effective patient management. Test utilization strategies that are initiated with collaboration of pathologist with their clinical counterparts in every area of medicine will improve clinical management of patients effectively.

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The Use of Proficiency Testing Results for Predicting Laboratories' Future Risk for CLIA Deficiencies

X. Yin, M. Earley, R. Astles, Y. Xia. *Centers for Disease Control and Prevention, Atlanta, GA*

Background: The Clinical Laboratory Improvement Amendments of 1988 requires approximately 35,000 U.S. clinical laboratories to participate in proficiency testing (PT) for > 80 specified clinical tests. Centers for Medicare & Medicaid (CMS) necessitates that these laboratories receive biennial on-site inspections. If the inspectors identify unsuccessful PT performance, they cite the mandatory condition deficiency tag (D-tag) D2016. Condition D-tags indicate an erroneous practice requiring correction for the laboratory to continue testing. We hypothesized that PT scores may be a leading indicator to predict risk of future inspection deficiencies, because laboratories cited with D2016 would need to demonstrate improved testing quality before the next inspection compared to laboratories with one-time unsatisfactory (less than 80%) and marginal scores (80%). This study investigates the use of PT performance, including unsatisfactory and marginal scores, to identify risks of more serious quality problems. **Methods:** The analysis used PT data (three events/year) and D-tag data from Certificate of Compliance laboratories included in the CMS Quality Improvement and Evaluation System database. Data from 2007-2016 were divided into five periods of two years each. Analysis of the association between the number of condition deficiencies in the next two years and whether a laboratory received a D2016 citation utilized Chi-square tests. Analysis of variance (ANOVA) tests assessed the differences between the mean number of condition deficiencies from unsatisfactory (≤ 60%), marginal (80%), and perfect (100%) PT scoring groups. All tests were two-sided and a two-sided p-value of <0.05 or a 95% CI not containing 1.00 was considered statistically significant. **Results:** When a laboratory received a D2016, it was 11 times more likely to have fewer non-PT related condition deficiencies in the next inspection. The odds ratio decreased to 9.7 after controlling for the number of analytes that require PT. Comparisons of the mean numbers of deficiencies for unsatisfactory, marginal, and perfect PT score groups, with and without D2016, between inspection intervals were statistically significant at the p=0.05 level except for the perfect score group without a D2016. We repeated the analysis with refined score groups to separate one unsuccessful or marginal score versus two or more. The change in the means from one inspection period compared to the next for the two or more marginal score group was 0.31. For all other groups the change ranged from -0.12 to -5.73. **Conclusion:** Our results suggest that unsuccessful PT performance (D2016) may be used to predict a laboratory's future performance. Laboratories with a D2016 deficiency were at a lower risk of receiving condition deficiencies cited in the next inspection compared to laboratories without D2016. Laboratories without a D2016 citation but with two or more marginal scores in a 2-year period were more likely to have condition deficiencies cited in subsequent inspections, suggesting successful PT performance with marginal PT scores increases future risk of receiving condition D-tags. This implies marginal PT performance is an actionable leading indicator of quality problems. Further studies will include additional variables including number of PT analytes, non-PT D-tags, and PT-related D-tags.

B-199

Our New-Resident Trainee Educational Intervention Efforts Play a Significant Role in Reduction of Inappropriate Laboratory Add-on Testing Orders

N. T. B. Tran, R. Jackson, S. Chakrabarty, M. Bronze, K. E. Blick. *Un of OK Health Sci Ctr, Oklahoma City, OK*

Background: Since our hospital's Meditech system lacks a sophisticated rules-based physician order entry system, we sought to improve add-on test (AOT) order accuracy through using resident training initiatives. An AOT is an order for a test to be performed on a specimen already collected for previous testing purposes. While AOT helps reduce new specimen collections on patients and can assist in the reduction of iatrogenic anemia or infection, several issues have challenged our laboratory in handling inappropriate AOT orders from our new resident physicians. The majority of our inappropriate AOT orders include: 1) a duplicate order for a test already performed, 2) the order is added on to a wrong specimen sample type and/or collection tube/container, 3) specimen instability issues for the add-on analyte requested, and 3) the remaining quantity of specimen is not enough for the new add-on order. Methods: We performed two studies with each using AOT data extracted from our Meditech laboratory information system in a one-week period in November, 2015 and August, 2016. The 2015 study served as a baseline for the follow-up study conducted one month after an educational initiative for new medicine residents

to improve the quality of AOT ordering at the beginning of the academic year in July, 2016, including introducing our specimen collection "pocket" tube guide and specimen collection requirements. Also, an order-entry alert was added to the AOT order module when ordering a test listed on our " inappropriate AOT" test list. We examined AOT patterns including ordering physicians, total number of AOTs, number and types of performed AOTs as well as the non-performed or rejected AOTs. Chi-square was used with significant criteria of $p < 0.05$. Results: We observed significant decreases in the total numbers of ordered AOT (941 to 874, p=0.001) and the rejected AOT (161 to 116, p= 0.027). However, within the latter group, we did not observe a statistically significant reduction in the total number AOT rejections for duplicate orders (p= 0.443), wrong specimen collection tube/container (p=0.597), quantity not sufficient, and/or specimen stability AOT rejections (p = 0.999). Conclusion: It appears that our resident educational intervention could have played a significant but relatively minor role in the improvement of AOT issues in terms of 1) reducing the total number of AOT and 2) the number of problem AOT and 3) perhaps shifting add-on testing over to increased tests ordered on the original test request.... yet another desirable educational outcome. We did not however observe a statistically significant reduction in the number AOT rejections for duplicate orders, wrong specimen collection tube/container, quantity not sufficient, and/or specimen stability AOT rejections. We therefore conclude that these latter issues cannot be effectively handled without the use of a sophisticated, rules-based expert physician order entry computer system that alerts the new resident physician interactively at the time of order when an AOT is not possible.

B-200

Comparison of Proficiency Testing Performance for Analytes of a Complete Metabolic Panel: Hospital Laboratories to All Other Testing Sites

G. Mitchell, L. Nguyen, Y. Xia. *CDC, Atlanta, GA*

Background: Clinical laboratory technologies and testing methods are changing at a rapid pace. Proficiency testing (PT) is an important tool for monitoring test performance, detecting and identifying problems, and improving laboratory quality. Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), laboratories performing nonwaived testing on patient samples are required to participate in PT. The majority of PT analytes are tested by clinical laboratories at a frequency of five challenges per event and three events per year. A testing event score of at least 80% is needed for a laboratory to be considered satisfactory for each PT analyte. This means that at least 4 out of 5 results per event must be within the CLIA criteria of acceptable performance for that analyte. Failure to achieve 80% in 2 consecutive events or 2 out of 3 events results in unsuccessful performance for that PT analyte. A complete metabolic panel (CMP) measures kidney and liver functions as well as electrolyte levels, and is one of the most frequently ordered laboratory test panels. The 14 analytes measured in this panel include alanine amino transferase, albumin, alkaline phosphatase, aspartate amino transferase, bilirubin, blood urea nitrogen, carbon dioxide, chloride, creatinine, glucose, calcium, potassium, sodium, and total protein. All are CLIA-required PT analytes. Most hospital laboratories and independent laboratories (HI) were required to perform PT prior to the implementation of CLIA and were shown to have lower PT failures rates than all other testing sites (AOT) (e.g. long-term care facilities, nursing homes, ambulatory sites, mobile clinics, and physician office laboratories) during 1994-2005, based on previous Centers for Disease Control and Prevention studies. This poster presents the 2006-2016 PT performance trends of HI and AOT for analytes tested as a part of a CMP. **Methods:** Using the Centers for Medicare & Medicaid Services Quality Information Evaluation System (QIES) database, we analyzed PT scores from 2006 to 2016 and compared PT failure rates for the CMP analytes tested at HI and AOT. This equated to approximately 450,000 HI laboratory tests and 390,000 AOT laboratory tests. **Results:** Failure rates for the majority of analytes decreased steadily within the 10-year period for both HI and AOT. Notable exceptions where failure rates decreased for HI but increased for AOT within the last year of the 10-year period were observed for alanine transferase, alkaline phosphatase, bilirubin, creatinine, and glucose. **Conclusion:** The observed improvement in PT performance for both HI and AOT has important positive implications relevant to the impact of CLIA PT regulations. For both groups, failure rates within the last 10 years (2006-2016) are generally lower than the prior years (1994-2005). While contributing factors are not fully understood, it is likely that differences in laboratory staff retainment, testing methodologies (and equipment), and managerial factors (e.g. how staff is managed and supported) between HI and AOT may have contributed to the observed discrepancies in PT performance. Additionally, grading strategies of PT programs may also be a factor. PT helps clinical laboratories to ensure accurate patient test results; therefore, offering objective evidence of laboratory competence.

B-201

A Lean Project Study with Return on Investment (ROI) to Eliminate Defects Associated with False Positive Results on Urine Bilirubin Screening

M. F. Palacios, G. Clark, K. E. Blick. *Un of OK Health Sci Ctr, Oklahoma City, OK*

Background: Our medical center laboratory performs approximately 210 urine bilirubin screening tests each day as part of a urinalysis profile. Of these, approximately 50 percent have a positive urine bilirubin screening result (+1, +2, or +3) which are reported to our physicians and must be evaluated. Currently, physicians we interviewed estimate that follow-up on these results takes approximately 20 minutes (19 +/- 4.2 minutes). And of course, follow-up is required because a positive urine bilirubin result can indicate significant liver disease which, without proper treatment, can progress to severe morbidity and mortality. Defects noted in our bilirubin screening reveal that only 70 to 80 percent of +1 and +2 urine bilirubin results by our screening method actually reflect true positive results, thus making the false positive Type I alpha error rate essentially 75 percent. On the other hand, a +3 screening results has a much higher predictive value and hence a much lower false positive rate. Methods: To address this problem, we instituted a urine bilirubin confirmatory procedure involving 1) confirmation of all positive urine bilirubin screening results with a new IctoCheck method and 2) additional quantitative confirmatory testing on our Beckman Coulter DxC800 chemistry analyzer using both the diazo and enzymatic bilirubin assays. Results: Using these confirmatory tests we were able to reduce our false positive bilirubin urine screening defect rate from 75 percent to 3 percent. The total cost of the research and validation phase of the project including reagents, technologist's time, and faculty time was $1,546. The cost of providing the additional confirmatory assay was $884 per month. Conclusions: Our physician time savings was based on an average time savings of 19 minutes per case amounts to an estimated savings of $10,752 per month. The ongoing return on investment from this project based on physician time savings alone amounted to 1,216 percent. Valuable patient time is also saved and also the patient would avoid having a false positive result attached to their medical record. Moreover, this project has resulted in 1) reduction of the expense and risk of additional follow-up urine and blood testing for liver function assessment and 2) avoidance of the family and patient's concern regarding a potentially devastating disease involving the liver.

B-202

Comprehensive evaluation of the internal and external quality control to redefine analytical quality goals

B. Varela, G. Pacheco, M. E. Olivera, M. N. Zubillaga, M. H. Fornella. *SIEMBRASUR, Montevideo, Uruguay*

Background: The aim of this work is to design a selection algorithm for a Total Allowable Error (TEa) source using a graphic tool that, by integrating Internal (IQC) and External (EQC) Quality Control performances, enables the laboratory to evaluate which is the TEa source that better fits the test analytical performance. It is worth noting that in the model proposed by the laboratory, the selection of the highest-in-hierarchy TEa (according to the Milan 2014 Consensus) as possible was always a priority. **Methods:** The results of twelve surveys of the External Quality Evaluation Program EQAS® BIO-RAD from 2017 were used to evaluate the performance of twenty-tree biochemistry tests. The evaluated assays were processed in a homogenous system, Abbott manufactured analytical platform Architect ci8200 and reagent. Two analytical performance indicators (sigma metric and bias) were estimated for each test during the same period of time, the year 2017. Sigma metric was calculated through the results obtained in the IQC and the Bias was estimated based on the EQC program. The sigma metric was charted as a function of the bias expressed as the percentage of the TEa [Bias (%TEa)]. Following the proposed algorithm (considering the hierarchy in the Milan 2014 Consensus) the TEa was evaluated depending on 2 areas. One area in the chart was defined as the objective area ($5.15 < \text{Sigma} < 12$ and $\text{Bias } (\%TEa)_{2017} < 50$ or $\text{Sigma} > 12$ and $25 < \text{Bias } (\%TEa)_{2017} < 50$) in which the used TEa is the appropriate one for the analytical performance of the test under evaluation. For any test located outside said area (second area), a performance reevaluation was required using another source of TEa. **Results:** In 19 of the evaluated tests, their analytical performance allowed for the selection of biologic variability as TEa source. In the 4 remaining cases (Calcium, Magnesium, Total Protein and Sodium), State of the Art was selected. **Conclusion:** Jointly, the chart and the selection algorithm for TEa source, enabled the laboratory to standardize the selection procedure of the most appropriate TEa for the test analytical performance.

B-203

Overview of Laboratory Sanctions from 1996 to 2016

l. fan, y. xia, j. zhong. *CDC, ATLANTA, GA*

Background: Every year the Centers for Medicare & Medicaid Services (CMS) publishes a list of laboratories that were found to have not been compliant with Clinical Laboratory Improvement Amendments of 1988 (CLIA). Objectives: To summarize and characterize the laboratories sanctioned by CMS or accrediting organizations from 1996 to 2016. Methods: Using the Sanctioned Laboratory Registry data, we compiled the laboratories recorded each year, summarized the types of sanctions and reasons, and linked the registry data with CLIA laboratory demographics to characterize the sanctioned laboratories. Results: Between 1996 and 2016, 3406 sanctions were recorded in the registry, representing 2924 individual laboratories and 100-250 sanctioned laboratories each year (Figure 1). The most common sanctions are certification revoke/suspense/limitation (1447, 35%), alternative sanctions (i.e., civil money penalty, 1328, 32%), and accreditation revoke/denial/withdrawn (1159, 28.3%). The most frequently cited reasons are proficiency testing failures (1589, 47%), out of compliance (861, 25%), deficiencies (491, 14%), failure to submit plans of corrections (316, 9%), and improper proficiency testing referral activity (232, 7%). The most common facility types of the sanctioned laboratories are physician office laboratories (1503, 51%), hospital laboratories (646, 22%) and independent laboratories (566, 19%). At the time of sanctions, most laboratories had a Certification of Accreditation (CoA, 1187, 44%) or a Certificate of Compliance (CoC, 1189, 44%), since only CoA and CoC laboratories are routinely surveyed. Among the 2924 sanctioned laboratories, 1495 or 51% had been deactivated by the end of year 2016, most of which (1107, 74%) were deactivated within 2 years of being sanctioned. Conclusions: As the most regulated aspect of laboratory practice, proficiency testing related issues are the most often cited reasons for sanctions. Deactivation appears to be the most common consequence of sanctions. Laboratory professionals, including laboratory directors, could use the lessons learned from the sanctions to improve practices, especially those related to testing quality.

B-204

Improving Intra-operative Parathyroid Hormone Analysis Turnaround Time

H. K. Lee, R. C. Benirschke, M. Belanger, K. Kaul. *NorthShore University HealthSystem, Evanston, IL*

Background: During parathyroidectomy, intra-operative parathyroid hormone (PTH) concentrations are used to guide surgeons in determining the extent of parathyroid excision. Delays in PTH analysis will lead to prolonged surgical time, increased cost, and increased risk of infection for patients. In February 2016, our institution implemented total lab automation in our core laboratory, including biochemistry analyzers. With this change, PTH analysis was moved from a point-of-care instrument in the operating room (OR) to the hospital's core laboratory. Turnaround times post change were unsatisfactory for surgical needs so an interdepartmental quality improvement project was initiated. **Objectives:** To shorten the transport time of each specimen from the OR to the laboratory to 10 minutes or less and shorten PTH analytical time to 20 minutes or less. **Methods:** The process for collecting, transporting, and analyzing an intra-operative PTH specimen was mapped in detail. Results showed that the most significant delays were in the delivery of the specimens to the laboratory and in longer than anticipated analytical time on the biochemistry automation. The root cause for the delay in transport time was attributed to the speed and unpredictability of the pneumatic tube system. In response, specimens were routed to the dumbwaiter currently used for surgical pathology specimens requiring frozen sections, which directly connects the OR to the laboratory for analysis. Delays in the PTH analytical time was attributed to the continuous stream of specimens entering the analyzer from the automation line, thereby interfering with the speed of analyzing the PTH specimens. This backup was remedied by requiring the OR nurse to notify the laboratory before a surgery started so that one of the automation lines could be stopped temporarily, allowing direct loading of the sample into the analyzer. **Results:** Median transport time of PTH specimens decreased from 12 mins to 6 mins by sending specimens through the frozen section dumbwaiter. Median analytical time decreased from 22 mins to 18 mins by stopping the automation line temporarily and manually loading the specimens.**Conclusion:** The median transport and analytical time of intra-operative PTH specimens was reduced from 34 mins to 24 mins (29%) by optimizing the workflow, resulting in better operative throughput and shorter surgery time.

B-205

Risk Analysis and Assessment Based on Sigma-metrics and Intended Use

Y. XIA, L. Ji. *Peking University Shenzhen Hospital, Shenzhen, China*

Background: To minimize the risk of harm to patients in the analytical process, a risk analysis and assessment model based on sigma-metrics and intended use was constructed, based on which differential Sigma performance expectations of 42 analytes were developed. **Methods:** Failure mode and effects analysis (FMEA) was applied to produce an analytic risk rating based on three factors, each test of which was graded as follows: 1) sigma-metrics; 2) the severity of harm; 3) intended use. By multiplying the score of sigma-metrics by the score of severity of harm by the score of intended use, each was assigned a typical risk priority number (RPN), with RPN≤25 rated as low risk. Low risk was defined as acceptable standards, the Sigma performance expectations were calculated in reverse. **Results:** Among the 42 analytes, tests with $\sigma \geq 6$, $5 \leq \sigma < 6$, $4 \leq \sigma < 5$, $3 \leq \sigma < 4$, $\sigma < 3$ were 21, 5, 5, 6, and 5, respectively; there were 7 high-risk tests, 8 of them medium risk tests. According to the risk assessment conclusion, 13 tests had Sigma performance expectations≥6; 15 test items had Sigma performance expectations≥5, while 3 test items had Sigma performance expectations≥4; 11 test items had Sigma performance expectations≥3. **Conclusion:** Using sigma-metrics and accounting for the intended use of test will help clinical laboratories design a comprehensive risk assessment system to identify the high-risk tests. The differential Sigma performance expectations can be also established by the RPN to satisfy the low risk to the patients and avoid repeated risk assessment.

The Risk Score of three novel factors			
Risk Score	Sigma-metrics	Severity	Intended uses
5	σ<3	Catastrophic	Diagnosis
4	3≤σ<4	Critical	Screening
3	4≤σ<5	Serious	Management
2	5≤σ<6	Minor	-
1	σ ≥6	Negligible	-

B-206

Evaluation of Positive Frequency as a Quality Indicator for Assay Performance

K. Galior, K. Ness, L. Regner, A. Algeciras-Schimnich, J. Bornhorst. *Mayo Clinic, Rochester, MN*

Background: Quality assurance and quality control procedures in the clinical laboratory ensure that the patients' results are reported with sufficient accuracy and reproducibility for clinical use. Quality control (QC) material is used to detect random assay error and systemic assay bias as well as long term shifts and trends. However, QC material may be susceptible to matrix effects which may cause it to behave differently from patient specimens. For some clinical tests, the frequency of distribution of patient results provides a potentially useful quality assurance indicator. In theory, the percent of patient results with values above the reference interval (positive frequency rate), may be altered by changes in patient population, but also can potentially provide insight into analytical shifts over time. Currently, the effects that changes in assay performance might have on positive frequency rates are not well understood. **Objective:** This study compares shifts in positive frequency rates with QC trends for several widely utilized markers to determine if there is a correlation between these two quality indicators within a large clinical reference laboratory. **Methods:** Positive frequency rates and quality control (QC) values were simultaneously tracked for several markers on Beckman Coulter Unicel DxI 800 immunoassay. Monthly QC and positive rates for alpha-fetoprotein (AFP), inhibin A (INHA), cancer antigen 19-9 (CA 19-9), carcinoembryonic antigen (CEA), and thyroglobulin (Tg) were recorded from January 2016 to September 2017. The number of tests per month on average was 2200 for AFP, 400 for INHA, 2200 for CA19-9, 4500 for Tg, 1000 for CEA and 1200 for FT3. For free triiodothyronine (FT3) data was recorded from January 2015 to October 2016. Observed monthly shifts in positive frequency were plotted relative to shift in monthly mean QC values for the controls that were closest to the positive/negative decision limit. **Results:** The coefficient of variation (CV) of positive frequency rates over this period for AFP, CA19-9, CEA, INHA, FT3 and TG was 5.3 %, 2.4%, 3.7%, 10.1%, 56.0% and 3.9%, respectively. The percent CV for QC values for AFP, CA19-9, CEA, INHA, FT3 and TG were 2.9%, 5.3%, 14.2%, 2.6%, 5.3% and 13.8%, re-

spectively. Correlation plots showed no correlation between monthly QC value and positive frequency shifts. However, FT3 provided an example where a significant change in the monthly positive rate reflected a change in assay performance that was not detected by QC. A reagent lot change resulted in a ~20% increase for the positive frequency with only a +0.8% shift in corresponding monthly QC values between February and April 2016. Further investigation revealed a reagent formulation change by the manufacturer that had resulted in a potential 10-14% increase in patient values across the reference range that was not reflected in QC data. **Conclusion:** Positive frequency was evaluated as a potential quality metric for assay performance. Our data suggests that positive frequency shifts are independent of monthly QC value shifts. However, in certain circumstances, monitoring frequency shifts can enable detection of assay changes and suggests that positive frequency monitoring has value as an additional quality indicator.

B-207

Consolidation of Therapeutic Drug Monitoring (TDM) Testing to the Automated Core Lab and Validation of Serum Separator Tubes (SST) for Drug Testing Yields Improved Turn Around Time (TAT) and Reduces the Number of Blood Tubes Collected

L. A. Rossini, R. J. Ybabez, D. A. Dalenberg, T. V. Hartman, C. T. Yoch, P. J. Jannetto, L. J. Langman, D. R. Block, N. A. Baumann. *Mayo Clinic, Rochester, MN*

Background: With improved technology and demand for faster results, clinical laboratories have an obligation to continuously reevaluate the processes for obtaining samples, testing, and delivering results to physicians. To improve efficiency, 23 therapeutic drug monitoring (TDM) tests were transferred from the specialty toxicology laboratory to the automated core laboratory. Process improvement opportunities were identified including validating automation-ready serum separator tubes (SST, Becton-Dickinson) to replace traditional red top serum tubes for 14 of the drugs. The expectation was that efficiency and turn-around-time (TAT) would be improved by consolidating testing to the core lab. Two tests were chosen as surrogates to measure the TAT improvement. **Objectives:** The aims of this study were to: 1) Assess TAT for phenytoin before and after consolidation of TDM testing from the specialty toxicology laboratory to the core laboratory; 2) Assess TAT for phenobarbital before and after consolidation in conjunction with a specimen type change from red top tube to SST; and 3) Evaluate whether changing the specimen type to SST for phenobarbital reduced the number of blood tubes collected when phenobarbital was ordered. **Methods:** Physician orders for phenytoin and phenobarbital were extracted from the laboratory information system (LIS) for one year pre-consolidation (2014) and one year post-consolidation (2017). Inpatient and outpatient specimens collected on-site (Mayo Clinic Rochester hospitals or clinics) were included. TAT was calculated as time (minutes) from blood collection to result verification. The mean +/- standard deviation (SD) TAT and % of orders meeting a TAT goal of 140 minute for phenytoin (red top tube) or 120 minutes for phenobarbital (SST) were calculated. To determine whether the change to SST impacted the number of blood tubes collected per patient when phenobarbital was ordered, post-consolidation phenobarbital orders were reviewed to determine whether other tests were ordered concurrently. **Results:** The TAT for phenytoin was 147 ± 56 minutes (n=220 orders) prior to consolidation (2014) and 90 ± 38 minutes (n=532 orders) post-consolidation (2017). The % of orders meeting the 140 minutes TAT goal was 42% pre-consolidation and 92% post-consolidation. The TAT for phenobarbital was 162 ± 78 minutes (n=311 orders) prior to consolidation (2014) and 74 ± 35 minutes (n=251 orders) post-consolidation (2017). The % of orders meeting the 120 minute TAT goal was 29% pre-consolidation and 94% post-consolidation. In 2017, 220 of the phenobarbital orders had additional laboratory tests ordered concurrently. The change to an SST for phenobarbital eliminated an additional blood collection tube in 60 cases (27%) and initiated an additional tube in 35 cases (16%). **Conclusions:** Using phenytoin and phenobarbital as representative tests, our results demonstrate that consolidating TDM testing from a separate specialty laboratory to the automated core lab greatly improved TAT. In addition, by changing from a red top tube to SST there was a reduction in the number of blood tubes collected when phenobarbital was ordered. This suggests that specimen type consolidation, when properly validated, is another mechanism by which laboratories can improve efficiency.

B-208

Derivation of short term biologic variation of platelets in inpatients with thrombocytopenia

E. Xu[1], G. S. Cembrowski[2], J. Park[3], T. Curic[4], M. Bodnar[2], B. Davis[5], G. Clarke[6], H. Gerges[7]. *[1]University of Manitoba, Winnipeg, MB, Canada, [2]University of Alberta, Edmonton, AB, Canada, [3]Alberta Health Services, Edmonton, AB, Canada, [4]Calgary Laboratory Services, Calgary, AB, Canada, [5]Horiba, Montpellier, France, [6]Canadian Blood Services, Edmonton, AB, Canada, [7]University of Alberta Hospital, Edmonton, AB, Canada*

Background: Biologic variation (BV) has become the primary criterion for deriving specifications for maximum allowable analytic error. While BV is usually assessed in healthy subjects, (generally with strict observation of preanalytical conditions), it is not clear whether similarly derived BVs are applicable in subjects with abnormal concentrations of the analyte in question. We use a unique methodology (Cembrowski et al, Clin Chem Lab Med) to derive BV from consecutive intra-patient data and demonstrate that short term platelet BV is significantly higher than the usual 3%. **Methods:** A data repository provided all of the low platelet results measured over a 2 year period at the University of Alberta and Royal Alexandra Hospitals in Edmonton, Canada). These measurements were made on tandem Sysmex XN 9000 analyzers. A total of 14,000 platelet count pairs under 120,000 were collected and were associated with both normal hemoglobin and neutrophil counts. We tabulated the pairs of sequential intra-patient platelet tests that were separated by 0-4, 4-8, 8-12,⋯ up to 48 hour intervals. The standard deviation of duplicates (SDD) of the paired platelet determinations was calculated for each time interval. The graphs of SDD vs. time interval were linear; the y intercept provided by the linear regression equation represents the sum of the BV and short term analytic variation (s_a): $y_0=(sa^2 + BV^2)^{½}$. s_a was determined from onsite control analysis. **Results:** The Table summarizes the ST platelet BV for 4 different platelet ranges. **Conclusions:** The relative platelet imprecision for patients with thrombocytopenia is about twice that of normal individuals (3.2% from Buoro et al, Clin Chim Acta 470 (2017), 125-132). As such, evaluations of platelet measurements in the thrombocytopenic range might permit higher allowable error. The y intercept multiplied by 2.5 yields 15%. Platelet increases or decreases of 15% in thrombocytopenic patients are statistically significant (P<0.01).

Patient Platelet Range x10⁹/L	Median Platelets x10⁹/L	s_a, x10⁹/L	y_0 x10⁹/L	Short term BV x10⁹/L	Relative Short term BV (%)
<120	95	7.76	5.5	5.5	5.8%
<100	79	7.24	5.4	4.9	6.2%
<80	60	6.38	5.2	3.7	6.1%
<60	43	5.77	5.1	2.7	6.2%

B-209

Establishment of Analytical Performance Goals Based on Total Error of Patient Misclassification

Q. Sun, M. Sampson, A. Remaley. *NIH, Bethesda, MD*

Background: The concept of total allowable error (TEa) was initially introduced to assess analytical performance of laboratory assays. A limitation of TEa is that its quantitative relationship to patient test misclassification is unclear. The objective of this study was to develop a new analytical performance goal based on minimizing test misclassifications. **Methods:** Simulation analysis was performed on 14 CLIA-regulated analytes to assess the impact of imprecision and systematic bias on total error of misclassification. For each analyte, 230,000 measurements were obtained with the Dimension Vista® system, between October 2008 and July 2012 at the National Institutes of Health. CLIA TEa limits were used for the analysis and the manufacturer's recommended upper and lower reference range were used to classify subjects. **Results:** No bimodal distributions were observed for any of the tests. Instead, distributions containing "heavy tails" were observed; therefore, we developed a mixed single population model and introduced either fixed bias or imprecision by simulation, with either a single or a double cutpoint. We observed a complex relationship between bias and imprecision, but for relatively low errors they had a similar impact on misclassification. As seen in the example of glucose (Figure 1), a TEa limit of 10% corresponds to 15% of misclassification for positive bias, and 20% for negative bias. Using this approach, we developed new equations for each analyte that allow laboratories to stay within the CLIA TEa limits and calculate what the limit represents in terms of patient misclassification. **Conclusion:** Our new index based on test misclassification has the

advantage that it correctly takes into account the differential effect of bias and imprecision. It provides a more intuitive number for assessing both analytical performance goals and the clinical impact of test errors.

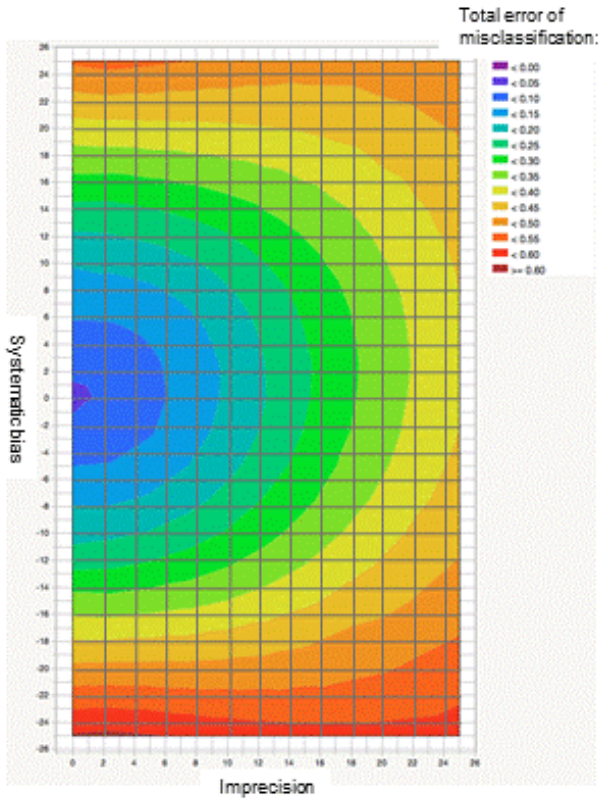

Figure 1: Impact of bias and imprecision on total error of misclassification (TEM) for glucose. The correlation between imprecision/bias and TEM is $\frac{imprecison^2}{X-intercept^2}+\frac{bias^2}{TEa^2}=1$. X-intercept, intercept of TEM contour line with X axis where the y axis is zero.

B-210

PCT-guided antibiotic stewardship versus usual care for hospitalised patients with suspected sepsis or lower respiratory tract infections in the US: a model-based cost analysis

J. C. Mewes[1], M. S. Pulia[2], M. K. Mansour[3], M. R. Broyles[4], B. H. Nguyen[5], L. M. G. Steuten[6]. *[1]Panaxea bv, Amsterdam, Netherlands, [2]University of Wisconsin-Madison, Madison, WI, [3]Harvard Medical School / Massachusetts General Hospital, Boston, MA, [4]Five Rivers Medical Center, Pocahontas, AR, [5]Loma Linda University, Loma Linda, CA, [6]University of Washington / Panaxea bv, Seattle / Amsterdam, WA*

Background: Procalcitonin (PCT) is a biomarker that supports clinical decision-making regarding initiation and discontinuation of antibiotic therapy. It is demonstrated to be safe and effective in identifying patients who do not require initiation of antibiotic therapy and in reducing antibiotic duration, thereby supporting global efforts to reduce unnecessary antibiotic utilization. Several cost(-effectiveness) analyses have been conducted on PCT-guided antibiotic stewardship, but so far none used US originated data.**Objective:** To compare effectiveness and costs of a PCT-algorithm to guide antibiotic prescription versus standard care for patients hospitalized with a diagnosis of suspected sepsis or lower respiratory tract infection (LRTI) in the US. **Methods:** A previously published health economic decision model was used to compare the costs and effects of PCT-guided care. The analysis considered the societal and hospital perspective with a time horizon covering the length of the hospital stay. The main outcomes were total costs per patient, including treatment costs and productivity losses, the number of patients with antibiotic resistance or *C.difficile* infections, and costs per antibiotic day avoided. Multiple sensitivity and scenario analyses were performed to test the robustness of model outcomes. **Results**: PCT-guided care for hospitalized patients with suspected sepsis and LRTI is associated with a reduction in antibiotic days, a shorter length of stay on the regular ward and the ICU, shorter duration of mechanical ventilation, and fewer patients at risk for antibiotic resistance or *C.difficile* infection. Total costs savings in the PCT-group compared to standard care were estimated to range between 20%-30% for patients with suspected sepsis and LRTI, depending on specific data inputs and scenarios modeled. Projected reductions in number of patients with ABR were approximately 5% to 23% and reductions in *C.difficile* infection ranged from circa 55% to 63%. Cost-savings were mainly driven by the reduction in LOS and a shorter duration of mechanical ventilation. **Conclusion:** Using a PCT algorithm to guide antibiotic use in sepsis and hospitalized LRTI patients is expected to generate cost-savings to the hospital that are sufficiently large to recoup the upfront costs of PCT-testing and lower the rates of antibiotic resistance and *C.difficile* infections in populations of patients hospitalized with suspected sepsis or LRTI.