Wednesday, August 2, 2017

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

Management

B-159

Total Laboratory Automation (TLA) - performance and improvements from 2013 to 2016

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Background and objectives: The Department of Pathology & Laboratory Medicine (DPLM) at King Faisal Hospital, Riyadh, Saudi Arabia embarked on an ambitious programme to consolidate services with initial discussions starting in 2009. In 2012, DPLM began to implement a TLA, which was the culmination of 5 previous contracts into one, with the following objectives to: be cost efficient (save money), be less labour intensive (use less staff), increase productivity and capacity (be able to do more) and enhance patient safety (reduce turnaround time and enhance predictability / reduce variation). **Method and results:** We went live with a partially implemented TLA in 2013 and have experienced a 7% increase in workload year over year. Routine random glucose was chosen as a sentinel to compare turnaround times (TATs) and whisker boxplots (WBPs) were chosen to visually present TAT by receipt hour of the day for 2012 and 2016. At the peak of workload (11am) we have the greatest variation in TAT; the least predictability in service delivery. The shape of the distribution (timing of workload) has not changed between 2012 and 2016. We present here we present what was delivered in relation to our objectives. There is a 32% reduction in TAT and enhancement in predictability as shown in figure 3 when comparing before (2012) and after (2016) the TLA implementation. **Financial impact:** The cost avoided by the consolidation of services was 5 million SAR per year in direct costs from previous contracts. The staffing costs for the TLA area were 5,411,704 SAR in 2012 (before consolidation); the cost is now 4,275,214 SAR in 2016 which is a saving of 1,136,490 SAR on staffing costs (reduction of 6 full time staff in this area). It is of note that the mix of staff has changed with less senior staff needed; there are now 3 senior staff whereas previously 5 were required (staff attrition posts were not back filled). Staffing and consolidation of contracts will have saved 30 million SAR by March 2018. **Discussion and conclusion:** Total Laboratory Automation, with integrated robotics and IT solutions, is becoming a crucial way to simplify operations - both reducing manual reliance and maximising patient safety. We delivered on our objectives to: be cost efficient (30 million SAR saved by March 2018), be less labour intensive (head count reduced overall by 15%), increased productivity and capacity (70% capacity available for additional work 12 hours per day), enhanced patient safety (reduced turnaround time and enhanced predictability by >30%), designed out opportunity for error (automated practices and adopted IT-logic rules based decisions such as auto-verification) and we have added more services to automation lines (i.e. infectious serology, to improve efficiency). Our experience with the transformation to a TLA has been very positive, resulting in effective and efficient service delivery whilst enabling huge potential for additional work and income generation; with keys to success including strong leadership, robust change management and clear performance metrics (key performance indicators).

B-160

Automated Core Facility - enhancing performance, reducing queuing

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Background: The Department of Pathology & Laboratory Medicine (DPLM) at King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia embarked on an ambitious programme to consolidate services and create an Automated Core Facility (ACF) which went live in 2013. In an on-going effort to further reduce the turnaround time (TAT) and enhance predictability, we reviewed systematically all elements of our ACF using the Roche Cobas 8000 series (Roche Diagnostics Middle East FZCO). The centrifuge spin time had been historically set at 10 minutes (mins). We present here an overview of the impact of reducing the centrifugal spin time down from 10 mins to 5 mins and the unexpected impact on TAT. **Method and Results:** Data was captured on the time from receipt in the ACF clinical laboratory to result availability before and after adjusting the centrifugal spin time down from 10 mins to 5 mins (June 2016). Data was captured for 27 common tests that are performed in clinical biochemistry. Data is presented in Whisker Box Plot (WBP) and histogram formats. 2 unremarkable, representative days were chosen to compare before and after changing the spin time (which had 20,510 and 17,828 tests respectively). The impact of reducing spin time by 5 mins was a significant reduction in some tests (reduction of TAT in mins for AFP 52, amylase 36 and ferritin 81 mins). Before the reduction in spin time, the mean TAT was 80, after this was reduced to 70 mins. There is a 32% reduction in TAT and enhancement in predictability as shown in figure 4 when comparing before (2012) and after (2016) the ACF with reduced spin times. **Conclusion:** The change in spin time of 5 mins delivered a significant change in TAT across many parameters of the ACF which can be explained by the capacity of the system being at a tipping point with the volume of work at the peak time of day. Reducing the spin time by 5 mins resulted in a mean TAT improvement of 10 mins overall. At the busiest time of the day this has resulted in an 18 min TAT improvement. After 3 years' experience with an ACF, there are minor tweaks to be made that may make demonstrable improvement. With a stable automated solution, further enhancements can still be achieved using a Lean approach and focusing on detailed workflow.

B-161

25 OH Vitamin D - Lean production and benefits of immuno-assay

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Background and objectives: The Department of Pathology & Laboratory Medicine has undertaken a systematic review of service provision to ensure that delivery is cost effective and efficient. One of the principles that underpins our service is to embed lean manufacturing principles - so that we are able to meet our customer needs (on time, every time). To that end, we reviewed the provision of 25 OH vitamin D using Xevo TQ-S liquid chromatography mass spectrometry (LC-MS/MS) versus an alternative immuno-assay method on a Roche Cobas 8000 series. It has been estimated that almost one billion people globally have vitamin D deficiency or insufficiency. Vitamin D status in Saudi Arabia is also well documented with >95% of adolescents having deficiency. The workload to screen for 25 OH vitamin D at our hospital has consistently increased by 10% year over year, and currently stands at 40,000 requests per year (September 2016). We present here a 2 instrument comparison study of 25 OH vitamin D using mass spectrometry and immuno-assay and the impact of changing technology on: staffing required, grade of staff and turnaround time (TAT). Our incumbent method required 2 full staff time staff to operate and delivered a mean TAT of 7 days. **Method and results:** EP Evaluator® was used for statistical analysis from the 2 platforms. 25 OH vitamin D was analysed using LC-MS/MS and a Cobas 8000 series system to determine whether the methods are equivalent (total allowable error permitted was 25%). 38 samples were compared which had a range of 8-117 nmol/L. The difference between the methods was within the allowable error for 37 of the 38 samples (97.4). The correlation coefficient (R) was 0.9789. Whisker box plots (WBPs) were chosen to visually show the TAT. Using LC-MS/MS the TAT ranged from 4 to 10 days (25th percentile was 6.89, mean 7.14, 75th percentile 8 days). Scatterplots and index error charts demonstrated good correlation between the methods; correlation coefficient (R) = 0.9789. **Discussion:** Accurate measurement of vitamin D is important as this is an important compound that absorbs calcium and phosphorous. Sufficient vitamin D levels are required for developing and maintaining bones throughout our lives. LC-MS/MS is renowned for its superior analytical performance particularly at the bottom end; our study found that an immuno-assay was comparable in performance. The choice of analytical platform is based on a variety of factors including: quality, hands on time, walk away time, technical expertise needed and cost. Due to the ease of use of the TLA to add another assay, by moving this assay from LC-MS/MS we have:

- Improved TAT (from a mean of 7 days) to a same day service (less than 24 hours),
- Reduced staff time (free-up 2 full time senior staff who were redeployed) and
- Saved money as the cost of immuno-assay less than LC-MS/MS.

Conclusion: Moving to an alternative method for vitamin D resulted in lean service improvements, benefits to patients from more timely results benefits to the hospital by cost avoidance and freeing up staff time whilst maintaining quality.

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Sigma Metric Quality Framework - Analyte Performance Indicator and Quality Improvement Tool

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Backgrounds: Although the concept of sigma metrics as advocated by Dr. JO Westgard in 2001 for quality design and control is widely accepted, professional adoption rate is extremely low. Embedded belief of "the more internal quality control (IQC) is done daily the lower is the risk of making mistake and chance of reporting erroneous result" hindered the profession from moving forward. As at 6 November 2016 fifteen PubMed identified publications with keyword search of [sigma metric and internal quality control (IQC)] stated application of sigma metrics as analyte performance indicator, none reported about the POSITIVE outcome of adopting sigma metrics as quality improvement tool. Since 2010 our laboratory established a **Sigma Metric Quality Framework** with which sigma value was applied not only as performance indicator, but also as quality improvement tool.

Methods: Starting from 1 January 2010 our laboratory determined sigma value of 54 chemistry and 22 immunoassay analytes in Cobas 6000 (Roche Diagnostic), with formula [Sigma metric = (TEa-bias)/CV]. TEa was obtained from respective defined allowable limit of performance of the Royal College of Pathologists of Australasia Quality Assurance Program (RCPAQAP), which is associated with biological variation and analytical goal. Bias and CV were determined from RCPAQAP end of cycle report and observed imprecision respectively. Sigma 3 or lower analyte was identified and compared with that of the RCPAQAP peer as benchmark, required improvement was executed without any delay. Service of below sigma 3 analyte was temporarily suspended until sigma value was improved. Instead of analysing IQC, every eight hours, frequency became analyte performance specific, once, twice and thrice for analyte of sigma >=5, 4 and 3 respectively.

Results: Among 76 analytes, 59(78%), 13(17%) and 4(5%) achieved sigma>=5, 4 and 3 respectively. Four sigma 3 analytes performed equally or better than those of the RCPAQAP peers. Reduction in daily IQC performing frequency of sigma>=5 and 4 analytes contributed to significant reduction in control materials and reagents consumption, which accounted for an annual cost saving of over USD 150,000. Time reduction in IQC preparation, analysis and performance review contributed to an annual man-hour saving of 0.3 full time employee. Without requesting hospital management for additional resource our laboratory increased service scope from 180 analytes to 238, 30% increment.

In 2015 and 2016 our laboratory was categorized by RCPAQAP as GOOD laboratory according to key performance indicator. In October 2016 our laboratory was selected by RCPAQAP as one of the reference laboratories for 2017 target value setting of 5 analytes: Glucose (sigma 8), Lactate (sigma 10), Phosphate (sigma 8), Protein (sigma 5) and Urea (sigma 12) because of past record of good performance and well documented evidence of good analytical performance in the RCPAQAP.

Conclusion: With Sigma Metric Quality Framework, incorporating sigma value as performance indicator and quality improvement tool, our laboratory was able to: (1) Identify bad performing analyte(s), (2) Relate analyte required performance clinically, (3) Set clear & achievable target, and (4) Allocate resources wisely.

B-163

Using the information system to monitor blood culture contamination rate to improve health care quality

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Background

Blood culture (BC) contamination is a common cause lead to misdiagnosis to the interpretation of a positive BC. Treat contaminants as pathogens may leads to unnecessary antibiotic therapy, and induces drug resistant strains. According to Clinical Laboratory Standards Institute (CLSI) standard, BC contamination rate should not exceed 3%. If the nursing staffs fail to follow the correct BC collection standard operating procedures (SOP), they may make the BC contaminated due to insufficient skin disinfection. High contamination rate increase laboratory workload and can cause incorrect changes to patient management. This can prolong patient hospitalization, lead to treatment failure and increase cost to health boards.

Object

In order to effectively monitor the BC contamination rate, our hospital use the information system to regularly feedback BC contamination rate monthly, the number of contaminated cases by each phlebotomist, and the blood volume collected to the emergency department (ED). By data analysis and discussion, we assist the ED to provide educational training and reduce BC contamination rate, then to improve the quality of BC.

Material and Method

To analyze the statistical data from 2015 to 2016, we found 34.0% BC contamination case came from new nursing staffs ; 32.6% contamination occurred at the duplicate staffs in 2015. The BC contamination rates were maintained less than 3% except April to July in 2015 and 2016. This is because the hot climate (>90 degrees) makes patients sweat easily. Routine disinfection methods cannot effectively reduce the number of microbial colonies on the skin surface. The nursing staffs should check patients' skin dirt level and do the appropriate clean before performing blood collection operations.

Result

Through monthly feedback regarding BC contamination rates, and through serious staff education and training in correct BC collection procedures, the number of contaminated BC fell to 13.2% among new nursing staff and 33.3% of duplicate staff were not involved in the collection of any contaminated BC in 2016. Since the ED SOP specified that nursing staff should engage in appropriate skin cleaning before per forming blood collection operations, BC contamination rates decreased from 3.61% to 2.23% from April 2015 to November of 2016. The total decrease was 61.88%.

Conclusion

Laboratory regularly uses the information system to monitor the BC contamination rate, and provide feedback to clinical unit. Through the use of a structured plan and teamwork, it is feasible to assist clinical units in reducing BC contamination rates, patient hospitalization and hospital charges, and to deliver high quality care.

B-173

Comprehensive evaluation of the Internal and External Quality Control Framework annual performance.

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Background: Pursuant to the Standard UNIT ISO 15189:2012 "Medical laboratories — Requirements for quality and competence" the direction of the laboratory must annually revise the performance of the External Quality Assurance Services (EQAS) and of the Internal Quality. The aim of this work is to design a tool to make the annual evaluation of the analytical performance of the tests easier for the Direction and to allow a revision of the used Total Allowable Error (ETa), integrating concepts of ETa, bias and sigma metric. **Methods:** The results of twelve surveys of the External Quality Evaluation Program EQAS® BIO-RAD from 2016 were used to evaluate the performance of twenty-four biochemistry tests. The evaluated assays were processed in a homogenous system, analytical platform Architect ci8200 and Abbott manufactured reactive. The performance indicator estimated through EQAS was the bias expressed as the percentage of the ETa [Bias (%ETa)]. The integration of results of the Internal Quality Control System evaluation was represented by the annual sigma metric, which was estimated for each test from the monthly calculation of the performance of the limiting control level, using as reference the results of the inter-laboratory comparison program (BIO-RAD) from 2016. Sigma metric was charted as a function of the Bias $(\%ETa)_{2016}$ and of the relationship Bias $(\%ETa)_{2016}$ / Bias $(\%ETa)_{2015}$. This graph made possible the integration of the performance of the internal and external quality control evaluation programs as well as the evolution of the EQAS performance throughout time. A test performance was considered satisfactory when the Bias $(\%ETa)_{2016}$ was lower than 50% and the sigma higher than 5.15. It was defined that all tests with Bias $(\%ETa)_{2016}$ higher than 25% and a relationship Bias $(\%ETa)_{2016}$ / Bias $(\%ETa)_{2015}$ higher than 1.5 and lower or 0.5 would be evaluated to monitor the evolution of performance. Two areas were identified in the graph for which a revision of the ETa was needed, one defined for an ETa [Bias $(\%ETa)_{2016}$] lower than 25% and a sigma higher than 12 and the other one defined for an ETa [Bias $(\%ETa)_{2016}$] higher than 50% and a sigma lower than 5.15. **Results:** The performance of the 24 evaluated biochemistry tests was satisfactory. No cases showed significant performance modification from one year to the following one. In eight tests a revision of the ETa was needed to evaluate the possibility of reducing it, no tests needed an increase in the ETa. **Conclusion:** The tool allowed for a way to simply and graphically summarize the annual performance of the analytical procedures. The means used for presentation were effective for the communication of the analytical performance to the Laboratory Direction and to carry out a revision of the ETa.

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Serum uric acid laboratory test in primary care: a high requested inexpensive test with potentially costly adverse effects

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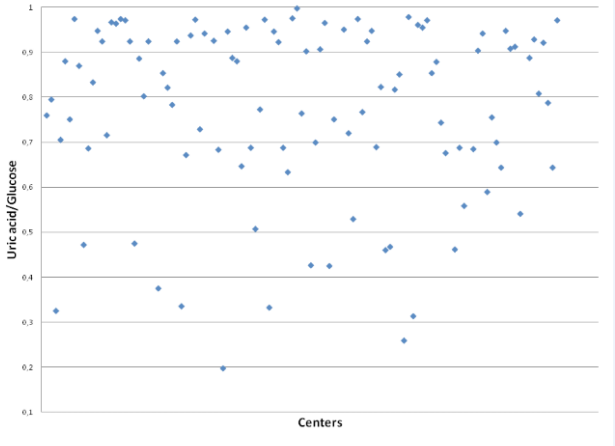
Background: The power of every diagnostic procedure will be closely conditioned to the clinician's use of it. The aim is to study the request of uric acid (UA) from primary care, regional variability, root causes of requesting patterns and potential demand inappropriateness.

Methods: A cross-sectional study was designed and conducted at a main core laboratory. Spanish laboratories were invited to report their number of serum glucose and UA tests for year 2014, and their organizational data. A survey was sent to every participant regarding UA inclusion in profiles. The request of UA per 1000 inhabitants and ratio of UA to glucose demand (UA/glucose) were calculated and compared between the different regions, and between laboratories where UA was included or not in "health check profile".

Results: 110 laboratories participated (59.8% Spanish population). The overall request of UA per 1000 inhabitants was 296.3 (CI95%: 272.7-312.8). The median UA/glucose ratio was 0.82 (IQR: 0.25); 41 out of the 110 participants had a value above 0.9 (Figure). There was a significant high regional variability for both indicators (P≤ 0.05). Laboratories where UA was not included in the "health check profile" had lower results for both indicators (P≤ 0.05).

Conclusion: There was a high regional variability and overall inappropriate over request for UA in primary care. Inclusion of the test in "health check profile" was probably the main cause behind the observed misuse.



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Request pattern, preanalytical and analytical variability and economic costs of urinalysis in primary care

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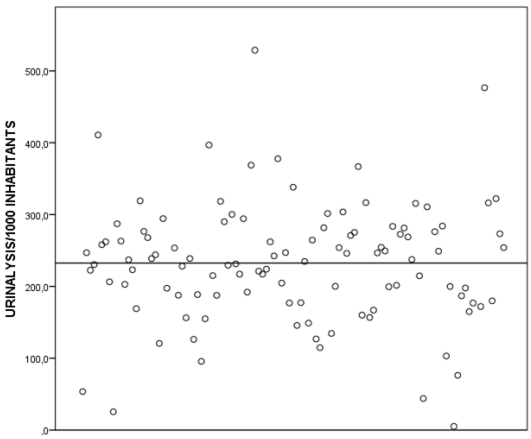
Background: The aim was to study the requesting pattern of urinalysis by General Practitioners (GPs), its potential regional variability, and the pre-analytical conditions and economic cost regarding sample collection and analysis. **Methods:** Participating laboratories across Spain reported the number of urinalysis performed in year 2014. We calculated the number of requests per 1000 inhabitants, and the regional differences between autonomous communities (AACCs). A survey was sent to participants regarding pre-analytical sample collection and transport, procedure of analysis, and strip reagent cost.

Results: 110 laboratories from 15 AACCs participated in the study. On average 232.5 urinalysis were requested per 1000 inhabitants. Figure displays the number of urinalysis requested per 1000 inhabitants in each laboratory. There were no statistically significant differences between AACCs. The strip cost in our patient cohort for year 2014 was 2526404.4€. There was a 63% in survey participation. It showed that most laboratories used the first morning urine, most frequently collected at home and delivered to a primary care center (PCC), and transported to the laboratory 2 to 4 hours later. Most laboratories combined initial test strip analysis followed by particle analysis based on automatic decision algorithms. The rate of particle analysis varied between laboratories. **Conclusion:** There is a variability in the request of urinalysis by GPs, no differences between regions and when included or not in Health Check Profile. Also we observed an overall lack of compliance with the time between micturition and analysis. Our results suggest the need for efforts to improve pre-analytical conditions and to standardize and systematize the algorithms for particle analysis.



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U.S Clinical Laboratories in the Era of the Clinical Laboratory Improvement Amendments (CLIA)

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Background: To describe the dynamics of the U.S. clinical laboratory system and investigate the characteristics associated with active clinical laboratories.

Methods: Using the Centers for Medicare & Medicaid Services CLIA database, we described the dynamics of clinical laboratory history since the inception of CLIA. We compared the characteristics of currently active laboratories vs those no longer active. We calculated lifespans of laboratories, and performed Cox regression to determine the factors associated with active laboratories.

Results: Since 1992, there have been 488,829 clinical laboratories ever operating. Among them, 257,621 (52.7%) were still active at the end of 2016. CA, FL, and TX each had more than 20,000 active laboratories; on per capita basis, FL, IA, SD, NE, and WV had more than 10 active laboratories per 10,000 population while CA, NV, NY, and WA had less than 6 active laboratories per 10,000 population. The number of active laboratories has been increasing since 1995. The net annual increase has been between2-6%. Based on self-designated laboratory type, the numbers of physician office laboratories increased the most (84,861 to 122,576). Based on certificate type, numbers of laboratories with certificates of waiver (CoW) increased the most (78,122 to 185,717). Among the 50 States, NE, ND, and SD had the highest proportions of laboratories that remained active (>65%) while CA, DC, DE, LA, ME, NV, NY, OK, and RI had less than 50% laboratories that remained active. When categorized by ownership, government laboratories (federal, state, county, city and other) had a higher proportion of laboratories that remained active (63.4%%) than non-government laboratories (54.8%). When categorized by laboratory types, 63.7% and 48.2% of hospital and physician office laboratories remained active respectively. When categorized by certificate, 64.0% of laboratories with certificates of accreditation (CoA) and 57.0% with CoW remained active. Laboratories that were no longer active had a mean lifespan of 6.6 years versus 12.3 years for laboratories that remained active (December 31, 2016 as cutoff date). For laboratories that were no longer active, the lifespans for government laboratories and non-government laboratories were 7.0 vs 6.6 years; CoA, certificate of compliance (CoC), certificate of PPM (PPM) and CoW laboratory lifespans were 9.4, 8.0, 8.7 and 6.5 years, respectively. Skilled nursing-home laboratories, public health laboratories, and hospital laboratories had the longest lifespans, while home health-agency laboratories, independent laboratories, and pharmacy laboratories had the shortest lifespans. In Cox regression analysis, government laboratories were more likely to remain active compared to non-government laboratories. CoA and PPM laboratories were more likely to remain active compared to CoW. Hospital laboratories, skilled nursing-home laboratories, ambulatory surgery center laboratories, and end stage renal disease dialysis laboratories were more likely to remain active compared to physician office laboratories.

Conclusion: The U.S. clinical laboratory system is dynamic. The number of laboratories has increased since 1995particular CoW laboratories. The lifespan was 12.3 years for current active laboratories as of Dec. 31, 2016. While other factors may have been reported as impacting laboratory sustainability, this study reveals new insight in that geographic location, ownership, certificate, and laboratory type are associated with laboratories' active status.

B-177

Clinical Significance of Duplicate Results for Components of Chemistry Panels Ordered on Inpatients

E. W. Holmes. *Department of Pathology, Loyola University Medical Center, Maywood, IL*

Background: There is a consensus that as many as 30% of the laboratory tests that are ordered on hospitalized patients might be unnecessary. While the sheer frequency of excessive ordering seems to be sufficient to justify limitations on the number of panels that can be ordered per hospital day, a more compelling reason to limit replicate ordering would be to demonstrate that the differences between the test results of frequently ordered panels are not clinically significant. This study was undertaken to evaluate the analytical and clinical significance of changes over time in the individual analytes of duplicate CMP and BMP panels that were ordered on hospital inpatients.

Methods: I evaluated the differences between 48052 replicate test results for each of the eight components of the BMP and 13200 replicate results for each of the 6 components that are unique to the CMP in 19995 inpatient encounters (of > 24 hr.duration) that occurred between 10/1/2014 and 1/31/2015. Data were obtained from my institution's HIS, de- identified, imported into a SQL database and analyzed with a query that compared the first result for each component of the first panel that was ordered with the result obtained for each component of the second panel (i.e. the first duplicate) that was ordered. The results for the second panel were, likewise, compared with the results for the third panel ordered (i.e. the second duplicate), etc. The query returned many details about each series of replicated panels including the absolute and percent differences between the analyte values for each pair of duplicate results, whether or not the difference between duplicate results exceeded the analytical error or the critical difference for the particular analyte, or differed from the previous result relative to the reference range for the particular test.

Results: In the case of the differences between duplicate results for the BMP components, an average of 50.7% (min: 31.8, max; 63.4) were within the analytical error of the respective test, an average of 19.8 %(min: 12.0, max: 41.2) percent exceeded the respective critical difference for a serially monitored test, and an average of 14.9 % (min: 7.5, max: 22.5) of the duplicates changed relative to the reference limits for the respective test. In the case of the duplicated results for the CMP components, an average of 61.0 % (min: 42.9, max: 88.8) were within the analytical error of the test, 13.5 % (min: 2.9, max: 24.8) exceeded the critical difference; and 9.5 % (min: 6.4, max: 14.7) changed relative to the reference limits for the test.

Conclusion: My data indicates that the majority of changes in the results of the BMP and CMP panels, as revealed by replicate testing within a 24-hour period, were not clinically significant. The time intervals between replicate panel orders suggests that most of the testing during the study period was driven by standing orders in the HIS rather than by changes in the clinical status of the patients.

B-178

Innovative use of Sunquest Blind Duplicate function for expanded quality control

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Background:

"Blind duplicates" provide a quality control process for using duplicate patient specimens to enhance additional quality control. Sunquest Laboratory™ has a blind duplicates function (BDUP) that allows Multicare Health System (Multicare) to easily check one instrument against another using established criteria to evaluate variations in actual patient results obtained and then graph them on a Levy-Jennings plot. We perform this daily at sites with two or more instruments and monthly between all additional sites to help validate that each instrument is turning out correlated patient results.

Multicare uses this function to both test similar instruments (i.e, Abbott Architects ci8200, ci4100) and check the analyte on different instruments. For example, daily we run BDUP patient samples on the Abbott Architect for five analytes and correlate this with four NOVA Stat Profile CCX instruments. This helps monitor the correlation of analyte results with other instruments and methodologies on a more frequent basis, instead of every six months, and removes the need to perform linear regression correlations. This frequent monitoring uses a software function to plot the values. The Sunquest BDUP results are then monitored using quality control rules and rule failure documentation like standard quality control materials.

Methods:

In all cases, we select an analyte and a primary instrument. We define the BDUP mean as zero and identify a standard deviation that is acceptable or targeted. The specimen is run on the primary instrument and the results are accepted in Sunquest. The same specimen is analyzed on different instruments and Sunquest will plot the variance on a Levy –Jennings plot. For example, the BDUP potassium QC mean is set to zero and the standard deviation is defined (we use 0.15 mmol/L – for one standard deviation). The specimen is analyzed on the primary instrument and a potassium value of 3.5 mmol/L is obtained. The same specimen is analyzed on a different instrument with a result of 3.7 mmol/L. Sunquest BDUP will plot this difference for Potassium BDUP as +0.2 mmol/L (which is within 2 standard deviations). Sunquest quality control flagging occurs so we can view results on a daily or weekly report and supporting graph.

Results:

Multicare has 11 Abbott Architects located at six laboratories and 18 Sysmex hematology instruments in 13 laboratories. Monthly: we run 25 chemistry and 19 hematology assays using three to four specimens on primary instruments in the core lab and compare to all other instruments. Daily: BDUP function is performed on 16 chemistry analytes every eight hours for labs with two or more analyzers.

Conclusion:

The BDUP quality control strategy is a fully automated report from Sunquest. We utilize our couriers to transport the monthly specimens to other laboratories. These comparisons allow us to identify shifts due to reagent lots, instrument and assay errors, and validate on a daily, weekly or monthly basis that all of our instruments are comparable and reporting consistent correlated patient results.

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Reducing Unnecessary Bilirubin Measurements

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Introduction: Serum index measurements, including icterus index (IC) measurement, are routinely performed on all clinical specimens in many laboratories. This studies examines whether IC values can predict hyperbilirubinaemia and can potentially be used to avoid unnecessary total bilirubin measurements. **Methods:** In our laboratory, serum index measurements are automatically performed on all samples analysed on the 3 Beckman Coulter DxC-800 clinical chemistry analysers. Anonymised details of all simultaneous IC and total bilirubin (diazo, manufacturer supplied reagent) measurements for 6 months (Jan to June 2016) were extracted from the laboratory database. The locally derived total bilirubin reference interval is 7-31 umol/L. Excel 2003 and Analyse-it were used to prepare a ROC curve to assess the ability of IC to predict TBil > 31 umol/L. **Results:** There were 51111 paired IC and total bilirubin results. In 5562 (10.9%) cases, total bilirubin > 31 umol/L. The sensitivity and specificity, with 95% CIs, for IC to predict total bilirubin > 31 umol/L were: for IC >0 (i.e >=1): sensitivity 1.000 (0.999-1.000), specificity 0.004 (0.003-0.005); IC >1 (i.e. >=2): sensitivity 0.992 (0.989-0.994), specificity 0.753 (0.749-0.757). Using an IC>0, 183 tests are avoided (at a cost of 2 false negatives) and IC>1, 34345 tests are avoided (at a cost of 47 false negatives). **Conclusion:** Withholding total bilirubin measurement on specimens with icterus index (IC) of 0 or 1 would reduce total bilirubin test volumes by 67% with only a 0.08% false negative rate. The false negative rate could potentially be reduced further on analytical systems reporting smaller IC increments. The logistics of performing IC measurement prior to initiating bilirubin measurement would require close collaboration with diagnostic manufacturers and middleware/ laboratory information system vendors.

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Project management tools for implementation of instruments across a multi-site academic medical center

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Background: The decision to change hematology platforms with new analyzers presented the issue of how to streamline the process of installing and validating thirteen instruments in five separate labs. A structured process required preliminary meetings with the hematology director. Project co-chairs were determined and a shared network folder was established. Participants in the implementation would include staff at varied levels of depth including directors (both clinical and administrative), managers, lead technologists and key operators. Clinical Laboratory Improvement Amendment (CLIA) and College of American Pathologist (CAP) guidelines would be followed for the instrument method validation.

Methods: Microsoft OneNote was utilized for the initial planning which included stakeholders, timelines, renovations, water system installations, expense tracking, and training resources. Managers were able to add individual lab information which could be viewed by all project members. Weekly meetings were established with the vendor project coordinator as well as internal project team meetings. A question and answer spreadsheet was created to address and follow-up with concerns. A shared network drive included specified folders for method validation subsets (accuracy, precision, carryover, linearity, correlations, raw data, differential flagging, mixing studies, reference range and stain validation), meeting minutes, safety, instrument specifications and vendor white papers. A method validation checklist was used to ensure all components were completed as required by CLIA. A task list and associated checkoff spreadsheet were created with targeted due dates. The checkoff included varied tasks from method validation to asset tracking to monitor each lab's progress. Staff training was accomplished using multiple methods: a key or lead tech spent one week with the clinical applications specialist, all staff were required to complete e-learning modules prior to using the instrument, and a virtual classroom was offered as an optional training setting.

Results: The implementation process required logical and strict timelines to complete the project. Staff were assigned to e-learning in segments to align education with implementation stages (overview, instrumentation, QC and software). Once instruments were installed and clinical applications completed, the raw data was evaluated by the division director. During this timeframe, the Laboratory Information Systems (LIS) department partnered with the vendor to develop and test the middleware application. Procedure writing, mixing studies, reference range validation, reagent purchasing application, and safety requirements were completed. One global procedure was instituted versus five individual procedures. Final testing with specimens led to the unified go-live date.

Conclusion: The implementation process required engagement by project members at weekly web conference meetings. Using OneNote facilitated a global overview of the project with each lab able to see the progress. However, due to most staff being unfamiliar with OneNote, this could be easily manipulated with the potential for data loss. Structured folders were used for storing and evaluating data to secure information. The project required a degree of trust that all components were being addressed, but needed to take place in an organized fashion. A participant survey was conducted after the live date to gauge the overall process. The project was effective and efficient utilizing the management tools with aligned communications.

B-182

Correlating Clinical Laboratory Characteristics to Proficiency Testing Misuses and Good Laboratory Practices

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Background: In 2013, the Centers for Disease Control and Prevention and the Association of Public Health Laboratories implemented a national survey about proficiency testing (PT) use and scored responses as good laboratory practices (GLP) or PT misuse [not allowed by the Clinical Laboratory Improvement Amendments (CLIA)]. Using statistical analysis, we investigated if specific laboratory characteristics correlated with PT GLPs or PT misuses.

Methods: The dependent variables were summary scores calculated from 10 PT GLP and 6 PT misuse questions. Higher GLP scores indicated better laboratory PT practices and lower PT misuse scores denoted less PT misuse. Descriptive statistical analysis characterized laboratories using laboratory certification, laboratory type, size by annual test volume, and rural/urban status according to Rural Urban Commuting Area codes (RUCA) as the independent variables. ANOVA analyses compared scores among laboratories with different attributes and multivariate linear regression identified independent factors associated with summary scores. The F test was used to examine if each independent variable was significant as a group because the independent variables were categorical variables.

Results: Among the 769 laboratories that responded to the survey, 309 (40.2%) laboratories were CLIA Certificate of Compliance (CoC) laboratories and 460 (59.8%) were under Certificate of Accreditation (CoA). There were 486 (63.2%) laboratories with annual test volumes of less than 300,000; 116 (15.1%) with volumes between 300,000 and 700,000; and 167 (21.7%) with volumes of more than 700,000. There were 468 (60.9%) laboratories in urban areas, 111 (14.4%) in large rural areas, 107 (13.9%) in small rural areas, and 75 (9.8%) in isolated rural areas. The mean score for PT GLPs was 5.6 (range 0-10). ANOVA analyses indicated differences in scores were statistically significant for laboratory certification, laboratory type, size, and RUCA classification. Multivariate linear regression results revealed statistically significant differences between CLIA CoC laboratories and CoA Laboratories. Compared to physician office laboratories (POLs), all other laboratory types had statistically significant higher GLP scores. Medium and large laboratories had statistically significant higher GLP scores compared with small laboratories. Compared to laboratories in urban areas, laboratories in small rural areas had statistically significant higher GLP score; however, rural /urban locations were not statistically significant as a group. The mean score for PT misuse was 0.4 (range 0-6). Most laboratories (552; 71.8%) had no PT misuse. Compared to (POLs), only hospital laboratories had statistically significant lower misuse score. Compared to laboratories in urban areas, laboratories in large rural areas had statistically significant lower misuse score. These differences were statistically significant at the p= 0.1 level. Laboratory certification and size were not statistically significant.

Conclusion: The results show that most responding laboratories did not misuse PT and suggest that medium and large laboratories tend to have higher PT GLP scores as do non-POLs. Laboratory size and certification did not correlate with PT misuse scores. The results can be used to identify strategies to target laboratories for efforts to reduce PT misuses and promote PT GLPs.

B-183

Impact of targeted test utilization strategy for Vitamin D testing

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Background and objective: Optimizing test utilization is an important responsibility of Clinical laboratories. Of particular interest is Vitamin D testing. Manitoba, Canada, has observed a significant increase in the number of Vitamin D tests ordered over the past few years, creating a significant backlog in its testing. To improve test utilization, a strategy for the optimization of Vitamin D testing was implemented in 2016. This included the use of a care-giver signed test-specific requisition and eight approved indications for which testing is allowed. The objective of this study is to evaluate utilization profiles of vitamin D testing post restricted ordering strategy. Specifically, the study aims to analyze the specialties ordering this test and the clinical indications. **Methods and results:** A sample of 1500 requisitions covering a period of 2 months (Aug 2016 and Oct 2016) were manually screened to obtain information on the patients age and sex, the clinical indication for ordering the test, and the medical specialty of the ordering physician. After the implementation of the test-specific requisition, a significant change was observed with regards to the medical specially ordering the highest number of tests. Before test-specific requisition implementation, test requests made by family physicians made up 70 % of all requisitions, while after, family medicine only accounted for 44 % of the tests ordered. This is indicative of a more targeted and relevant use of Vitamin D testing. Analysis of the test-specific requisitions also demonstrated that the top two clinical indications for ordering Vitamin D testing are malabsorption syndromes (40 % of all Vitamin D tests) and suspicion of metabolic bone disease (30 % of all Vitamin D tests). Furthermore, greater than 75% of tests ordered by a particular specialty were for indications directly relevant to that specialty. For example, 88 % of all tests ordered by rehabilitation medicine corresponded to a clinical indication of metabolic bone disease. **Conclusions:** The introduction of a test-specific requisition for restricted clinical indications to improve test utilization for Vitamin D has proven to be a success. The strategy has enabled targeted vitamin D testing where needed. Information gathered from this study may help to further refine test optimization strategies, not only for Vitamin D, but for many other analytes that are currently plagued with over utilization.

B-184

Use of the Westgard Sigma Approach to Plan and Evaluate QC Rule Management in a New Automated Core Testing Line in an Integrated Regional Healthcare System

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Background: The Geisinger Medical Laboratories support an integrated healthcare system in Central PA which includes 7 hospitals, 3 specialty clinics, 8 regional clinic laboratories and a central reference laboratory. We have annually reported on enterprise-wide use of Westgard sigma statistics and a customized QC rules approach to routine Roche chemistry, Sysmex hematology and Stago coagulation instruments. We recently reported five years experience of monthly monitoring of sigma statistics for continuous verification of instrument performance (Clin Lab Med 2017; 37:207-41). A new central laboratory building with expanded core automation was opened in late 2015, and we herein report the sigma statistics for the first full year of operation of the new chemistry automation line.

Methods: The new automated laboratory line consists of a Roche Cobas 8100 automated preanalytical processing line with three Add-on buffers and a p701 robotic sample refrigeration unit. Attached to the 8100 are three Cobas 8000 chemistry lines, two Stago Star Evolution coagulation units, and a Sysmex 9000 hematology line. The three Cobas line configurations are 702-502-502-602, 702-502-602, and 602-602-602-602. The Cobas 702 and 502 analyzers are chemistry and the Cobas 602 analyzers are Immunoassay instruments. Control materials were from Bio-Rad with results data transmitted to Bio-Rad Unity Real Time through Roche DI middleware.

Results: Sigma values were calculated, tabulated, and averaged for twelve months for the instruments and control materials listed above using the equation Sigma = (TEa-bias)/CV, where TEa was determined by CLIA or CAP PT performance requirements, and bias was determined against the Bio-Rad peer group. The data for the new line were compared to Sigma data that was previously generated on Roche instruments replaced by the new automation. In addition to identifying many world class assays, we also identified a number of assays that had sigmas that varied substantially between low and high measurement ranges. These are mainly precision effects and represent targets for analytical improvement.

Conclusion: The new chemistry line incorporates some 80 analytes whereas the older line had 50. Although some of the assays had lower sigmas that required standard Westgard rule implementation, the majority of assays on the new line (44 of 80) had average Sigmas in excess of 6, and QC precision well within CLIA error limits. An additional 14 assays had sigma values between 4 and 6 and, as anticipated, this level of performance allowed us to use a 1-3s or 1-4s rule on more than two-thirds of assays. Our data also showed nine common assays with sigma values substantially higher than values cited by Marques-Garcia F, et al (Revista de Caldidad Asistencial 2015; 30:302-9) for the 8000 c701 in 2015, perhaps reflecting assay or instrument changes.

B-185

Switching from MDRD to CKD-EPI - A Singapore Hospital Experience

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Background: Glomerular Filtration Rate (GFR) is used in the diagnosis of chronic kidney disease (CKD) and is an independent predictor of all-cause and cardiovascular mortality and kidney failure in a wide range of populations. Clinical guidelines recommend reporting estimated GFR when serum creatinine level is measured. Although the Modification of Diet in Renal Disease(MDRD) Study equation is recommended for estimating GFR, the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) has recently proposed an alternative equation, which applies different coefficients to the same 4 variables used in the MDRD Study equation (age, sex, race, and serum creatinine level). The aim of this study was to assess the agreement between kidney function as estimated by the MDRD and CKD-EPI equations.

Methods: We retrieved all creatinine test results performed in our laboratory using Abbott Architect enzymatic assay from 01 January to 30 September 2016. **Results:** There were 93,343 tests performed with the following demographics and presentations: Age (21 - 91, 2.5th - 97.5th percentile respectively), Sex (Male 54.7%, Female 45.3%), Presentation (Inpatient 38%, Emergency 38%, Outpatient 24%). Estimated GFR was classified into 6 categories (≥90, 60-89, 45-59, 30-44, 15-29, and ≤15 L/min/1.73m2) by both equations. Compared with our current MDRD Study equation (IDMS traceable multiplier 175), 21.2% and 10.5% of participants from our study population were reclassified to a higher and lower estimated GFR category, respectively, by the CKD-EPI equation, and the prevalence of CKD stages 3 to 5 (estimated GFR ≤60 mL/min/1.73 m2) was reduced from 30.8% to 30.2%. In estimated GFR of 45 to 59 mL/min/1.73m2 by the MDRD Study equation, 11.2% of participants were reclassified to estimated GFR of 60 to 89 mL/min/1.73m2 by the CKD-EPI equation. **Conclusion:** The CKD-EPI equation classified fewer individuals as having CKD. We recognized that this simple exercise needs validation on overall diagnostic efficiency and associated clinical outcomes. It is hoped that this switch will mostly benefit people with mildly to moderately reduced GFR but who have otherwise no evidence of kidney disease, avoiding them from unnecessarily becoming "patients with a chronic disease" and allowing nephrology resources to be more concentrated on the patients that require it.

B-186

Computing a Risk Management Index: Correlating a Quality Control Strategy to Patient Risk

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Background:

Managing the risk of patient harm from erroneous test results has become a focus for quality control strategy design in modern laboratories. Unfortunately, many of the solutions addressing this issue lack quantitative rigor.

Using the *CLSI EP23-A: Laboratory Quality Control Based on Risk Management* risk model, we present a method for using a quality control strategy, test method performance, and test method reliability to compute the predicted probability of patient harm from erroneous test results (erroneous results have measurement error that exceeds the allowable error, TE_a).

The predicted probability of patent harm is compared to the acceptable level of probability of patient harm to determine if the risk of patient harm has been adequately managed.

Methods:

The predicted probability of patient harm as a function of systematic error can be computed as:

$P_H(SE)=\{P_E(0)+E(N_{ut}(SE))/[MPBF+ANP_{ed}(SE)]\}*P_{h|u}$

Where:

$P_E(0)$ is the probability of producing erroneous results in the stable state.

$E(N_{ut}(SE))$ is the expected number of erroneous final results reported due to out-of-control condition, magnitude SE.

MPBF is the average number of patient results reported between out-of-control conditions.

$ANP_{ed}(SE)$ is the average number of patient results reported during out-of-control condition, magnitude SE.

$P_{h|u}$ is the probability that a reported erroneous result leads to patient harm.

Acceptable P_H is derived from the risk acceptability matrix.

RMI=Predicted P_H/Acceptable P_H

Results:

Example calculation:

Glucose: CV=2.5%,TE_a=±10%.

QC Strategy: 2 QC levels, 1:3s/2:2s/R:4s Rule, evaluated every 50 results.

Mean days between test system failures=90.

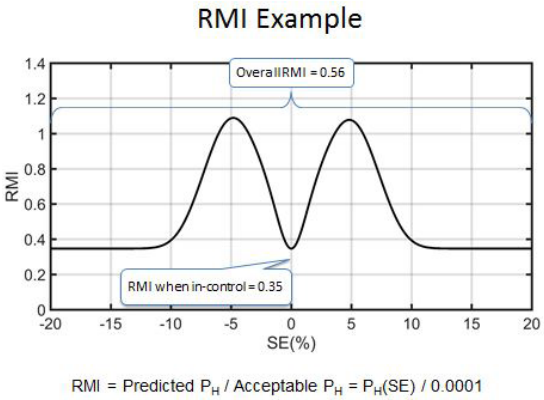
Average #patient results/day=100.

MPBF = 100*90=9,000.

Probability of harm given erroneous result, $P_{h|u}$=0.5.

Severity of Harm for Glucose=Minor

Acceptable frequency of harm=Occasional(1/10,000).



Conclusion: Computing a Risk Management Index (RMI) based on the ratio of predicted probability patient harm and the acceptable probability of patient harm makes it easy to assess acceptable risk management. An RMI ≤ 1 indicates managed risk. An RMI > 1 indicates unmanaged risk.

B-187

Application of Statistical Process Control (SPC) for Evaluation of Immunoassay Reagent Manufacturing

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Background: Statistical Process Control (SPC) is a statistical tool for the recognition of potentially assignable variations from random variations in a process (Statit Software, Inc., 2007). Fujirebio reported a preliminary application of SPC in monitoring of the manufacturing of one immunoassay product (He KL, et al, 2012). In the current study, SPC was applied to evaluate the manufacturing processes of six immunoassay reagent sets. **Methods:** All of the six assay reagent sets represent a chemiluminescent microparticle immunoassay (CMIA). Each set of the assay reagents is primarily composed of a bottled solid phase and a bottled conjugated antibody. Acceptable values (performance limits) of specific parameters, which include signal response for Calibrators and concentration response for Controls and Panels, were routinely reviewed from the Quality Control (QC) testing of the bottled reagents. SPC analysis was conducted to evaluate the process capability of the assay reagent manufacturing. Process capability index CpK represents the proportion of one side of the normal probability distribution curve of variables that will fall between the average and the nearest performance limit. In the current study, a CpK value was generated for each of the Controls, Panels and selected Calibrators for a two year period (n = 23 to 85) for each of the six assay reagent sets. **Results:** The distribution of the measurements for each of the specification parameters showed a normal distribution pattern for each reagent set. In total, 53 CpK values were obtained for the six reagent sets for up to nine specification parameters (Calibrator A and F signals, B/A ratio; Control L, M, H; Panel 1, 2, 3 and 4). 73.6% (39) of the 53 bottled reagent processes with a CpK value ≥ 1, demonstrated a process capability at acceptable 3-sigma or higher levels with at least 99.73% processes meeting requirements; 17.0% (9) with a CpK value ≥ 0.67 but < 1.00, demonstrated a 2-sigma of process capability with at least 95.45% processes meeting requirements; and 5.7% (3) with a CpK value < 0.67, indicated only a 1-sigma of process capability in which only 68.27% or more of the processes meet requirements. Assay reagent set wise, one set showed at least 99.73% of chances meeting requirements, and one set showed at least 95.45% of chances meeting requirements. One of the lowest CpK values at 0.487 was found to be attributable to a raw material switch. After the raw material switch issue was resolved, this CpK value at 0.487 was obviously improved to 1.68, demonstrating an improved process capability higher than 3-sigma level with greater than 99.73% processes meeting requirements. **Conclusion:** SPC allows for detection of variability of reagent manufacturing processes, provides a statistical tool for the detection of potential process trends, and identifies areas for improvement opportunities to support the commitment to Total Quality Management.

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Urinalysis with Reflex Culture - Test Utilization Initiative and Quality Improvement Model

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Practicing effective laboratory test utilization has become a necessity. Performing medically unnecessary lab tests increases operational expenses, results in staff burnout, leads to more abnormal results to be followed, more critical results needing notification and hospital-acquired anemia which can reduce patient safety as well as cause iatrogenic disease.

By the end of 2015, more than 3,000 urine cultures were performed in our Microbiology Laboratory per month. There were concerns that many urine cultures were ordered unnecessarily, yet still yielded positive results due to specimen contamination and not true infection. A potential best practice for ordering a urinalysis with reflex to culture was identified to decrease the performance of unnecessary urine cultures while improving utilization. We hypothesized that setting a result threshold for leukocytes for automated urinalysis could reduce the performance of these needless cultures which falsely elevated the rate of catheter-associated urinary tract infection (CAUTI). Furthermore, this could lead to better antimicrobial stewardship by reducing the number of patients exposed to unnecessary, expensive and potentially toxic antibiotics.

Staff and faculty from the lab were selected to establish a new process for urinalysis with reflex to culture. A project charter identified the sponsor (sets direction, allocates resources, removes barriers, makes decisions), manager (coordinates the project team), project team members (help define charter, provide input, complete assigned tasks), and other stakeholders affected. A business case with problem statement was created to ensure that team members had a common understanding of all aspects of the project. The overall project goals were to reduce urine cultures performed by 33% with a stretch goal of 50%.

With the support and involvement of our Chief Medical Informatics Officer as well as members of our EMR team (Epic) and LIS team (Sunquest), a new Urinalysis with Reflex Culture (UARC) order was developed to replace the previous stand-alone urine culture order. In the new process, urinalysis is performed prior to all urine cultures with reflex cultures only being performed when criteria for pyuria (≥6 WBC/hpf) are met unless one of six pre-determined clinical patient exceptions are met. EMR ordering allowed for these exceptions to be recorded at time of order in which case the culture was performed even if the urinalysis was negative for pyuria.

Successful implementation also necessitated buy-in and input from other stakeholders. Project team members met with clinicians from Infectious Disease, Urology, Obstetrics, Neonatal, Pediatrics and Maternal Fetal Medicine to ensure that the unique needs of patients managed by these departments were addressed. An extensive communication plan was developed, to ensure that all providers, caregivers and other stakeholders were knowledgeable regarding implementation of ordering urinalysis reflex to cultures. Effective communication and collaboration between multiple departments yielded impressive results. In the first thirty days after implementation,

urine culture workload decreased to 1,713 (57 /day). Over the next six months, a 47% reduction in urine culture workload was sustained with substantial estimated annual savings in direct lab operational expenses while the quality metric target for the institution's CAUTI rate was reached.

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An enzyme-linked immunosorbent assay for therapeutic drug monitoring of golimumab

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Background: Golimumab is a therapeutic anti-TNF monoclonal antibody approved for use in moderate to severe ulcerative colitis (UC). The PURSUIT trials showed a significant exposure-response relationship of golimumab in UC. Interindividual differences in response to golimumab treatment may be explained in part by interindividual variability in pharmacokinetics.

Methods: Microtiter plates were coated with recombinant human TNF-alpha. Samples diluted at 1:100 were added to the microtiter plate for binding, and bound golimumab was detected using mouse anti-human immunoglobulin G1 (HRP-anti h IgG1). Performance characteristics of the assay were determined according to the European in-vitro diagnostic devices directive 98/79/EC.

Results: An enzyme-linked immunosorbent assay (ELISA) for the detection of golimumab drug concentration was developed. The limit of detection (LoD) for golimumab determination in human serum samples was 3.56 ng/mL. The measuring range of the assay was determined to be 0.415-22.5 µg/mL. Intra-assay variation (n=19) was ≤6.6%, while inter-assay variation (n=11) was ≤5.3%. Linearity testing was performed by analysis of three serially-diluted samples spiked with golimumab; golimumab concentrations measured by the new assay were within 98-129% of the expected concentrations. The assay detected no false-positive signals from samples taken from untreated patients. Due to the use of TNF-alpha as a capture reagent, other TNF-alpha blockers were detected.

Conclusions: This newly-developed ELISA method is rapid, accurate and reproducible. The use of monoclonal antibodies to golimumab could improve the specificity of the assay. The ELISA may be useful not only for pharmacokinetic/pharmacodynamic studies, but also in therapeutic drug monitoring of golimumab.

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Evaluation of analytical performance and internal quality control procedure of an enzymatic method for measurement of Glycated albumin

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Background: Strict control of plasma glucose levels is critical in the management of diabetes to avoid the potentially serious complications. The measurement of glycated albumin (GA) has been widely used in clinical practice as a new diabetes maker and intermediate glycation index for diabetes control. When monitoring the effects of therapy in patients with a varies of pathological state, such as gestational diabetes, unstable plasma glucose levels, varian themoglobins, and diseases that shorten the lifespan of erythrocytes, the GA level could provide useful information for the management of glycemic control. Lucica GA-L assay kit is a novel enzymatic diagnostic test for GA measurement and has been introduced for use in automated chemistry analyzers.The aim of our study is to evaluate the analytical performance and internal quality control procedure of an enzymatic method for measurement of Glycated albumin

Methods: The enzymatic GA assay was carried out in the ADVIA2400 chemistry system and the imprecision, accuracy, limit of quantification (LoQ), and linearity were evaluated according to the recommendation of CLSI documents (EP-15A2, EP-17A, and EP-6A). The internal quality control (IQC) data were collected from June to December 2016.The imprecision was calculated by accumulative CV, while the bias was calculated by the mean value of the IQC data across of global regions. Individual quality control scheme for GA analysis was developed combined with Function Power Graph and Six Sigma Chart based on 10% allowable total error (TEa) to improve the probability of error detection (Ped) and reduce the probability of false rejection (Pfr).

Results: The CV values of the within-run imprecision at low and high levels of the QC subjects were 1.6% , 1.0%, respectively. The CV values of the total imprecision at low and high levels of the QC subjects were 2.3% , 1.5%, respectively. The bias% was 0.8% when the manufacturer's standard material was used to assess the accuracy of the assay.The limit of quantification was 0.030 g/dL .Excellent linearity was observed in the range of 0.030[[Unsupported Character - Codename]][[Unsupported Character - Codename]]-3.563 g/dL(R^2=0.9996). It was also demonstrated that the index of 90%Ped, 5%Pfr, and 7.5Sigma could be achieved using only 1-5s quality control rules with two levels of the QC in daily routine work (Figure1, Figure 2).

Conclusion: Function power graph and Sigma control chart can provide an objective assessment of the current analytical quality of laboratory examination procedures. Lucica GA-L kit, the enzymatic method with liquid reagents requiring no step of preparation, can be applied to general automated biochemical analyzers. In our study, we determined that the analytical performance of using Lucica GA-L kit in the ADVIA2400 analyzer was excellent and could meet requirements of the clinical application.

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Effectiveness of Practices to Foster Quality Improvement Through Reaching Adequate Blood Volumes in Microbiological Tests in Taiwan: from Systematic Reviews to Validity Assessments

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Background: Blood cultures play a crucial role in the diagnosis of life-threatening bloodstream infection. The CLSI and many guidelines recommend an optimal volume of 20-30 mL for each set of blood bottles. However, in Taiwan, a lot of hospitals could not meet criteria of appropriate blood volumes due to difficulties in sampling process. In this way, we evaluate the effectiveness of increasing blood volumes to improve performances of blood cultures. First, we conducted a systematic review and meta-analysis to reassess the importance of blood volumes with positive rates. Due to positive correlations between the blood volumes and positive rates, we further used two strategies to foster quality improvement through reaching adequate blood volumes in blood cultures.

Methods: We searched MEDLINE from inception to March 2016 and all identified titles and abstracts were carefully examined by two independent reviewers. Of 531 studies, 4 papers were included and differences of positive rates between adequate volumes (8~10 ml) VS. low volumes (<3~5mL) were compared. For validity assessments, we used a series of assistive devices and educational programs for phlebotomy in our emergency department.**Results:**For the meta-analysis, the pooled estimates under the random effects model suggested the greater the blood volume, the greater the culture rate in adults. Between the two groups, each additional 1 ml volume of blood could almost lead to 0.5% increase in positive rates. Furthermore, after an evidence-based approach through two serial strategies were conducted in our emergency department in 12 months, the average of blood volume has increased form 1.5 mL to 4.5 mL, and the positive rates has also increased from 11.6 % to 13.6%, respectively. **Conclusion:** Reports concerning the importance of the volume of blood cultured with the new continuous-monitoring blood culture systems are scarce, and this is the first meta-analysis to evaluate the effectiveness of increasing the blood volume to improve the performance of blood culture between similar culture systems. However, the inconsistency may arise through study populations with different underlying diseases between different labs. In conclusion, to backup the lab practice, further analysis will need to assess direct relationships between blood volumes and positive rates and time to positivity.

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Performance Evaluation of ADVIA Chemistry XPT and ADVIA Centaur XPT Immunoassay Systems in a University Hospital Laboratory

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Objective: Hospital Clinic de Barcelona is a public university hospital in Barcelona, Spain. Within the hospital, the Core Laboratory (Core Lab) is a highly automated 24/7 facility that combines routine activities and emergency requests using Aptio® Automation. In 2015, its annual workload included about 3.4 million clinical chemistry tests and 347,000 immunoassay tests, among other testing disciplines. Core Lab sought to improve efficiency, productivity, service to physicians, and patient outcomes by upgrading its clinical chemistry and immunoassay testing capabilities. To achieve this goal, Core Lab added a new ADVIA® Chemistry XPT System and an ADVIA Centaur® XPT Immunoassay System (Siemens Healthcare Diagnostics

Inc.). Both new analyzers were connected to the existing Aptio Automation track. The objective of this study was to evaluate the following performance parameters for the new analyzers compared to the legacy ADVIA 2400 Clinical Chemistry and ADVIA Centaur XP Immunoassay Systems: throughput, turnaround time (TAT), analytical precision of ISE results for chemistry testing, and operator intervention and hands-on time.

Methods: Assay performance was observed on routine samples over a 6-month period for the ADVIA Centaur XPT Immunoassay and ADVIA Chemistry XPT Systems. These analyzers ran in parallel with one ADVIA Centaur XP Immunoassay System and one ADVIA 2400 Chemistry System. ISE module stability was determined using BIO-RAD Liquid Assayed Multiqual 2 controls and BIO-RAD Unity Real Time software. To assess the impact on turnaround times (TAT) by incorporating both ADVIA XPT systems into the daily routine, Core Lab calculated the average turnaround (TATav) for determination of the glucose oxidase assay on the ADVIA Chemistry XPT System and the eHIV assay on the ADVIA Centaur XPT system. These assays were chosen because they are the tests most frequently performed on their respective instruments. Core Lab also assessed time savings for instrument maintenance, calibration, and reagent-loading processes.

Results[1]: For chemistry testing, average turnaround time improved by 15%, while throughput increased more than 5%. ISE analytical precision was excellent with a CV <2.5% for all analytes. The ADVIA Chemistry XPT System needed 58% fewer calibrations and 7% fewer quality control (QC) results than the ADVIA 2400 system. By reducing maintenance activities, the improved ISE module allowed 70 more hours of run time annually, and streamlined reagent loading saved about 42 hours annually. For immunoassay testing, average turnaround time was reduced by 6%. Automated daily controls saved 42 hours of labor per year, and automated water reservoir cleaning saved 18 hours of labor per year.

Conclusions: Significant improvements in throughput, turnaround time, and operator intervention and hands-on time were achieved for chemistry and immunoassay testing with the ADVIA Chemistry XPT and ADVIA Centaur XPT Immunoassay Systems. ISE module analytical precision for chemistry testing was excellent for all analytes.

[1] The outcomes obtained by Siemens' customer in this study were achieved in the customer's unique setting. Since there is no typical setting, there can be no guarantee that others will achieve the same results.

B-193

Performance Evaluation of Consolidated, Automated Chemistry and Immunoassay Testing in a Reference Laboratory

H. Lang, H. Wickert. *Labor Blackholm MVZ GmbH, Heilbronn, Germany*

Objective: Labor Blackholm MVZ is a private, independent reference laboratory in Heilbronn, Germany. Its annual workload includes about 6 million clinical chemistry tests and 1 million immunoassay tests. Labor Blackholm sought to improve efficiency, productivity, service to physicians, and patient outcomes. To achieve this goal, two existing laboratories were consolidated into one, and a high-capacity Siemens Aptio® Automation solution with connected ADVIA® Chemistry XPT Systems and ADVIA Centaur® XPT Immunoassay Systems was introduced to harmonize and standardize workflow. The objective of this study was to quantify the performance improvement obtained from the new Siemens Healthineers solution, primarily in terms of reduced turnaround time (TAT) for chemistry and immunoassay testing, compared to the laboratory's original equipment and configuration.

Methods: Labor Blackholm's existing facility comprised two laboratories on separate floors of a building. Key components of these labs were the Roche modular analyzer series configuration with connected clinical chemistry systems and the Siemens ADVIA® LabCell® Automation Solution with connected immunoassay systems. In this scenario, optimizing efficiency was a challenge, primarily because of complex tube-sorting and distribution processes for the two separate laboratories.

The new consolidated laboratory employs ADVIA Chemistry XPT Systems, ADVIA Centaur XPT Immunoassay Systems, and a variety of automated sample-handling modules connected to a single Aptio Automation track. Lab workflow for this new system was assessed during a single day of normal operation in January 2016. A total of 12,330 sample tubes of all disciplines were registered. Of these, 5701 sample tubes had test requests for the ADVIA Chemistry and ADVIA Centaur assay portfolio and went directly onto the automation system. Complete process control for Aptio Automation, including intelligent sample routing and workload balancing, was performed by the Siemens CentraLink® Data Management System (middleware) based on lab-defined rules. Total TATs, from order generation to result transmission to the LIS and including reruns, dilutions, and add-on tests, were assessed for chemistry and immunochemistry test results.

Results[1]: Tests performed on ADVIA Chemistry XPT Systems had a mean TAT of 22 minutes and a 95th percentile of 38 minutes, a 45% faster time compared to chemistry tests run on the original systems. Tests performed on ADVIA Centaur XPT Immunoassay Systems had a mean TAT of 34 minutes and a 95th percentile of 69 minutes, a 40% faster time compared to the previous immunoassay system configuration.

Conclusion: Significant improvements in processing times were achieved for chemistry and immunoassay testing with the combination of the Aptio Automation solution and connected ADVIA Chemistry XPT and ADVIA Centaur XPT Immunoassay Systems. Additional benefits included reduced manual hands-on time and easier training for operators, improved productivity and utilization of resources, reduced overtime labor costs, and improved physician satisfaction with the laboratory's services.

[1]The outcomes obtained by Siemens' customer in this study were achieved in the customer's unique setting. Since there is no typical setting, and many variables exist, there can be no guarantee that others will achieve the same results.

B-194

Failure to retrieve: a follow up study on unacknowledged send-out results

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Background: A systematic study of send-out testing result retrieval was conducted in 2011 at a tertiary care pediatric hospital. The results of that study showed that over a period of one month 20% of all send-out tests were flagged as abnormal, yet only 45% of those abnormal results were acknowledged in the electronic medical record. Furthermore, a 1% harm rate was estimated directly related to unacknowledged results. Since that time, several interventions have been enacted to improve the rate at which send-out tests are acknowledged by the clinical team. These interventions included improvements to the HIS messaging system, patient portal with access to laboratory results, individual email notifications and increased discussion about failure to retrieve.

Methods: The goal of this study was to reevaluate the state of retrieval of send-out test results at a pediatric hospital in the western United States. One month of send-out tests were analyzed by volume, order type, normal/abnormal status and order-to-result turn-around time. All abnormal results were characterized as acknowledged or unacknowledged. Results were considered unacknowledged if there was no reference to, mention of, or change in care related to the result within 90 days of result verification. The Time to Acknowledge an Abnormal Send- out Result (TAASR) was also determined. Unacknowledged abnormal results were further analyzed by sending a questionnaire to the ordering provider and assessing possible patient harm. Send-out tests that were excluded from the study were nutritional and allergy testing as well as drug screens. Adult (21) patients were excluded. Deceased patients who expired prior to the close of the 90-day acknowledgement window were also excluded.

Results: During the study period, a total of 1991 send-out tests met the above criteria. The median order-to-result turn-around time was 3 days (mean 5 days). Seventeen percent of the results took longer than one week to return, with a maximum of 102 days. Of these results, 15% were abnormal. Of these abnormal results, 79% were acknowledged in the chart, and 21% were not. The TAASR had a median of 4 days (mean 8 days). Thirty-five percent of acknowledged results took greater than one week to acknowledge, with a maximum acknowledgement time of 57 days. Comparing current data to the 2011 study, we found that the total volume of send-out tests has increased by 59%. The median order-to-result turn-around time was consistent, however the average TAT decreased by 28% (7 days to 5 days). Current data shows that abnormal send-out test results are currently unacknowledged 21% of the time. This represents a 24% reduction ($p < 0.0001$) in the number of unacknowledged results. The median TAARS decreased (7 days to 4 days), but there was a 13% reduction in the number of abnormal results that took longer than 1 week to acknowledge.

Conclusions: The findings of this study suggest that interventions aimed at reducing the number of unacknowledged send-out results have made an impact at this institution leading to a 24% decrease in unacknowledged results.

B-195

Should critical values be repeated prior to release?

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Background: Certain laboratory results are deemed as critical to patient care, and immediate action may be needed. In our laboratory, upon obtaining a critical value the test was often repeated to confirm analytical accuracy before notifying the care team. This step resulted in delayed result reporting and additional lab resource expenditure. With the current state of high precision technologies and sophisticated quality assurance programs employed in modern laboratories, the continuance of this practice was questioned. **Objective:** The purpose of this study was to investigate the need to retest for a critical value and assess the time savings if the repeat is not performed. **Methods:** Randomly selected critical values and the repeat results were collected for glucose and potassium tests in our clinical chemistry laboratory. These two tests were performed on Cobas c 702 (Roche Diagnostics, Indianapolis, IN). The time savings were estimated by calculating the difference in timestamps from the first and second result posting times. **Results**: Initial and the corresponding retesting values for glucose (n=100) and potassium (n=100) were closely matched with a maximum difference of 2mg/dL for glucose results and 0.2 mmol/L for potassium. The differences were well within the CLIA criteria for assay precisions (glucose target: ±6mg/dL or ±10% and potassium target: ± 0.5mmol/L). The mean elapsed time between the initial and retesting results posted in the lab information system was assessed for January 2016, and was found to be 14 minutes (ranging from 11-49 minutes) for glucose (n=31) and 4 minutes (ranging from 0-37 minutes) for potassium (n=197). **Conclusions:** This study demonstrated that repeat testing for critical values prior to release is not necessary due to the high precision of the modern technologies and sophisticated quality assurance programs employed in the clinical laboratory. Eliminating the unnecessary step has allowed our laboratorians to reach out to our clinicians at a more rapid pace thus enabling them to provide a quicker response to the critical values. In addition, eliminating unnecessary analytical runs improves operation efficiency and overall turnaround time for all patient resulting in our high volume laboratory.

B-196

Managing test results disagreement complaints: the experience of a large clinical laboratory

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Background: Accurate laboratory tests are vital to ensure that healthcare professionals provide the best care for their patients. Therefore, it is essential that the laboratory offers a complaint handling service which is easily accessible, trustworthy and transparent. The aim of this study was to access the dimension and efficiency of the established process for managing outpatient and physician's disagreement complaints about tests results. **Methods**: To understand the performance of the current process of management of disagreement complaints, we analyzed the records from a large clinical laboratory Quality Management System (QMS) from January to December of 2016. Complaints from all contact points are recorded (drawing facilities, website, email, social media and phone calls), and managed by the medical staff, remotely based from the central lab. The first feedback to the claimant is performed within 12 commercial hours after the complaint is recorded on the QMS, in order to better understand the questioning. Parallel to that, medical team analyzes the client's report, previous and concomitant tests results in the laboratory database, investigate the equipment analytical performance, and post analytical information from the central lab, using either the LIS and/or QMS. **Results**: During the study period, 27.4 million laboratory tests were performed. A total of 521 cases of complaints of result disagreements were recorded, distributed as follows: biochemistry (130, 24.9%), hematology (106, 20.34%), hormonology (86, 16.5%), microbiology (70, 13.4%), and others (129, 24.8%). The claimant was a patient in 82% (n=427) and a physician in 18% (n=94) of recorded cases. After medical staff analysis, 22% (n=115) of complaints were judged as laboratory errors, representing 4.19 defects per million opportunities (DPMO). The process performance evaluation showed that 97.7% of first feedbacks took less than 12 hours to be concluded and 85.8% of complaints were solved and closed within 48 commercial hours. In 30 (0.06%) cases the report result was rectified. **Discussion**: Results obtained by different laboratories may vary for several reasons. Even results from the same laboratory may vary, especially if there is a time gap between collections. Properly managing the disagreement complaints, under the supervision of the medical staff, improves the relationship between patients, physicians and lab, generating greater transparency and, consequently, confidence in the future results. Our data show that only the minority (22.0%) of complaints could not be explained after deep investigation. It is of notice that the current management of complaints is fast and efficient, taking less than 48 hours for conclusion in the majority of cases, leading to a Net Promoter Score (NPS) of 69.4% by the end of 2016. **Conclusion**: The medical process of investigation and discovery of causes for discordant results take some time and technical expertise. However, this process should proceed with the utmost transparency and respect, since pursuing quality should be the main goal of a clinical lab.

B-198

Beckman Coulter AU Chemistry Method Performance Three Years Later - Any Improvements?

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Background: Clinical chemistry laboratories should know the analytical performance of their laboratory methods. Six Sigma quality metrics are an excellent way to quantify the precision and accuracy of analytical methods. Three years ago at the 2014 AACC Annual Meeting, we presented data from 26 clinical chemistry analytes on an AU 5800 platform, which were used to calculate sigma metrics. Some of the methods failed to achieve Six Sigma quality. Since then, we deployed two new AU 5800 instruments. We wanted to discover if any improvements occurred compared with our observations in 2014. **Quality Goals**: Quality goals to evaluate the performance of the tested methods were generally derived from CMS CLIA PT goals, but also included criteria from the Biologic Variation Database and from RCPA. **Collection of data**: Precision and accuracy were evaluated for each chemistry analyte. Within-instrument precision was calculated by measuring quality control materials over one month. Accuracy was estimated by calculating observed bias (mean of the actual data minus an average mean). **Results**: The AU 5800 results for 12 methods exhibiting Sigma metric values of 4 or less in 2014 are summarized in the Table. Seven of these methods showed noticeable improvement from the 2017 data, several now achieving Six Sigma performance. These methods should now be easy to control with cost-effective QC practices. In contrast, a few analytes continued to not achieve desired status and therefore require more rigorous QC practices. **Conclusions**: The great majority of clinical chemistry methods function at world-class specifications using the Beckman Coulter AU5800. The methods that fail to achieve such performance demand analytical improvement from the method research community. The data presented here help the clinical laboratory profession again to emphasize certain analytes to focus on for method improvement. Additionally, optimal QC practices for laboratory production are suggested.

Sigma Metric Results					
analyte	2014	2014	2017	2017	2017
level	1	3	1	2	3
Alk Phos	3.5	16	2.5	10.6	13.7
ALT	3.8	14	5.1	14.9	19
BUN	3.1	3.4	3.3	3.5	3.4
chol	3.2	6.4	4.1	5.0	5.4
Cl	4.0	4.7	3.8	3.1	3.8
CO_2	1.9	1.7	2.0	1.8	1.9
d bili	1.4	3.6	3.6	10.3	13
Fe	3.0	7.1	2.4	5.9	8.4
glucose	3.3	6.8	5.9	7.8	6.3
lipase	1.9	2.7	7.1	8.5	12.3
Na	1.6	1.4	3.7	2.7	2.2
PO_4	2.2	3.7	8.1	8.4	12.1

B-200

Rapid serum tubes to facilitate specimen processing and improvement of cost savings at patient service centers

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Objectives: To compare the numerical result from the analytical instrumentation between the rapid serum tubes (RSTs) and serum separator tubes (SSTs) in order to evaluate potential bias and to determine the amount of savings that have been realized when RSTs are used for the final hour of operations at community patient service

centers (PSCs) following definition of the potential bias. Relevance: Traditional SSTs require an approximate 30 minute incubation to clot prior to being separated from cells and sent to the laboratory for testing. When patients arrive at community PSCs to undergo collections for laboratory testing in the last hour of the day, at least two medical laboratory assistants commonly have to stay overtime for safety reasons and to allow these samples to clot before they can be sent to the lab. This results in an enormous added cost for staff time with little benefit. The purpose of this study is to evaluate a new type of blood collection tube called RSTs which reduce the clot time to less than 5 minutes as compared to routine SSTs. These tubes could be implemented for use in the final hour of daily operations at PSCs, allowing the medical laboratory assistants to separate serum from blood cells sooner, thereby saving overtime and significant cost savings. Methods: This study was split into two separate parts. For the first phase, 20 healthy volunteers were enrolled for evaluation of routine lab tests 25-hydroxyvitamin D, sex hormone binding globulin, apolipoprotein B, tissue transglutaminase (tTG) , serum folate, anti thyroid peroxidase, alpha 1 anti trypsin, lithium, cyclic citrullinated peptide antibodies (CCP), hepatitis A antibody IgG, hepatitis A antibody IgM, hepatitis B surface antigen, hepatitis B surface antibody, hepatitis B core antibody, hepatitis B core antibody IgM, hepatitis Be antigen, hepatitis Be antibody, anti nuclear antibody, protein electrophoresis, neutrophil cytoplasmic antibody (ANCA), and extractable nuclear antigen antibodies (ENA). These tests were selected according to test volumes during the final hour of daily operations. For the second part of the study, patients were consented and enrolled at a designated community PSC for evaluation due to the rare nature of positive results from the first phase of the study such as lithium for therapeutic drug monitoring and other serological tests for infectious disease and autoimmune conditions. All blood samples were collected from subjects with a de-identified matched set of RST and SST tubes. The numerical results for each test from the two tube types were compared and analyzed for significant differences according to total error. Results: When compared to SSTs, RSTs were acceptable to the majority of the tests except for tTG, anti-CCP, ANCA, and ENA due to the lack of samples with positive results. The collection strategy for these analytes will be altered to address this issue. Overtime costs at PSCs have significantly decreased and further studies will be initiated to expand RST collections on other tests. Conclusions: Implementation of RSTs for use in the final hour of daily operations at community PSCs led to reduction of overtime hours and significant cost savings.

B-201

The impact of TEa selection on patient risk

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Objectives

1. To quantify the impact of setting Acceptable Risk Criteria as the acceptable number of medically unacceptable results/year, rather than statistical metrics

2. To demonstrate how Margin for Error (ME) - the number of standard deviations the mean can shift before risk becomes unacceptable - responds to acceptable risk criteria while sigma metrics remain unchanged

3. To illustrate how Mathematically-OptimiZed Risk Evaluation can evaluate risk and design QC processes to vary with defined acceptable risk criteria

Background:

To evaluate risk, laboratories must "compare the estimated risk against given risk criteria to determine the acceptability of the risk" (CLSI EP 23-A). Acceptable risk criteria are implied in acceptable sigma values or error rates. Selection of Acceptable Risk Criteria as the number and cost of medically-unreliable results drives the perceived and factual acceptability of patient risk. Acceptable risk criteria set standards of acceptable analytical process quality and QC process effectiveness.

Methods:

1. We created a calcium data set with of recently 1. measured mean; 2. measured SD; 3. Peer Mean equivalent to a sigma values or z-value of 5.7 based on the CLIA limit

3. We used CatalystQC software (AWEsome Numbers Inc.) to evaluate analytical process quality relative to to Acceptable Risk Criteria of 5% allowable error; 2 sigma, 3 sigma and 1 Medically-Unreliable Result/year

Results:

Below is a table of the results of the study. The data used is the same within each case, only the Acceptable Risk Criteria is changed within each case.

Discussion

Risk management and IQCP present new challenges and new opportunities. CLSI EP 23-A states that risk evaluation is the "process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk." Laboratories must "Evaluate the potential costs both in terms of the patient's well-being and in terms of financial liability of the treating parties vs known benefits to the patient." Laboratory methods have been previously considered acceptable if QC charts showed no rejects and summary results passed generally accepted standards if 5% allowable error, or had an acceptable sigma metric of 2 or 3 sigma at a regular/monthly review. To meet risk management standards, laboratories must measure and evaluate risk as the number and clinical/legal cost of results that exceed TEa limits. However, z-values (sigma values) do not vary with either patient volume or the acceptable risk criteria. Here we present the Margin for Error (ME) - the number of standard deviations the mean can shift before risk becomes unacceptable.

We see that by only changing acceptable risk criteria there is a significant change in the amount of patient risk and clinical cost allowed before QC will alert staff to stop and take action.

Conclusion

1. Comparing the results of evaluation with statistical and clinical acceptable risk criteria demonstrates that clinical acceptable risk criteria will play a major role in clinical acceptability, patient risk, and cost due to medically unacceptable errors.

2. The process of Mathematically-OptimiZed Risk Evaluation should be further evaluated

B-202

Managing risk with Acceptable Risk Criteria and Mathematically-OptimiZed Risk Evaluation

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Objectives

1. To quantify the impact of setting Acceptable Risk Criteria as the acceptable number of medically unacceptable results/year, rather than statistical metrics

2. To present the Margin for Error (ME) - the number of standard deviations the mean can shift before risk becomes unacceptable -

3. To illustrate how Mathematically-OptimiZed Risk Evaluation can evaluate risk and design QC processes to vary with defined acceptable risk criteria

Background:

To evaluate risk, laboratories must "compare the estimated risk against given risk criteria to determine the acceptability of the risk" (CLSI EP 23-A). Acceptable risk criteria are implied in acceptable sigma values or error rates. Selection of Acceptable Risk Criteria as the number and cost of medically-unreliable results drives the perceived and factual acceptability of patient risk. Acceptable risk criteria set standards of acceptable analytical process quality and QC process effectiveness.

Methods:

1. We created a calcium data set with of recently 1. measured mean; 2. measured SD; 3. Peer Mean equivalent to a sigma values or z-value of 5.7, based on a TEa CLIA

2. The QC data were compared in CatalystQC software (AWEsome Numbers Inc.) to Acceptable Risk Criteria of 5% allowable error; 2 sigma, 3 sigma and 1 Medically-Unreliable Result/year

3. We set the clinical/legal cost of each MUR at $100 based on the NIST study

4. We compared the interpretation of acceptability of quality and probable action based on the selected Acceptable Risk Criteria

Results:

Below is a table of the results of the study. The data used is the same within each case, only the Acceptable Risk Criteria is changed within each case.

Discussion

Risk management and IQCP present new challenges and new opportunities. CLSI EP 23-A states that risk evaluation is the "process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk." Laboratories must "Evaluate the potential costs both in terms of the patient's well-being and in terms of financial liability of the treating parties vs known benefits to the patient."

Laboratory methods have been previously considered acceptable if QC charts showed no rejects and summary results passed generally accepted standards if 5% allowable error, or had an acceptable sigma metric of 2 or 3 sigma at a regular/monthly review. To meet risk management standards, laboratories must measure and evaluate risk as the number and clinical/legal cost of results that exceed TEa limits. However, z-values (sigma values) do not vary with either patient volume or the acceptable risk criteria. Here we present the Margin for Error (ME) - the number of standard deviations the mean can shift before risk becomes unacceptable.

Conclusion

1. Comparing the results of evaluation with statistical and clinical acceptable risk criteria demonstrates that clinical acceptable risk criteria will play a major role in clinical acceptability, patient risk, and cost due to medically unacceptable errors.

2. The process of Mathematically-OptimiZed Risk Evaluation should be further evaluated

B-203

The Lab Quality Continuum & The Current State of Lab Quality

J. Dawson. *Proove Biosciences, Irvine, CA*

Building on existing models, distinct phases of laboratory quality were identified and organized into phases comprising the Lab Quality Continuum(LQC), a tool to aid laboratories in determining their current level of quality. Collaborating with Roche Lab Leaders, a self-assessment was developed to assist labs in understanding their current phase of quality and to provide improvement recommendations (www.lableaders.com/quality).

Objective: The objective of this study was to assess the current state of clinical laboratory quality utilizing the LQC Self-Assessment.

Methods: An anonymous online survey captured demographics and self-assessment results. LinkedIn was utilized to identify potential respondents and was administered utilizing convenience sampling. Data were extracted into a spreadsheet and analyzed for trends.

Results: 117 respondents participated in the study. Most respondents are employed by hospital and independent laboratories spanning a wide variety of titles. Respondents' laboratories represent all CLIA specialties, all U.S. regions with widely varying annual volumes and organizational sizes. The distribution of the self-assessment results: Oblivious 5.13%, Analytical Quality (AQ) 11.11%, Quality Assurance (QA) 52.14%, Quality Management (QM) 18.80%, Total Quality Management (TQM) 7.69%, Performance Excellence 2.56%, Pinnacle of the Lab Quality Continuum 2.56%. 59.83% of respondents reported that their laboratory employed at least one full-time quality professional (55.00% QA and below, 70.27% QM or higher). 70.09% reported that they felt their lab's quality program was adequate (62.82% QA and below, 86.49% QM or higher, 93.33% TQM or higher).

Conclusions: The current state of lab quality is that 68.38% are at QA or lower on the LQC (study ongoing), suggesting that most labs are currently focusing on merely meeting minimum regulatory requirements. Positive correlations exist between employment of a full-time quality professional and perception of an adequate quality program and progression along the continuum.