Wednesday, July 29, 2015

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

Automation/Computer Applications

B-372

Improving Compliance with Practice Guidelines through Changes in Physician Order Sets

S. W. Njoroge, A. Woodworth, J. Field, K. Wolfe, M. M. Zutter, E. Johnson, J. H. Nichols. *Vanderbilt University School of Medicine, Nashville, TN*

Introduction: Unnecessary or inappropriate laboratory testing can lead to delays in diagnosis, treatment and/or other potentially harmful clinical outcomes. Inappropriate test ordering also contributes to increased healthcare costs. Clinical practice guidelines provide physicians with best practice recommendations on the appropriate diagnostic workup for preventive health and disease management. The American Congress of Obstetricians and Gynecologists (ACOG) provides clinical guidelines for prenatal testing, including a CBC, virology screening for HIV, rubella and syphilis, and hemoglobinopathy screening in high risk groups. According to these guidelines, hemoglobin variant screening is recommended for individuals of African, Southeast Asian, and placeMediterranean ancestry. It is not recommended for low risk ethnic groups such as Caucasians. Daily review of hemoglobin variant screening tests at our institution revealed numerous tests ordered on pregnant Caucasians. We investigated restricting this testing to the guideline recommended patient populations.

Objective: The aim of this study was to intervene and improve compliance with ACOG guidelines and to evaluate the effects of our interventions.

Methods: Hemoglobin variant screening tests ordered on pregnant women were tracked over an eight month period (July 2014 to February 2015). Patient race/ethnicity was determined from electronic medical records. Interventions undertaken to improve utilization of hemoglobin variant screening tests in pregnant women included: 1) polling physicians about reasons for test orders and knowledge of ACOG guidelines, 2) reviewing ordering patterns to identify sources of misorders, and 3) changing the electronic order set to remove universal hemoglobinopathy screening for pregnant females (January 18, 2015). Hemoglobin variant screening was performed by BioRad Variant II HPLC and patient cost per test determined using CPT codes.

Results: Discussions with ordering physicians revealed awareness of ACOG guidelines and intent to follow but that test orders were directed by an electronic order set. This order set included universal hemoglobin variant screening, regardless of ethnicity. In keeping with consensus guidelines, we recommended removing the hemoglobin variant test from the order set and requiring physicians to add the test for high risk patients. Prior to our intervention, 245 hemoglobin variant tests were inappropriately ordered on pregnant Caucasians, an average of 35 times per month. One month post-intervention, no hemoglobin variant tests were ordered in this ethnic group. Based on a patient charge of $120 per test, this amounted to a decrease in patient charges of $4,200 per month. At a reagent cost of $5 per test, we estimated a monthly savings of $175 for the laboratory. We also noted significant labor savings for technologists, residents and medical directors who run, report and review the results of hemoglobin variant tests.

Conclusions: Periodic review of the laboratory tests included in order sets, as well as regular communication with ordering physicians, helps achieve compliance with practice guidelines and can contribute to improved patient care and cost-savings. Removal of hemoglobin variant screening tests from the pregnancy order set resulted in a substantial decrease in patient charges and laboratory resources. Evaluation of the clinical impact of these changes is ongoing.

B-374

Development of a Computer Program for Exploring Large Quality Assurance Datasets

C. Crutchfield[1], M. Hurston[2], K. Martin[2], B. Hartlove[3], M. Marzinke[1], L. Sokoll[1]. *[1]Johns Hopkins University School of Medicine, Baltimore, MD, [2]Johns Hopkins Hospital, Baltimore, MD, [3]Johns Hopkins Medical Laboratories, White Marsh, MD*

Background: Quality laboratory testing depends on low pre-analytical, analytical, and post-analytical error rates. There is an urgent need for open-source computational solutions that effectively summarize quantitative data related to the quality of laboratory testing. We have developed software that enables the analyst to actively engage large quality assurance datasets through interactive elements and statistical graphics (histograms, bar graphs, heat maps, etc.). As a result, key statistics of the data are rapidly and intuitively queried.

Methods: This software analyzes LIS output and produces an interactive workspace accessed via a web browser. It does this by combining the very powerful statistical, logical, and graphical capabilities of R with the intuitive framework of a web page (generated using a combination of HTML and JavaScript). As a result, the analysis may be leveraged by individuals lacking programming experience.

Results: Prior efforts to analyze LIS output at our institution were done manually using built-in functions within Microsoft Excel. This workflow was time consuming and only resulted in a summary table. Our software reduces this analysis time to three minutes of data formatting and entry and four minutes of computational time for analysis of ca. 150,000 test order entries. In the figure we demonstrate a heat map analysis of test order cancellations which provides a visual stratification of the frequency of cancellation events, including receipt issues, labeling issues, hemolysis, etc., by ordering location. The actual output of the program would enable interaction by clicking on individual summary statistics. This interaction would display additional statistical graphics for specific cancellations for that location as well as all more details of the associated test orders. Here, the analyst would prioritize investigation of the locations with high QNS and clot frequencies.

Conclusion: We have developed software for generating intuitive workspaces for complex analysis of clinical laboratory quality assurance datasets.

B-375

Initial Implementation of a Risk Based Quality Control Scheme Using Bio-Rad Mission: Control Software

M. A. Cervinski[1], F. A. Polito[1], L. Kuchipudi[2]. *[1]Dartmouth-Hitchcock Medical Center, Lebanon, NH, [2]Bio-Rad Laboratories, Plano, TX*

Background:A robust quality control (QC) program is a balance between detection of critical systematic errors (SEc) and false rejection of an analytical run. Hundreds of patient samples are typically run between QC events and the number of results affected by SEc depends on the likelihood of detecting the error with the next QC event. In the course of converting from a Medically Allowable Limits (MAL) strategy to a risk analysis model, we investigated whether the Bio-Rad Mission:Control software program could guide our analytical risk assessment QC strategy. The objectives were to use the Bio-Rad program to analyze our current MAL strategy for its ability to detect SEc in selected analytes and to design a QC strategy that would reduce the number of QC events needed to detect a shift in assay performance.

Methods: Six high volume serum assays (Sodium, Potassium, Chloride, Bicarbonate, Creatinine and Hemoglobin A1c) were selected for analysis. Current QC data (running QC mean and SD) were loaded into the Mission:Control software. CLIA allowable total error limits and the repeat 1:2s QC rule were used to assess protocol performance. The expected number of QC events until detection (EQCE) of a critical systematic error condition for each assay were calculated by the Mission: Control program. Detection of SEc using the running QC mean and SD were compared to fixed QC mean and SD limits. Finally, new user defined fixed means and SDs were selected in order to improve SEc detection while minimizing false rejection.

Results: For all assays analyzed, assuming no bias in the measurement procedures, the least number of QC events needed to detect SEc were those QC protocols designed using the running QC mean and SD to define QC limits. For example, the sodium running mean(SD) values for QC levels 1 and 2 were 125mmol/L(0.847) and 152mmol/L(0.732). Using the running mean and SD in the QC rule, a SEc = +/-1.7 mmol/L was predicted to be detected in 1.3 QC events with a false rejection rate of 1%. Alternatively, if the measurement process is biased with correct values for QC levels 1 and 2 of 126 mmol/L and 153 mmol/L, then using QC rule fixed mean(SD) values of 126mmol/L(1.2) and 153mmol/L(1.2) is predicted to detect a SEc = 2.9 mmol/L in 4.2 QC events with a false rejection rate of 0.4%. Narrowing the fixed SDs to 1.1 mmol/L at 126mmol/L and 1.0 mmol/L at 153mmol/L reduced the expected number of QC events to 2.1 with a false rejection rate of 1.9%.

Conclusion: The Bio-Rad Mission: Control software program allowed us to assess the performance of our current QC strategy and to design new QC limits that are predicted to reduce the number of QC events needed to detect SEc. This strategy will also reduce the number of unreliable patient results that would be reported prior to detection of the SEc. Further implementation of a risked based QC strategy will optimize error detection without added expense of additional QC analysis.

B-376

Design of Autoverification Review Codes Using Historical Data

C. R. McCudden. *The Ottawa Hospital, Ottawa, ON, Canada*

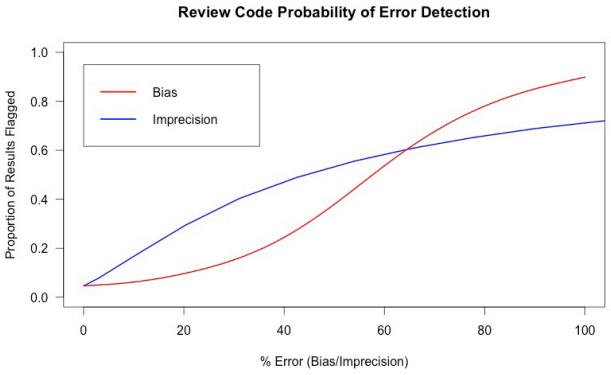
Background: Autoverification is used to automate the reporting of patient results, ensuring consistency and improving turnaround times. Autoverification is based on evaluating each result against pre-defined rules. These rules may include reference intervals, quality control results, analytical ranges, critical values, and delta checks.

Objective: The goal of this study was to establish a set of review limits for automated chemistry tests that don't have critical values or delta checks.

Methods: Two-years of laboratory results were extracted from the LIS database. Extracts included 286 unique reportable results from the Siemens Dimension Vista 1500; results included urine, serum, and plasma and calculated parameters, such as eGFR. Histograms were generated for each analyte and the 95% non-parametric confidence intervals were determined from the 2.5th and 97.5th percentiles. Visual inspection of the histograms and confidence intervals were combined to establish review codes where results outside of these historical limits would occur <5% of the time; for high volume tests, limits were widening to minimize the volume of false positives. Error simulation was used to model the efficacy of the review codes. Error was simulated by randomly introducing bias or imprecision (each separately). The modeled error was compared to the review code cutoffs to determine what proportion of results would be flagged.

Results: Review codes were established for 241 reportable tests. Error simulation models yielded error-dependent probability (see Figure showing error detection probability curves). The figure shows the % error introduced against the probability of error detection, where color denotes bias or imprecision. Real world implementation demonstrated a good trade-off between false-positive rate (y-intercept in figure) and error detection probability depending on the amount of bias or imprecision.

Conclusions: The review codes designed herein provide an additional quality tool for tests that do have critical values or delta checks. This approach is readily implemented in a typical autoverification workflow.



B-377

Enzymatic HbA1c assay on ARCHITECT c8000: Effect of extended wait time prior to sampling

S. Reed[1], L. Stubbs[2], R. Wonderling[2]. *[1]St. Joseph Regional Health Systems, Bryan, TX, [2]Abbott Laboratories, Abbott Park, IL*

Background: The enzymatic Hemoglobin A1c (HbA1c) assay on the ARCHITECT c8000 instrument is used to determine HbA1c levels. The results could be used not only for monitoring of patients with diabetes mellitus but also for diagnosis of diabetes mellitus. Therefore, precision and accuracy of results becomes extremely important. With this assay, HbA1c levels can be determined from whole blood samples without a manual pretreatment. Process efficiency can be increased by having this assay on the Automated Processing System (APS). The package insert for the assay instructs to mix all specimens thoroughly by low speed vortexing or by gently inverting 10 times prior to loading on the instrument. This raises the questions as to how long the mixed specimens can wait prior to sampling and if settling of blood cells due to extended wait time affect the HbA1c results obtained.**Methods:** To determine the effect of extended wait time before sampling on the HbA1c results obtained from the ARCHITECT c8000 instrument, several samples were mixed gently by inverting 10 times and loaded on to the APS. Each sample was tested immediately and then tested after various time points (every 30 minutes up to 5 hours) without further mixing. The results obtained at various time points were compared.**Results:** The results indicated that the HbA1c results were not affected by extended wait time prior to sampling (up to 5 hours after mixing) since the %CV between the results obtained at various time points was less than 1.5%. **Conclusion:** Process efficiency can be increased by having the HbA1c assay on the APS . The results indicate that there was no significant difference in the HbA1c result whether the samples were tested immediately after mixing or up to 5 hours later without further mixing.

Table 1: HbA1c results for 14 different samples tested at different time points after mixing.

Sample No.	0 hr	0.5 hr	1 hr	1.5 hr	2 hr	3 hr	4 hr	5 hr	%CV
Sample 1	5	4.9	4.9	4.9	4.9	5	5	5	1.3
Sample 2	4.5	4.6	4.7	4.6	4.6	4.7	4.7	4.6	1.45
Sample 3	5.2	5.2	5.2	5.3	5.3	5.3	5.3	5.3	0.89
Sample 4	5.2	5.2	5.3	5.3	5.3	5.3	5.3	5.3	0.77
Sample 5	6.5	6.5	6.5	6.5	6.5	6.6	6.5	6.5	0.62
Sample 6	5	5	5.1	5	5.1	5.1	5.1	5.1	0.92
Sample 7	9.8	10	10	10	10	10.1	10.1	10	0.83
Sample 8	5.6	5.6	5.6	5.6	5.6	5.7	5.7	5.7	0.92
Sample 9	6.4	6.4	6.5	6.5	6.5	6.5	6.5	6.5	0.62
Sample 10	4.9	4.9	4.9	4.9	4.9	4.9	4.9	4.9	0.00
Sample 11	4.9	4.9	4.9	4.9	4.9	4.9	4.9	5	0.82
Sample 12	5.5	5.5	5.6	5.6	5.6	5.6	5.6	5.7	0.96
Sample 13	7.9	7.8	7.8	7.9	7.9	7.9	7.9	7.9	0.51
Sample 14	6.9	6.9	7	7.1	7.1	7.1	7.1	7	1.16

B-378

New Solution to Patients Identification with Laboratory Information System

L. Wang[1], Y. Tsai[1], Y. Yang[1], H. Chou[1], L. Wu[1], J. Li[2]. *[1]Chi-Mei Medical Center, Tainan City, Taiwan, [2]Chi-Mei Medical Center, Chiali, Tainan City, Taiwan*

Background:

Blood transfusion is a life-saving medical procedure and over 779,344 people have blood transfusions annually in Taiwan. However, it could lead to devastating consequences and fatality even if there is only one defect like miscollected samples (wrong-blood-in-tube, WBIT), mislabeled samples or misused patient samples in the laboratory. Given that laboratory errors accounted for approximately 30% of errors resulting in mistransfusion, this project applied an information system with barcode technology to avert the potential clerical errors in the transfusion laboratory.

Methods:

The study retrospectively reviewed the outcomes of laboratory information system introduced in 2011 and completed in 2014. The information system with barcode technology was designed to exactly match the facts from recipient to donor samples and verified reports of ABO typing, RhD typing, crossmatching and the antibody screening test. Once an error had been detected, a warning message was shown on the screen, the procedure was discontinued and then this record was kept. Additionally, a wireless information barcode system had been administered for inpatient identification and for checking the consistency of the wristband and the labeled tube.

Results:

A total of 24560 inpatients requiring blood transfusions were identified in a medical center. In 2010, the 14 mislabeled incidents of the18322 samples were found; however, in 2014, no mislabeled case was reported (N=19016). Besides, the records showed that the phlebotomists had good compliance with the use of the new system.

Conclusion:

The transfusion laboratory developed a zero-tolerance policy to identify patients and manage samples. The writer believed that a successful information system should be stable and user-friendly. After implementing the information system with barcode technology over a year period in the facility, the incidents of misidentified and miscolleced transfusion samples were totally eliminated.

B-379

Enhancing Quality Control in Clinical and Point of Care Settings

S. Mansouri, M. Wright. *Instrumentation Laboratory, Bedford, MA*

OBJECTIVE

Published documents by the Clinical and Laboratory Standard Institute including EP18 and EP23 and by the International Organization for Standardization have provided guidance for managing quality in clinical devices. Suggested methodologies rely on understanding sources of error and designing integrated QC methods for rapid error detection and correction. One approach for designing an integrated QC method is to identify error patterns and devise targeted corrective actions. Timely error detection is necessary and can only be achieved through continuous monitoring of the measurement system. Methods for gathering and identifying error patterns can be accomplished through detailed examination of past end-user data. Such end-user data analysis can be achieved reliably only if the measurement system is closed. The measurement system should also be capable of collecting extensive information for proper identification of error patterns.

METHODOLOGY

GEM Premier 3000 blood analyzer (Instrumentation Laboratory, Bedford, MA, USA) has a single cartridge (GEM PAK) that includes all the analytical components needed for testing and, therefore, fits the criteria for a closed analytical system. The analyzer is designed to collect a large amount of data during its operation. Years of investigating cartridge data from healthcare facilities has provided an extensive library of identifiable patterns associated with specific error modes. The methodology has allowed the development of Intelligent Quality Management (iQM), replacing the use of traditional external quality controls. Collected data from several GEM PAKs at a clinical site were used for analyzing error detection capability of internal versus external controls. The iQM corrective action report was used to identify any analytical issue and corrective action performed by the analyzer.

RESULTS

More than 1000 samples including 300 QC's were evaluated among four GEM PAKs. Sigma values as total allowable error divided by standard deviation were used to assess error detection capability of the internal and external QC methodologies. Sigma values greater than four indicated a high probability of detecting abnormal analytical change. There were only three cases for internal controls with sigma less than 4. In contrast, there were eight cases for external controls with sigma less than 4. Furthermore, high frequency of internal control checks in iQM allowed faster error detection time even for parameters having less than 4 sigmas. As a result, iQM was capable of detecting several transient failures including four micro-clots while no failure was detected with external QC in any of the PAKs. All clot-related errors were detected within 1-2 minutes after sample introduction and followed by immediate user-notification and automatic start of corrective action.

CONCLUSION

Data analysis of the GEM PAKs in clinical use demonstrated the effectiveness of iQM in timely detection of errors that would otherwise go undetected with traditional external QC method. Errors were detected immediately after the sample that caused them. Real time and continuous monitoring of iQM allowed for immediate and automatic error detection and corrective action, further enhancing the analyzer's quality assurance at the clinical or point-of-care settings.

B-380

Performance Evaluation of Automated Clinical Chemistry Analyzer for Indocyanine Green (ICG) R15 Test

J. Park[1], H. Lee[1], M. Heo[1], E. Won[1], S. Kee[1], M. Shin[1], J. Shin[1], D. Ryang[1], B. Park[2], S. P. Suh[1]. *[1]Chonnam National University Hospital, Gwangju, Korea, Republic of, [2]Mokpo National University, Muan, Korea, Republic of*

Background: Indocyanine green retention rate at 15 minutes (ICG R15) test has been used to predict the residual liver function before hepatic resection or the prognosis of patients with liver cirrhosis. Conventional ICG R15 test is inefficient and inconvenient because it requires spectrophotometer manually and four samples in a patient. Here, this study aimed to establish the automation of ICG R15 test using automated clinical chemistry analyzer and evaluate the calculation of ICG R15 with small number of samples.

Methods: Performance of AU5832 analyzer (Beckman Coulter, Brea, CA, USA) for measuring ICG concentration was evaluated in accordance with the guidelines of the Clinical Laboratory Standards Institute (CLSI). Precision, linearity and carry-over were tested using standard materials prepared with five different concentrations. Plasma samples obtained from the patients were used for the comparison between manual and automation method. A total of 54 patients were requested for ICG R15 test at two university hospitals from July to October in 2014. We measured concentrations of ICG at the wavelength of both 800nm and 805nm by spectrophotometry, and at 800nm by AU5832. R15 of 54 patients analyzed by the two methods was compared using the Bland-Altman method and paired t-test. We evaluated the calculation of ICG R15 with three samples, except for the one of samples obtained at the time before injection, or 5, 10 and 15 minutes after injection of ICG to the patient, compared to that with 4 samples. The agreement of each method was assessed according to the three categories of R15 (Category A, R15 < 15%; Category B, 15% ≤ R15 <30%; and Category C, R15 ≥ 30%, respectively).

Results: The automated ICG test by AU5832 established in this study showed the proper performances according to CLSI. All coefficients of variation of ICG concentration showed values below 3% with linearity in the 0.1~1.0 mg/dL range ($r^2 \geq 0.999$). The test value of percentage sample carry-over was less than 1%. The significant correlation was found between the ICG concentration by automated method (800nm) and manual method (805nm) ($r^2 = 0.954$). Although the difference of ICG R15 results between the two methods was within 95% confidence interval, R15 was adjusted by the regression equation for being slightly lower by automated than manual method. R15 with 3 samples (0, 5 and 15 minutes) showed the best correlation with conventional R15 with 4 samples ($r^2 = 0.997$). Compared to manual method, R15 of AU5832 showed the excellent agreement with 4 samples (kappa value 0.891) and also with 3 samples (kappa value 0.820).

Conclusions: Beckman Coulter AU5832 for the determination of ICG concentration and R15 test performed well and showed good correlations with conventional spectrophotometry. Thus, ICG R15 test using AU5832, even with three samples, may be comparable to conventional method in the clinical use.

B-381

Overall Equipment Effectiveness (OEE) as a Tool to Improve Productivity in a Clinical Laboratory (Dasa, Brazil)

L. C. M. Silva, F. Niglio, O. Fernandes. *DASA, São Paulo, Brazil*

Background:

Improving productivity, with focuses on the efficiency of the production, should be fostered in clinical laboratories. By doing so the provision of higher amount of goods and services to different health stakeholders, such as (i)patients, (ii)physicians and (iii)health insurance companies, can be translated into higher profits. Currently, productivity is considered a competitive advantage to clinical laboratories. One methodology to measure productivity is the OEE (Overall Equipment Effectiveness) metric which states the effectiveness of manufacturing process, using three different components: (i)availability (down time loss, which includes any events that stop planned production), (ii)performance (speed loss, which includes any factors that cause the process to operate at less than the maximum possible speed) and (iii)quality (in terms of unnecessary tests performed). It is unlikely that any manufacturing process can run at 100% OEE, therefore the vast majority of manufacturers benchmark their industry to set a challenging target of 85% OEE.

Objective:

This study aims (i)to demonstrate the improvement of productivity through the implementation of OEE, (ii)to understand the most common causes of efficiency loss in clinical laboratories ("Six Big Losses": stops, setup and adjustment, idle time and short stops, reduced speed, quality errors and reaching and startup errors) and (iii)to provide management tools to control and eliminate losses.

Methods:

The largest DASA Central Laboratory that is located in Rio de Janeiro (60 Million tests annually) was chosen for the implementation of the OEE analysis, focusing on the fully automated serum working area, comprised of clinical chemistry, immunology and hormones. The OEE index was calculated using the formula: (Availability)*(Perf ormance)*(Quality). Responsibilities were assigned to the production team, suppliers and support areas in order to (i)measure the three components of the aforementioned formula and (ii)to define the goals for these components and therefore of the OEE approach as a whole. These metrics composed the OEE dashboard that was analyzed on a weekly basis by the team and action plans were developed whenever the goals were not achieved. On a monthly basis, strategic meetings were held with the executive board of the company in order (i)to guarantee that the action plans were fully implemented, (ii)to supervise deviations and (iii)to brainstorm regarding new possibilities of how to improve productivity in that setting.

Results:

After two months of implementation, the OEE percentage of the serum working area increased by 11%, representing 23% improvement in productivity. The most significant increase was in "Availability". One of the main focus of the project was to improve the main losses, such as breakdowns, setup and adjustments, reducing the downtime of equipment. The OEE of immunology increased by 31%, clinical chemistry by 20% and hormones by 13%. These results allowed the enhancement of the production capacity without adding new assets to the production site.

Conclusion:

The results have shown that productivity increased thanks to OEE implementation. The method helped in terms of enhancing production capacity and therefore avoided wrong investment decisions, ensuring that the processes were adequate. In essence, OEE worked as the missing link between capex implementation and production processes.

B-382

Implementation of equipment management and its impact on a Clinical Laboratory production

J. R. OLIVEIRA, L. NERY, L. LOPES, R. CARDOSO, R. JACOMO. *LABORATORIO SABIN, BRASILIA, Brazil*

Background: Recent technological development on clinical laboratory tests led to higher production effectiveness and security. Meanwhile, a great number of equipment must be managed regarding to preventive and corrective maintenance. Thus, an effective system to manage equipment, technical resources, services, and cycle of life as far as aiding in viability studies for new technologies and risk management is necessary.

Methods: Case-study applied to a clinical laboratory in Brasilia, Brazil. To further manage the technological park and in order to improve productivity a sector of clinical engineering was created. Aiming an secure and sustainable process we elaborated a procedure and a software for equipment management was afforded (Engeman 7.6, Engecompany, Itaúna, Brazil). All analytical equipment were catalogued as well as its maintenance and critical information. The new software permitted to manage calibration, preventive maintenance and to monitor corrective maintenances. Information about documentation and the working team qualification was also recorded in the database. A training schedule for all professionals involved with equipment handling and maintenance was established.

Results: After the implementation of the new procedures the analysis of performance-related indicators such as: mean time between fails (MTBF), service-level agreement (SLA), preventive maintenance plan compliance, number of calibrations per test per equipment, effective availability of each equipment during working hours, could be promptly accessed from the database. Following these indicators led to better equipment management, reduction of unexpected failures and higher agility on problem-solving. Productive efficiency raised from 75% in 2013 (before implementation) to 98% in 2014.

Conclusion: Implementing an electronic management process to the equipment led to higher confidence to end-user and also to patients, since a predictable platform permit lower delays and trustful results.

B-383

Development of an Automated Solid Phase Extraction of Procainamide in Serum Samples

S. S. Gill, M. Wang, R. K. Gill, T. Lum, N. Bandy, D. C. Liang. *Aurora Biomed Inc, Vancouver,, BC, Canada*

Background: In determining patient compliance and assessing dosage of antiarrhythmic drugs like procainamide ($C_{13}H_{21}N_3O$), quantification in the patient serum or plasma samples is essential. As the demand on sample processing and analysis increases, laboratory automation solutions become necessary for a testing facility. Automated solutions not only facilitate greater sample processing throughput, but these solutions also minimize the variation and error between samples. However, robotic systems can be subject to positional or spatial biases - intra-performance differences between positions on the deck of the system. Here we investigated potential positional biases of solid phase extraction (SPE) column positions on the VERSA 10 SPE deck.

Methods: A fully automated assay on VERSA 10 SPE Workstation was used for water and serum samples spiked with procainamide using 3mL columns (C8 / SCX). A set of 12 columns were simultaneously processed for activations, wash and elution steps of the protocol. The samples and reagents were mediated through the columns by an automated 12 channel positive pressure module. The eluted samples were subjected to drying with an automated nitrogen dryer in combination with automated heating and shaking. The dried pellet was reconstituted in 1mL of mobile phase and transferred to HPLC vials for high performance liquid chromatographic (HPLC) analysis. The reconstituted procainamide HCl samples (10µL) were analyzed on a Plastisil ODS column.

Results: Positional biases were investigated on the VERSA 10 SPE by examining the recovery of 20µg of procainamide HCl serum samples after SPE on all column positions. Four batches of twelve samples were tested (11 procainamide samples and 1 negative control). The average procainamide HCl recovery per batch (n=11) shows a recovery range between 87.86% - 98.35%. Analysis of Variance (ANOVA) and Tukey-Kramer HSD analysis on post SPE procainamide HCl recovery indicated no statistically differences between column positions on the VERSA 10 SPE deck. Furthermore, the average coefficient of variance (CV%) across column positions was 4.05% (±0.859%).

Conclusion: The presented data and analysis show that there are no positional biases in column positions across the deck of the VERSA 10 SPE automation system. The overall coefficient of variance within each batch was low indicating high precision across each column position that suggests a well-suited solution for increasing throughput and reproducibility while minimizing hands-on sample preparation time.

B-384

Comparison of Two Automated Microscopy Image-Based Urine Sediment Analyzers

A. Yaman[1], F. Gerin[2], O. Baykan[3], M. Arpa[4], P. Vatansever[1], O. Sirikci[1], G. Haklar[1]. *[1]Marmara University, Istanbul, Turkey, [2]Central Laboratory of Public Health, Istanbul, Turkey, [3]Ataturk State Hospital, Balikesir, Turkey, [4]Rize Recep Tayyip Erdogan University, Rize, Turkey*

Background:

Urinalysis is one of the most commonly requested and performed tests in clinical laboratories. The microscopic analysis of urine gives valuable information about many clinical conditions encompassing kidney and urinary tract diseases. Neverthless, traditional microscopic examination is time consuming, not suitable to analyze large number of urine samples, and poorly standardized. Therefore, automated urinalyzers have been widely used instruments especially in high-throughput laboratories in recent years. The objective of the present study was to compare the performances of two automated urine sediment analyzers.

Methods:

A total of 151 fresh urine samples sent for urinalysis were assessed using IQ200 (Iris Diagnostics, USA) and FUS200 (Dirui Industry, China) analyzers. Precision, linearity, and carry-over studies were carried out for IQ200 and FUS200. Also, we evaluated the performance of FUS200 in accordance with IQ200 for detection of red blood cells (RBC) and white blood cells (WBC) in high power field (HPF). Detected urine particles were classified by both two automated systems and images edited by same laboratory technician.

Results:

The cell count results were compared by Passing-Bablok regression analysis and Bland-Altman plots. Comparative analysis with these automatic systems, IQ200 and FUS200, revealed concentration-dependent differences for the counted cells. Bland-Altman plots showed slightly higher results by IQ200 for both RBC and WBC counts. Passing-Bablok regression parameters for RBC and WBC are showed in Table 1.

Conclusion:

Both of the urine analyzers showed similar performance and clinically insignificant variability of RBC and WBC counts. Standardization of urine analyzers and evaluation of particle images are needed to improve and ultimately the quality of patient care.

Passing-Bablok regression						
	n	Intercept	95% CI	Slope	95% CI	Significant deviation from linearity
FUS200-IQ200 (RBC)	151	0,14	0,00-1,00	1,28	1,00-1,63	p<0.01
FUS200-IQ200 (WBC)	151	1,00	0,00-1,00	1,00	1,00-1,30	p<0.01

B-385

On-line flagging monitoring - A new quality management tool for the analytical phase

K. Goossens, K. Van Uytfanghe, L. Thienpont. *Ghent University, Gent, Belgium*

Background: Traditionally, it is difficult to demonstrate the influence of analytical quality on daily medical decision making. This is partly due to the fact that analytical quality specifications should be related to the highest hierarchical model, which is their effect on clinical decisions. Strictly, this would require complex and expensive outcome studies which, however, still are lacking in the field of laboratory medicine. We, therefore, looked for other tools that could translate analytical quality, in particular, assay stability problems into their influence on daily medical practice.

Methods: We investigated the effect of analytical shifts on so-called "surrogate" medical decisions, such as flagging of laboratory results using local cut-offs. We developed an on-line tool for monitoring of daily flagging rates, which we called "The Flagger" (www.theflagger.be). The time course of the data is followed by variable moving medians (n = 5, 8, 16). Instabilities are mainly assessed from limits based on biological variation. State-of-the-art limits are used for analytes with low biological variation.

Results: We report our first experiences about the value of flagging monitoring with the "surrogate" medical decision "hypercalcemia". For example, an analytical shift of ~0.06 mmol/L (~2.5%) is "translated" by the Flagger application into a 3-fold increase of the flagging rate (from ~3% to ~9%). Clinical chemists indeed considered this increase in flagging rate important. Currently, this tool is programmed by local IT-departments, however, laboratory information system providers are interested to develop generally applicable solutions. Moreover, with our Flagger platform, we are able to perform peer-group monitoring of flagging rates opening all the benefits of peer group comparisons.

Conclusion: We consider on-line flagging monitoring in the individual laboratory and external by peer group monitoring an interesting quality management tool for the analytical phase. It is particularly useful because it directly translates analytical quality into quality of medical decision making using locally important cut-offs.

B-386

Efficiency of Automated Online CAP Proficiency Testing Submission in a Multisite Laboratory System.

J. B. Jones, L. E. Quinton, B. G. Vendel, H. H. Harrison. *Geisinger Health System, Danville, PA*

Background: Proficiency testing (PT) from the College of American Pathologists (CAP) requires that sample challenges for all tests reported by a CLIA moderately complex laboratory be received three times per year and handled in a manner identical to patient testing. The PT process within the laboratory is often a laborious manual process with transcription steps subject with error that may result in PT failure. **Methods:** Multiple Roche instruments supported on a wide area network by virtual server-based Data Innovations (DI) middleware were integrated into a CAP driver application, e-LAB Solutions Connect, via online database connectivity (ODBC). A single core chemistry lab was utilized as a pilot site for the entire Geisinger lab enterprise consisting of 6 hospital labs and 6 rapid response outpatient labs. Instrument operators were blinded as to which specimens were CAP PT samples; hence, a much closer emulation of patient testing was achieved. Workload mapping was performed and side by side comparisons of manual versus automated CAP PT processes compared for time efficiency. Cost/benefit analysis for rolling this system out to our multisite system was performed factoring in costs for software installation as well as estimated time savings. Troubleshooting/remediation costs were also estimated for CAP PT failures due to manual clerical errors.

Results: Installation of this middleware-mediated CAP connectivity was straightforward with the exception of integrating DI driver software on PC workstations with the Windows 7 Enterprise 64-bit/citrix operating system. Once a patch was installed the system has worked flawlessly for 10+ months. Current CAP method codes and other demographic information were automatically uploaded by e-LAB Solutions Connect and a CAP PT sample identification and labeling system established in the laboratory information system (LIS). 30 CAP PT challenges performed on Roche instruments since April of 2014 have been submitted by this automated connectivity as survey samples were accessioned into the LIS and interspersed with tested patient specimens by supervisory personnel. An average time savings of 45 minutes was estimated for each PT survey challenge. The number of clerical errors was reduced from 3 to zero for comparable PT surveys over a comparable time period. The time savings for each PT error investigation/remediation was estimated at 115 minutes.

Conclusion: CAP PT testing with automated results submission was found to be more efficient and less error prone than the previous manual method. Time savings justify installation cost of the automated system for DI connected Roche instruments in typical hospital labs. Installation of the automated system in rapid response labs performing routine chemistry were also judged as justified from a quality and regulatory compliance standpoint with an extended payback period. The CAP e-LAB Solutions Connect system will be rolled out in the future to all Roche instrumented labs for chemistry/immunochemistry testing and to other lab areas as vendor middleware automated solutions are developed. The aggregated enterprise time savings is expected to grow as a total of 363 PT testing events/year impact the Geisinger Lab system. This stable DI-ODBC extraction capability offers tremendous opportunities for expanding similar real time data management functions in the future.

B-387

Desire to Stem Lab Test Overuse Leads to Software Development

K. Russell, D. Maennle, Z. Uddin. *St. John Macomb-Oakland Hospital, Warren, Warren, MI*

The spiraling cost of laboratory tests (currently estimated at $60-70 billion/year) has been a major concern to healthcare administrators. A significant increase in testing costs is also anticipated as a consequence of the Affordable Care Act. Several cost-containment plans were initiated during the last decades but with limited success. The objective of our study is to develop two solutions for the cost-containment of laboratory tests. They include: a) building of an informatics structure to support utilization management; b) organization of the physician education program starting from the residency level.

A computer database was created to house > 4400 tests. The test names, test code, cost and respective turn-around time (TAT) are listed based on various reference laboratories in the area. The test is orderable by the physician if the cost is ≤ "Gatekeeper" value, e.g. $200.00. If the cost of the test is >$200.00, then the physician must contact the medical director or pathologist of the hospital laboratory for his or her approval before ordering the test. This "Gatekeeper" value is determined by the Medical Executive Committee of the hospital and may vary from one hospital to another.

We have developed two independent software applications to support utilization management of laboratory tests. They include native code computer programming and web site based application software.

A retrospective data analysis for a period of six months for laboratory send-out tests by a 410 bed tertiary care hospital with an active residency program provided the following information: a) Total costs of all the send-out tests = $671,054.90 b) Cost of the send-out tests > $200 i.e. the "gatekeeper value" = $271,003.54 c) Cost of tests which were reported after the discharge of the patient = $137,918.13.

All hospitals strive to minimize the length of stay of the patient in order to reduce the cost of doing business. However, there is no mechanism to control the ordering of send-out laboratory tests with long turnaround times. This means that the result of the send-out test has no relevance in the immediate treatment rendered by the physician. We recommend that regardless of the cost of the send-out test, the physician should consider the turnaround time of the test result before ordering. We have no way to know the role of the "gatekeeper value of > $200" in our retrospective data analysis. This question can only be answered after the institution of the application software in the laboratory information system (LIS), as this involves consultation between the physicians and pathologist.

The second step in the cost-containment process is physician education. This will contain a detailed synopsis of the software including: an explanation (Google search), clinical significance, turnaround time, and cost of all tests and lab support for non-orderable tests.

We believe that this two-pronged effort, an informatics structure and the physician education program, shall contribute significantly towards controlling the sky-rocketing cost of laboratory tests.

B-389

Quality specification calculation: Total Error and imprecision in Cerebrospinal fluid (CSF) Analysis in a reference laboratory in Brazil

R. C. M. Barbi[1], L. S. Carvalho[1], C. F. A. Pereira[2]. *[1]DASA, Cascavel, Brazil, [2]DASA, São Paulo, Brazil*

Background: Since the end of the 19th century, Cerebrospinal Fluid (CSF) analysis has been used as an aid in diagnostic and monitoring of Neurological diseases and, through the years, its ordering to clinical laboratory is increasing, so that it is very important to advance in the laboratorial quality control for this biological matrix, assuring continuous quality control improvement. Total Error and imprecision are different for each laboratory test, and establishes test performance so that it fits the purpose of use. The Analytical Total Error can be calculated by different approaches; the most common form is the sum of Random Error and Systematic one. Total Error Limits defines how much results can vary and/or approach targets values aimed at clinically acceptable performance for these laboratory tests.

Objective: To propose a quality specification value for total error and imprecision for 10 different analyses in cerebrospinal fluid.

Methods: Total Error was calculated by the sum of Random and Systematic Errors of 10 different analyses in cerebrospinal fluid that were previously analyzed with Advia 2400 - Siemens® from January to December 2014. For the Random Error we used the coefficient of variation (CV) of each test multiplied to 1,65 for a desired confidence level of 90%. For Systematic Error calculation, we used results from two Proficiency Test providers: Control Lab® and PNCQ® - National Program of Quality Control.

Results: The medium CV of the period for each CSF analyte obtained was 2,77% for lactate, 2,48% for albumin, 1,25% for chloride, 1,42% for glucose, 4,99% for IgG, 6,22% for IgM, 1,32% for lactate dehydrogenase, 1,19% for potassium, 1,89% for protein total and 0,88% for sodium. Total Error obtained was 10,64% for lactate, 6,90% for albumin, 3,63% for chloride, 4,99% for glucose, 12,31% for IgG, 22,18% for IgM, 4,68% for lactate dehydrogenase, 3,73% for potassium, 6,30% for protein total and 2,28% for sodium.

Conclusion: Taking into account the medium CV of the period for each analyte, when compared to the CV reported by Advia 2400 Siemens® manufacturer package insert, we realized that all our obtained CVs were smaller than the informed ones. As our Proficiency Testing performance were all inside acceptable limits, we can consider that the quality specification values of total error and imprecision are adequate for use as an aid in quality continuous improvement in monitoring of laboratorial analytic quality control.

B-390

Assessment of utility of daily patient results averages as adjunct quality control in a weekday-only satellite chemistry laboratory

D. Alyemni, L. J. McCloskey, A. M. Treweek, B. M. Goldsmith, R. T. Stapp, D. F. Stickle. *Jefferson University Hospitals, Philadelphia, PA*

Background: Our department operates a weekday-only (8AM-5PM) satellite laboratory in an infusion center with a menu of 18 chemistry tests on a Roche c501 analyzer. We examined whether daily patient results averages (PRA) in this setting might be useful as a patient-based quality control (PBQC) adjunct to standard daily liquid quality control (LQC) measurements. First, we evaluated the reproducibility (coefficient of variation, CV) of daily PRAs for each analyte, and compared these to CVs of LQC. Second, for select analytes found to have relatively low PRA CVs, we evaluated the extent to which use of daily PRA measurements could improve detection of analytical errors when combined with LQC.

Methods: Patient results data for approximately one month (21 weekdays) were obtained from the Sunquest laboratory information system. For calculation of patient results averages (PRA), qualifying results were restricted to those within the reference range for each analyte. PRA and standard deviation (S) of PRA across 21 days was calculated for each analyte. Coefficients of variation for PRA (CV-PRA) were compared to those observed for standard liquid quality control (LQC) measurements (CV-LQC). For those analytes for which CV-PRA was less than CV-LQC, we evaluated the potential advantage of addition of PRA to daily LQC. For each analyte, a presumed PRA shift was determined such that probability of detection (P) was 0.5 when using LQC alone (viz., using high LQC and low LQC measurements), according to criterion that at least one 1-2S deviation from mean was obtained. For this same PRA shift, P = 0.5 for LQC alone was compared to P obtained for LQC + PRA (viz., using high LQC, low LQC, and PRA measurements), according to the same criterion.

Results: Across 21 days, the number of results per day per assay ranged from 23 ±4 (uric acid) to 75 ±21 (electrolytes). Qualifying results (results within the reference range) ranged from 70 ± 6 % (LDH) to 99 ± 1 % (Cl). Seven analytes had CV-PRA < CV-LQC (analyte, CV%): albumin, 1.25%; Ca, 0.67%; Cl, 0.62%; CO2, 1.13%; creatinine, 3.44%; K, 1.14%; Na, 0.65%. The remainder did not meet this criterion: ALP, 3.7%; ALT, 5.2%; AST, 5.1%; BUN, 4.6%; glucose, 1.4%; LDH, 2.0%; Mg, 1.4%; P, 2.5%; protein, 0.9%; TBIL, 6.1%; uric acid, 4.3%. Among the seven analytes for which CV-PRA < CV-LQC, probability (P) of shift detection by LQC for circumstances as described in Methods (LQC P = 0.5) was increased substantially by inclusion of PRA (analyte, shift in analyte concentration, P): CO2, ±1.07 mmol/L, 0.97; creatinine, ±0.099 mg/dL, 0.93; albumin, ±0.126 g/dL, 0.85; Ca, ±0.14 mg/dL, 0.80; K, ±0.097 mmol/L, 0.76; Cl, ±1.24 mmol/L, 0.74; Na, ±1.48 mmol/L, 0.68.

Conclusions: For 7 analytes, daily PRA demonstrated CVs less than those for LQC. For these analytes, calculations demonstrated that daily PRA can increase probability of detection of small results shifts when used as an adjunct to LQC. Daily PRA is a simple and essentially cost-free form of PBQC that may be useful for certain analytes in part-time laboratory settings.