Wednesday, August 2, 2017

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

Automation/Computer Applications

B-006

Cyclical time-of-collection variation of calcium results for inpatients and outpatients at a university hospital: implications for patient-based quality control

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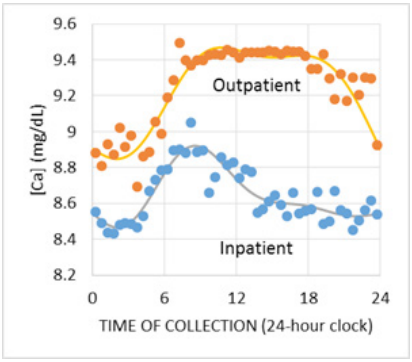
BACKGROUND: Patient-based quality control (PBQC) is typically based on running averages (RA), which may be affected by regular time-of-day (TOD) variation of results. This variation may occur due to multiple factors, including the mix of inpatient (IP) and outpatient (OP) results, and the possibility of physiological TOD variation. As calcium ([Ca]) is known to have physiological TOD variation, our objective was to examine whether this variation was evident in laboratory results for [Ca] based on time of collection (TOC), for IP and OP samples. **METHODS**: A six-month database (Mar-Aug 2016) of laboratory results for [Ca] was extracted from the laboratory information system to include TOC. Exclusions were patients <1 year of age, and results other than first-or-only results for a given patient within a given day. Average [Ca] was calculated for 30-minute bins within a 24-hour clock-time cycle (0000-2400) for IP and OP populations. **RESULTS**: After exclusions, the database contained 70,275 results (41.4% IP: median age 62, 52.5% male, average [Ca]=8.6+/-0.83 mg/dL, median 8.6 mg/dL; 58.6% OP: median age 61, 46.7% male, average [Ca]=9.4+/-0.58 mg/dL, median 9.4 mg/dL; reference range for [Ca] = 8.5-10.2 mg/dL). Results for average [Ca] vs. TOC are shown in Figure (CV = 7%-10% for all points). For both IP and OP, a clear TOD pattern was evident, in which both nadir and apex occurred in AM (0000-1200). Apex for IP (delta from nadir = approximately 0.4 mg/dL) was transient in comparison to apex for OP (delta from nadir = approximately 0.6 mg/dL), for which high [Ca] was sustained much longer. **CONCLUSIONS**: TOD variation was evident in laboratory results for [Ca] vs. TOC. TOC patterns were distinct for IP and OP. Results suggest that accounting for TOC variation in [Ca] might be useful in PBQC.



B-007

SMART CARD AND INTEGRATION WITH EMR

V. Hampapur. *Tata Memorial Centre, Navi Mumbai, India*

Objective

Tata Memorial Hospital **(TMH)** is a Comprehensive Care Centre for Cancer with a standing of 7 decades. Patients from all over India and some from neighboring countries choose to travel to Mumbai (Bombay) to take at our centre. Given the Geographical constraints TMH has adopted Information Technology to reach out to it's patients in distant communities.

TMH has a home grown Electronic Medical Record System the contents of which is shared with patients and providers over the Hospital Wide Intranet and globally through the website. The hospital has paperless and filmless operations since 2013 which enables real time exchange of information and continuum of care. Paper Records of yester years are scanned, archived and is part of the EMR.

In spite of the above automation and due to a heavy patient load queues for services in the hospital had resulted in patient inconvenience and dissatisfaction. It was in this context an innovative step was taken to adapt Smart Card Technology to address issues pertaining to health care services and business rules of the Institution.

Planning & Implementation

Every patient is issued a Photo ID Smart Card(SC) at the time of Registration with our Institution. The SC is personalized by recording a Personalized Information Number (PIN). The SM has an inbuilt chip which contains unique details of the patients for retrieval at all points of service.

Hospital Staff access information and provide services using Smart Card Readers. This helps in identifying patients and prevention of transcription errors. Patients authenticate all financial transactions by using their PIN. Short Messaging Service (SMS) is used to notify patients about debits to their Accounts and also when reports are finalized. Information Kiosks placed at strategic locations allow patients to access their EMR using their SC.

Results

The implementation of the above system was an exercise in change management involving training of all the stake holders and this study was undertaken to assess the impact of these changes on Turn Around Time (TAT), Patient Safety, Transparency and Audit Tracking.

The TAT for requisitioning of diagnostic services has reduced by 56% due to end to end automation. Similar reduction in Transaction time is seen in dispensing of drugs in the pharmacy based on electronic prescriptions.

The no of Transcription errors due to manual entry resulting in repeat tests has been eliminated in toto which is a significant measure of Patient Safety.

The patients and providers have instant access to the EMR and are notified through SMS as and when service provision is completed.

The no of Service transactions have increased from 593/day (2013) to 1545/day in 2015 a jump of nearly 160%. Similarly the Dispensary transactions have increased from 1522/day in 2013 to 1910 a jump of 25.42%.

Needless to say the perception of care has improved significantly.

B-008

Improving Laboratory Process with Total Laboratory Automation

H. E. Yu, J. Olson. *Geisinger Health System, Danville, PA*

Background: In recent years there have been tremendous advancements in laboratory automation systems, and an explosion in the number of options available for laboratories. In the past, total automation systems were offered only by third party vendors who specialize in automation. Today, many vendors who specialize in analytics also offer state-of-the-art options for total lab automation.

Methods: Our laboratory has moved from having an automation system for only the chemistry testing to one of the newly available total laboratory systems that connected our preanalytic systems, hematology, coagulation, chemistry, and sample storage unit. To determine whether there is efficiency gain and workflow improvement, we quantified various matrix before and after the implementation of total laboratory automation system.

Results: Our data show that the implementation of total laboratory automation system results in 73% less of discreet processing steps of specimen handling, even when starting from a partially automated laboratory. Consolidation of testing resulted in reduction in testing footprint and reduced 2.5 testing personnel. It also results in 82% reduction in hands-on time associated with add-on process. Even with the combination of both STAT and outreach work on the testing system, turnaround time remains consistent.

Conclusions: Implementation of total lab automation system can transform laboratory process and efficiency. Careful planning and optimization is required to bring this change to the laboratory.

B-010

Data mining for establishing limits for release of results by auto-verification—study of the parameters of the biochemical renal panel in cancer patients

S. Chakraborty. *Tata Medical Center, Kolkata, India*

Background: Setting limits for result release by auto-verification (review limits) is a challenging process and there are no clear guidelines. The review limits (RL) should be sufficiently wide to let moderately deranged results to pass automatically, yet retain clinically significant results for manual verification. The use of linearity of the assays to calculate the RL, commonly recommended in literature, often results in very wide intervals which perforce have to be reduced by subjective decision of the biochemist. Moreover, this method does not take into account the statistical distribution of the analytes in the population served by the hospital. We describe a novel approach using data mining to calculate the RL in ambulatory cancer patients who are not in need of emergency care or from inpatients during their first day of admission. A study with serum renal panel tests (sodium, potassium, blood urea nitrogen (BUN) and creatinine) is presented.

Methods: The renal panel data was obtained for 2014- 2015 (18-60 years). Only one result per patient was included. The internal quality controls and the proficiency test programs had a stable performance for the said period. The patients were categorized into outpatients and inpatients. Gender partition was done for serum BUN and creatinine. Data were trimmed by removal of the overtly diseased population and by the use of interquartile rules. Data mining was performed using the Bhattacharya method on the 'R' statistical platform. The Bhattacharya method can identify hidden Gaussian distribution in a dataset. The review limits were set at ± three standard deviations (3SD) from the population's mean. The obtained RLs were compared to linearity based limits. The average number of results auto-verified were expressed as a percentage for a period of two months.

Results: The RLs were derived from 6996, 6917, 2993, and 2679 patients for serum sodium, potassium, creatinine, and BUN respectively. The review intervals derived by data mining followed by linearity based intervals given in brackets in ambulatory outpatients are as follows: Serum sodium: 133-148 (33-196) mmol/L, serum potassium: 3.1-6.1 (1.65-9.20) mmol/L, serum creatinine(male): 0.58-1.36(0.48-7.5) mg/dL, serum creatinine (female): 0.41-1.02 (0.35-7.38) mg/dL, serum BUN (male): 1-19 (6-67) mg/dL, serum BUN (female): 1-17(5-66) mg/dL.

The review intervals in inpatients are as follows: Serum sodium: 125-147 mmol/L, serum potassium: 2.9-5.6 mmol/L, serum creatinine(male): 0.37-1.87 mg/dL, serum creatinine (female): 0.41-1.02 mg/dL, serum BUN (male): 1-20 mg/dL, serum BUN(female): 1-19 mg/dL. The linearity based RLs remain the same for inpatients. About 65% of the renal panel were auto-verified using the derived RLs.

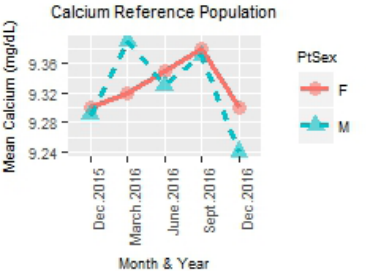
Conclusion: A population-based RL has been developed which can successfully verify a good proportion of the results during the first visit of the patient in our cancer hospital. RLs set at 3SD from the population means of each analyte provide a strong clinical basis for their calculation as compared to the static linearity based RLs. The linearity derived intervals on the other hand are very wide and may even be outside survival limits.

B-011

Data mining and reference interval studies indicate total calcium seasonal variation

A. B. Muenzenmeyer, E. Z. Reineks. *Cleveland Clinic, Cleveland, OH*

Background: Total Calcium's reference range was updated in September 2016 to 8.6-10.0 mg/dL on the basis of a reference range establishment performed using historical data from December 2015. Prior to September 2016, the range was 8.5-10.5 mg/dL. Although the abnormal flag frequency was expected to increase with this change, the observed increase was higher than expected. The goal of this study was to determine whether seasonal variation was a factor that could account for the unexpected rate of high abnormal flags. **Methods:** We used data mining and business intelligence software to establish Calcium reference ranges for following timeframes: March 2016, June 2016, September 2016 and December 2016. This study utilized Altosoft (*Kofax*, Irvine, CA), business intelligence software to readily identify suitable existing patient samples for results in our laboratory information system (*Sunquest*, Tucson, AZ). Data was exported into Excel (*Microsoft*, Redmond, WA) and filtered according to the December 2015 pre-defined criteria. The datasets were evaluated using an EP Evaluator® (*Data Innovations*, South Burlington, VT). Descriptive statistics were determined for all of the datasets, including subsets of male and female partitioned data. **Results:** The number of Calcium results for each study period ranged from N=408 to 551. For all healthy subjects, lower reference ranges were established from 8.5 to 8.7 mg/dL and upper ranges from 10.0 to 10.2 mg/dL. Total Calcium reference range will be updated to 8.5-10.2 mg/dL. **Conclusions:** Changes in Total Calcium concentration have a seasonal variation for populations served by our laboratory, which is important to address when establishing population based reference ranges. We excluded the possibility of instrument drift/analytical variation based on the observed differences between male and female populations. Data mining makes this type of evaluation feasible, both in terms of time and affordability.



B-012

A strategy to decrease the manual microscopic examination by introduction of the automated urinary sediment analyzer

J. Kim, E. Cho, K. Park, H. Hong, E. Shin, W. Lee, S. Chun, W. Min. *Asan Medical Center, Seoul, Korea, Republic of*

Background: Routine urinalysis consists of an assessment of physicochemical characteristics and manual microscopic examination (MME). MME is labor-intensive, time-consuming, and imprecise. The introduction of automated urinalysis systems based on flow cytometry or image-based analysis could eliminate or replace MME, improving the turnaround time. The aim of this study was to evaluate workflow processes when introducing automated urine sediment analyzers in terms of reduction in the requirement for MME.

Methods: We compared the two automated urine analyzers, the UF-1000i (Sysmex Corporation, Kobe, Japan) based on flow cytometry, and the cobas 6500 urine analyzer (Roche Diagnostics International, Rotkreuz, Switzerland) based on sediment microscopy. A total of 1055 and 1119 urine samples from inpatients and outpatients, respectively, were tested between June 14 and June 29, 2016. All samples were analyzed using both the UF-1000i and the cobas 6500. MME was performed according to the following criteria: With regard to RBC and WBC tests, when mismatch was discovered from the results of urine strip test and automated analyzers; when flag signs of automated analyzers occurred. Urinalysis was performed with four workflow processes including solitary assay of each automated analyzer and combined assay of the two analyzers. We compared the reduction rate of MME between the four workflow processes. When using cobas 6500, MME was performed after conducting the image review.

Results: In the case of UF-1000i single-use, MME was conducted on 361(34.2%) specimens of inpatients and 188(16.8%) specimens of outpatients. In the case of the cobas 6500 single-use, the image review were performed on 446(42.3%) specimens of inpatients and 211(18.9%) specimens of outpatients, and then MME for 165(15.6%) specimens of inpatients and 41(3.7%) specimens of outpatients was carried out. When using the Cobas 6500 after using the UF-1000i first, 361(34.2%) specimens of inpatients and 188(16.8%) specimens of outpatients underwent the image review, and then 119(11.3%) specimens of inpatients and 30(2.7%) specimens of outpatients, respectively, underwent the MME. When using UF-1000i after using the Cobas 6500 first, MME was conducted on 119(11.3%) specimens of inpatients and 30(2.7%) specimens of outpatients. When automated urine sediment analyzers were used, the rate of MME was reduced by 22.9% in the inpatient specimens and 14.1% in the outpatient specimens.

Conclusion: By introducing the automated urine sediment analyzers, the rate of MME was reduced, especially when combining the two automated analyzers which have different method principles. The reason for the difference in the rate of MME reduction by four workflow processes using the automated urine sediment analyzers would be elucidated according to the specimen characteristics.

B-013

Identification of steps necessary for general implementation of moving average for continuous QC in medical laboratories

H. H. van Rossum[1], H. Kemperman[2]. *[1]NKI-AvL, Amsterdam, Netherlands, [2]UMC Utrecht, Utrecht, Netherlands*

Background: Moving average (MA) can be used for continuous analytical quality control. Though MA has been described decades ago, general implementation in clinical chemistry laboratories has failed. We addressed several issues that we considered to be important to support a more general implementation of MA as continuous QC instrument in medical laboratories.

Methods: A MA optimization method described by our group (1,2) was used to generate optimal MA procedures that were implemented for continuous analytical quality control in daily practice(3). During the various phases of MA implementation, issues that potentially complicated the MA implementation and application were identified. Furthermore a MA-alarm case, describing a temporary sodium ion selective electrode (ISE) failure, was used to demonstrate the value of MA.

Results: The first step to support clinical laboratories to obtain and use optimal and validated MA for continuous QC is to make newly developed MA optimization methods commercially available for clinical laboratories. Secondly, improvements in MA management software are required to allow optimal support of MA management on clinical laboratories. These include continuous generation of MA values, adequate continuous alarming, MA resetting, exclusion of samples and presentation of MA in an accuracy plot. Finally, laboratory management issues were identified that included development of a clear protocol how to handle MA alarms and training of technicians.

Conclusion: The issues we encountered during implementation and application of MA illustrate the need to make newly developed MA optimization methods available for clinical laboratories and for improvements in the available MA management software. This should allow a more general implementation of continuous QC by MA on medical laboratories.

References

1) van Rossum HH, Kemperman H. A method for optimization and validation of moving average as continuous analytical quality control instrument demonstrated for creatinine. Clin Chim Acta 2016;457:1-7.

2) van Rossum HH, Kemperman H. Optimization and validation of moving average quality control procedures using bias detection curves and moving average validation charts. Clin Chem Lab Med 2017; 55(2): 218-224

3) van Rossum HH, Kemperman H. Implementation and application of moving average as continuous analytical quality control instrument demonstrated for 24 routine chemistry assays. Clin Chem Lab Med 2017, in press

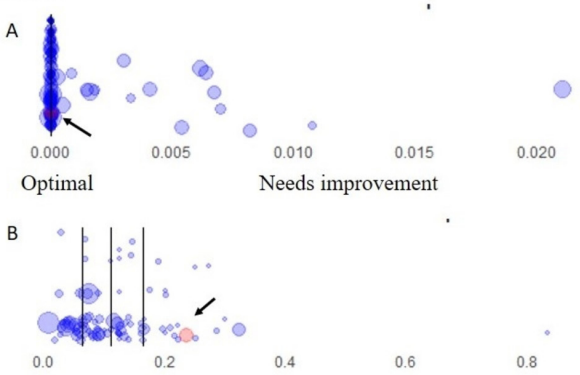
B-015

Prioritizing local quality improvement projects using national laboratory and clinical data

K. Lankachandra[1], A. Cheng[2], R. Johnson[3], S. Sahil[2], M. A. Hoffman[4]. *[1]Truman Medical Center, University of Missouri Kansas City, Kansas City, MO, [2]University of Missouri Kansas City, Kansas City, MO, [3]Truman Medical Center, Kansas City, MO, [4]Childrens Mercy Hospital, Kansas City, MO*

Background: Quality improvement (QI) projects, informed by diagnostic laboratory and clinical data, are important for healthcare operations. By improving workflow in the lab, reducing errors, optimizing test utilization and enhancing provider application of lab test results, QI projects can reduce costs and improve patient outcomes, safety and satisfaction. Prioritizing QI project candidates can be difficult. Our objective is to apply a de-identified national data laboratory and clinical data warehouse to guide QI project prioritization decisions. **Methods:** We utilized Cerner Health Facts ™ (HF), a national data warehouse populated with de-identified data extracted from electronic health records, to develop a methodology to assist Truman Medical Center (TMC), Kansas City, MO, in prioritizing QI projects. The version of HF utilized in this project includes data from 63 million unique patients, 863 healthcare facilities and 4.3 billion laboratory results from 2000 until December, 2015. We identified QI project candidates, parsed the projects into discrete machine readable parameters utilizing standardized medical terminologies and queried the HF data. HF contributor sites meeting the inclusion criteria were stratified for each QI candidate project. **Results:** For one project we evaluated antibiotic prescribing discord relative to antibiotic resistance findings, in this case oxacillin prescriptions for encounters with oxacillin-resistant *Staphylococcus aureus*. TMC ranked in the top group of the 174 facilities meeting the inclusion criteria (Figure 1A), with zero contraindicated orders. For another project candidate, the objective was a low frequency of hemoglobin A1c orders for patients with sickle cell disease. TMC patients with a sickle cell disease diagnosis were tested for hemoglobin A1c for diagnosis and management of diabetes mellitus more frequently than most of the 86 sites meeting the inclusion threshold (Figure 1B). **Conclusion:** Based on these findings, TMC should consider the sickle cell project as a higher priority QI project.

Figure 1: Health Facts facilities (circles, scaled by number of beds) grouped by QI project candidate, TMC facilities in red, with arrows. Y axis height is arbitrary. A – % oxacillin prescriptions for encounters with oxacillin resistant *Staphylococcus aureus*. B –Hemoglobin A1c orders / patients with sickle cell disease.



B-016

Multiple Approaches to the Improvement of the Turnaround Time in a Large Core Laboratory

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Background: Core laboratory (CL), as a new business model, facilitates consolidation and integration of laboratory services to enhance efficiency and reduce costs. This study evaluates the impact of total automation system (TLA), electric track vehicle (ETV) system and auto-verification of results on overall turnaround time (PR-TAT=Phlebotomy to Reporting TAT) within a core laboratory setting. **Methods:** Mean, median and outlier percentages (OP) for PR- TAT were compared for pre- and post- CL eras using five representative tests based on different request priorities. Comparison studies were also carried out on the intra-laboratory TAT (IR-TAT= in-lab to reporting) and delivery-TAT (PI-TAT= phlebotomy to reporting) to reflect the efficiency of the TLA and ETV systems respectively. **Results:** For all the STAT requests, the median PR-TAT did not show significant differences between the pre- and post- CL periods for both potassium and urea tests when samples were centrifuged off-line; however, the median PR-TATs for both CBC and PT in the post- CL period were longer by 12min and 19min respectively when compared to the pre- CL period. Comparing the goal of PR-TAT for the STAT requests, the outlier percentages (OP) exceeding 60min were 26%, 57%, 64%, and 66% for CBC, potassium, urea and PT testing respectively in the post- CL period, which were all higher than those from the pre- CL era. Median PR-TATs for the urgent samples were 91mins, 106mins and 111mins for CBC, PT, and both urea and potassium with an average reduction of 16% across all the analytes. Median PR-TAT for the routine samples was curtailed by 51%, 50%, 49%, 34% and 22% for urea, potassium, TSH, CBC and PT respectively. The shorter PR-TAT was attributed to a significant reduction of IR-TAT by 68% and 73% for urgent and routine CBC as well as 52% and 37% for urgent and routine PT respectively. However, the median PI-TAT was delayed by an average of 14min for urgent samples but there was no significant difference for routine samples when the ETV was used. Application of various auto-verification rules shortened the median IR-TATs for both potassium and urea tests. Median IR-TATs were significantly reduced for both potassium and urea tests by an average of 6 min and 4 min for STAT and Urgent requests respectively. The median IR-TATs were slightly decreased for both routine tests, however, the differences were not significant. In addition, there was a significant reduction of the OP exceeding 60 min for both tests from all priority requests that ranged from 38- 77%. **Conclusions:** TLA and auto-verification rules help to efficiently manage substantial volumes of urgent and routine patient samples, evidenced by significant improvement in median PR-TATs and OP-TAT. However, the ETV application as it stands shows a negative impact on the PR-TAT.

B-017

Analytical evaluation of soluble fms-like tyrosine kinase 1 (sFlt-1) and placental growth factor (PlGF) on Brahms Kryptor automated immunoassay for the diagnosis of preeclampsia

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Background: Preeclampsia is one of the leading hypertensive disorders in pregnant women worldwide. It is estimated to cause more than 60,000 deaths per year. This disorder is induced by placental and maternal vascular dysfunction, which affects both maternal and neonatal health. Current diagnosis of preeclampsia in the U.S. is based on non-specific tests such as new onset of hypertension and proteinuria after 20 weeks of gestation. More recently, two emerging biomarkers anti-angiogenic factor soluble fms-like tyrosine kinase 1 (sFlt-1) and pro-angiogenic factor placental growth factor (PlGF), have been demonstrated to be involved in the pathophysiology of preeclampsia. Studies have shown that the usefulness of sFlt-1/PlGF ratio in confirming or ruling out suspected preeclampsia cases. Thus wider availability of the automated measurement of sFlt-1 and PlGF has the potential of improving the clinical management of preeclampsia.

Methods: This study examined K_2-EDTA plasma samples from 50 patients on Brahms Kryptor, an automated immunoassay platform. QC materials were used to access intra- and inter-precision of the assay. Lower limit of quantitation and interference studies were determined using pooled patient plasma.

Results: The sFlt-1 and PlGF assays demonstrated an analytical measuring range of 90-69,000 pg/mL and 11-7000 pg/mL, respectively (r^2>0.99). Lower limit of quantitation (20% CV) was interpolated to be 35 pg/mL for sFlt-1 and 10 pg/mL for PlGF. Total precision for both assay displayed CVs of <10%. Interference studies showed that both assays were not significantly affected by hemolysis up to an H-index of 1100 for sFlt-1 and 300 for PlGF; L- and I- index of 800 and 80 respectively for both assays. Passing-Bablok method comparison with an identical platform from another institution showed the equation y=0.9939x-37.15 with an overall bias of -90.35 for sFlt-1; and y= 0.8936x+2.562, with an overall bias of -39.644 for PlGF. The larger differences in overall bias based on individual tests however was greatly improved when a ratio of sFlt/PlGF is taken into account for method comparison, yielding an equation of y=1.05x+0.02, with an overall bias of 0.84.

Conclusion: The pre-eclamptic biomarkers, sFlt-1 and PlGF assayed on the Brahms Kryptor platform, demonstrate good analytical performance and are acceptable for clinical studies defining the role of these biomarkers for preeclampsia.

B-019

An Abbott Alinity ci-series Instrument system familiarization study

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Background: We performed a familiarization study of a manufacturing prototype of the Alinity ci ® clinical chemistry (c) and immunoassay (i) instrument systems (Abbott, IL, USA). The Alinity ci-series is a fully automated analyzer allowing random and continuous access as well as priority and automated retest for both clinical chemistry and immunoassays tests.

Method: Calibration and quality controls including automated quality controls (QC) processing and QC analysis were assessed. The performance of selected assays (seven clinical chemistry parameters: ICT, calcium, glucose, creatinine and urea, and two immunoassays: TSH and hsTn-I) were evaluated through precision on QC, linearity using provided standards, and limits of blank (LoB), detection (LoD) and quantitation (LoQ), based on CLSI guidelines. Method comparison was performed using the ARCHITECT instrument system C8000 and i2000 system. Throughput and internal controls stability on board were also evaluated. Performance analyses were completed using quality control materials from the manufacturer and biological samples from our institution. Statistical analyses were performed using PC SAS 9.3.

Results: The coefficients of variation (CVs) for within-run precision for clinical chemistry tests ranged from 0.5 to 2% and were of 1.77% for TSH and 3.35 % for hsTn-I. The CVs for day-to-day precision for clinical chemistry tests ranged from <1 to 2% and were of 1.2 % for TSH and 1.94 % for hsTn-I. Linearity testing verified the assay linearity claims for all parameters (r = 0.999). Comparison studies showed good correlations with ARCHITECT instruments (r ranging from 0.974 to 1). All estimates of LoB, LoD and LoQ met the manufacturer's claim. Throughput study revealed 1204 tests/hour and 167 tests/hour capability for clinical chemistry assays and immunoassays, respectively. On board stability of chemistry QC was in the range announced by the manufacturer.

Conclusion: Taken together, the familiarization study performed on a selected set of parameters tested on a manufacturing prototype of the Alinity ci-series analyzer revealed satisfactory analytical performances, allied to simplified maintenance procedures, software easy-to-use, shortened hands-on time and overall system reliability.

B-020

Method verification fully automated with R and LYX

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Background

Method verification is an essential control step for the introduction of new commercial tests or test generations in accredited laboratories. Especially during platform changes, a large number of methods has to be verified at once – a cumbersome, repetitive task generating formalized reports for the quality management. Applying R and LYX, two freely available open source tools, the report generation can be fully automated, yielding highly standardized verification reports within seconds.

Methods

Raw data is obtained by the lab technicians in a formalized Excel™ sheet, containing two columns for the method comparison data (old vs. new), three for the QC levels, three for the intra-day data of the three QC levels, three for the between-day data of the three QC levels, and several columns for data that is inserted in the report text (e.g. method name, platform, matrix, etc.). For the report generation we use LYX, a free TEX processor, which is able to call R and execute R code in "chunks" defined via the R package "knitr". The standard TEX code covers the scaffold of the report, that is replenished by data and results drawn from the excel input files via R chunks. The method description from the vendor is attached to provide all supplementary information necessary for the final clearance of the document. LYX generates a clickable pdf form, which is commented by the lab supervisor and electronically signed.

Results

Providing the verification raw data in a standardized Excel™ form is a fast and simple procedure for the lab technicians, that requires no programming or statistical skills.

The files are saved in a specified directory and LYX is pointed at the filename. Processing takes about 20 seconds, and a PDF form is generated, containing the raw data table, a data summary, the intra-day and between-day CVs, standard deviation, bias, measurement uncertainty, correlation testing, Passing-Bablok regression, and Bland-Altman plots. Dropdown menus are automatically filled, e.g. for the selection of old or new reference ranges. The form also contains a comment field for the final verification clearance.

Discussion

Following an update of our clinical chemistry platform we verified 92 methods without substantial problems (besides minor formatting issues). During re-accreditation, the reports were reviewed and considered as *exemplary* and *comprehensive*. The ease-of use, the speed, the high degree of formalization and standardization as well as the use of free and open software are the major advantages that easily outweigh the efforts necessary to build the process. Automation of verification report generation with LYX and R is a rapid and comfortable way to generate high-quality reports for accreditation and regulatory authorities.

B-021

Daily variation in thyroid function test results: A data mining approach

D. I. Topcu, M. S. Gungoren, C. Züngün. *Duzen Laboratories Group, Ankara, Turkey*

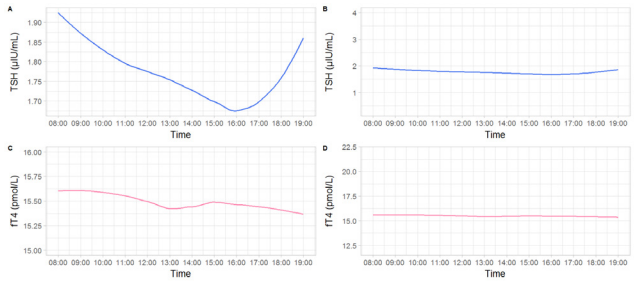
Background: Thyroid function tests are useful diagnostic tools for patient management. For more accurate clinical assessment, any factor causing variation of results should be recognized and avoided. One of the most considerable source of variation is the diurnal pattern of TSH secretion. Prospective studies to determine biological variation values are challenging to design and conduct in daily practice. Recently, data science applications allow laboratories to investigate retrospective data

efficiently. The aim of this study is to demonstrate the distribution patterns of TSH and fT4 results timewise by data mining approach.

Methods: 5-year laboratory records including TSH and fT4 results of patients from 18 to 65 years of age were obtained from laboratory information system (LIS). Initial number of records was 61,229. As information of thyroid medications and diagnosis were not commonly available for all records, individuals with recurrent TFT reports were considered as follow-up patients and not included (n=34,465). Also, patient records including any outlier results of TSH and fT4 tests were excluded by utilizing Tukey method. Final number of patient records included was. 27,393. For each test, all test results distributed within daytime (08.00-20.00) were evaluated according to their sampling times as 1-hour intervals. All statistical analyses were performed with R 3.3.2 (R Working Group, Vienna, Austria).

Results: Results were given in Figure 1. Median of TSH results varied from 1.66 to 1.95 µIU/mL whereas median of fT4 results varied from 15.3 to 15.6 pmol/L.

Conclusion: According to our results, we can conclude that serum TSH levels vary considerably while same amount of variation cannot be observed in fT4 levels. This kind of information can be easily obtained by data mining applications for any other analyte.



B-022

Establishment and Application of an Autoverification System for Chemistry and Immunoassay Tests

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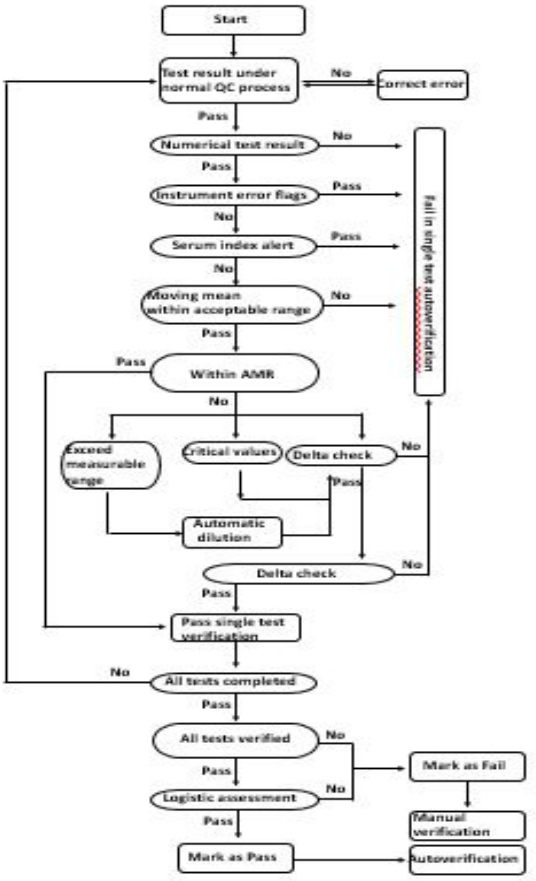
Background: Autoverification is a process of using computer-based rules to verify clinical test results. We aimed to establish an autoverification system for clinical chemistry and immunoassay tests, thereby shortening the turnaround time (TAT). **Methods:** Seven categories of 472 verification rules covering 63 routine chemistry and 26 chemiluminescence tests were encoded using the autoverification functionality of the CentraLink® Data Management System on the Aptio® Automation platform (Siemens Healthcare Diagnostics Inc.). **Results:** We setup and tested the autoverification system from August 2015 to April 2016. In total, the system ran 4,496,425 tests on 366,180 chemistry specimens. The autoverification rate increased from 53.4 to 87%. Average TAT for verification decreased by 97.7%. The system ran 410,040 tests on 160,119 chemiluminescence specimens. The autoverification rate increased from 40.2 to 89%. Average TAT decreased by 77.4%. From May 2016 to January 2017 (when autoverification was operational), compared with the same period in 2014 (when manual verification was employed), the following changes were observed: a) Volume of routine chemistry tests increased by 46.4%; b) Median TAT for tests decreased by 41.9%; c) Median TAT for critical values decreased by 50.5%; d) Rates of tests that didn't go through autoverification were 88.2% for NS(Normal Severity), 6.05% for SS(Sample Status), 2.40% for DS(Delta Check Severity), 2.00% for LS(Logical Assessment Standard), 0.97% for IS(Instrument Severity), and 0.43% for CS(Clinical Diagnostic Standard); e) Rates of abnormal specimen status identified by various modules of Aptio Automation were 7.13‰ for jaundice, 5.39‰ for blood lipids, 2.20‰ for hemolysis, 0.17‰ for barcode error, and 0.15‰ for insufficiency; f) Error rate decreased by 93.3%; and g) patient and staff satisfaction increased by 85%. **Conclusion:** Our results indicate that using the CentraLink Data Management System to perform autoverification can decrease TAT, minimize the error rate and reduce the pressure of performing manual verification.



B-024

Changes in Laboratory Testing Turnaround Times at a Major Academic Medical Center After Converting to a Total Laboratory Automation System for Chemistry and Hematology

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Background: Laboratory turnaround time (TAT) has a major impact on patient care. Longer TATs can delay decision making and prolong hospitalization. In April 2016, our large academic medical center (1300 beds) became one of the first two hospitals in the country to implement the Roche 8100 total laboratory automation (TLA) system, with integrated chemistry and hematology analyzers. Previously, we had a partially automated laboratory with separate spaces for chemistry and hematology. Improvement of TATs was a major goal of this conversion.

Objective: To determine the effect of implementing a TLA system on TAT in a major hospital laboratory.

Method: Median and 90th percentile TATs for surrogate tests of the basic (BMP) and complete (CMP) metabolic panels (sodium and protein, respectively), and complete blood count (CBC) (platelets), as well as cardiac troponin I (cTnI), from one month before and six months after the conversion were compared.

Results: Mean and 90th percentile TATs fluctuated and even increased at times in the first months following the conversion due to mechanical, work flow and software issues. However, after working with the manufacturer to make hardware and software adjustments, TATs markedly improved. Median and 90th percentile TATs for BMPs decreased 38% and 34%, respectively. Similarly, median and 90th percentile TATs for CMPs decreased 35% and 27%, respectively. More modest decreases were observed for CBC TATs (Median: 23%, 90th percentile: 10%). Finally, decreases were also observed for troponin (Median: 23%, 90th percentile: 11%), despite the fact that it is measured on an off-line analyzer after processing on the 8100. The latter suggests that automation of processing alone can appreciably decrease TAT.

Table 1. Turnaround times before and after TLA implementation.				
Test	Median (min)		90th percentile (min)	
	Before	After	Before	After
BMP	45	28	71	47
CMP	46	30	75	55
CBC	13	10	49	44
Troponin I	43	37	65	58

Conclusions: Our data demonstrate that adoption of a TLA system can significantly reduce TATs for both common and critical laboratory tests but that close interactions with manufacturers is critical to optimizing the advantages of TLA.

B-025

Modular automation for immunoassays in the clinical laboratory

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Background: Pre-analytical sample processing of specimens for immunoassay involves several repetitive manual tasks including sample dilution to the minimum required dilution (MRD), generating calibrator curves and delivering diluted samples to assay plates. Variability is introduced by pipetting technique and operator and throughput is limited. Laboratory automation was introduced to minimize the variability of these pre-analytical steps, identify and track samples within the workflow, and increase throughput via the parallel preparation of up to eight (8) 96-well plates for each multi-plexed immunoassay. A modular design was used to increase the overall throughput, with the flexibility to support the development process and transfer to the clinical laboratory.

Method: The pre-analytical sample processing pipeline is comprised of two Tecan EVO automated liquid handling systems (ALHS). A standardized plate map is applied to all assays, allowing for the development of common modules for sample arraying, diluting, and plating as well as calibrator curve generation and process control specimen handling. A shared sample source plate is used for all assay dilutions, reducing sample loss to the well dead volume and overall processing time. Samples are introduced to the pipeline pre-arrayed in the source plate or in barcoded test tubes. Sample identification is tracked throughout the process via barcoded labware and tools within Evoware, and reported to text files for the LIMS system. After plating, the assay operator controls the timing of incubations and subsequent process steps, reducing ALHS downtime and allowing the laboratory to maximize platform use.

Individual process modules were transferred to the intended ALHS platform and verified by comparing endpoint assay measurements with those produced by the manual laboratory process.

Results: Before implementing the ALHS platform, the laboratory processed up to two immunoassay plates per operator per run by a fully manual process. At capacity, the ALHS platform handles the pre-analytical tasks of calibrator curve generation, sample dilution and duplicate plating of up to 296 samples across five immunoassay panels, each with an MRD between 1:4 and 1:300,000. The processing time for 296 pre-arrayed samples is approximately five hours and results in eight (8) 96-well assay plates for each immunoassay panel, for a total of forty (40) plates. Arraying samples from source tubes adds approximately 1.5 hours to the overall runtime.

Calibrator curves prepared by the ALHS were comparable to manual preparation when evaluated for percent recovery and signal-based coefficient of variance (%CV) of each calibrator point. Signal-to-noise improved for the tested calibrator curves at all MRDs. Calibrator curves were plated by the ALHS and manually on separate assay plates. Similar replicate %CV and intra-plate %CV were obtained for each calibrator point by both methods. Sample dilution was tested at each MRD with ten plasma samples with four parallel preparations each. Replicate and intra-plate concentration-based %CV for samples diluted by the ALHS platform were equivalent to manual dilutions.

Conclusion: A four-fold improvement in batch capacity was achieved with comparable assay performance by transferring key pre-analytical tasks to an automated platform. Sample identification is tracked throughout the workflow via barcoded labware and scanning devices.

B-026

Nova tecnologia para otimização de produção

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Background: Technological innovations are increasingly present in clinical analysis laboratories, providing great progress in production and safety processes. With this in mind, we believe it is essential to search for more agile and efficient solutions, maintaining the quality of results. For this, the immunology sector requested the acquisition of a new set of equipments, which made possible a series of improvements in the production of FAN and DNA exams. Thus, the objective of this work was to execute performance comparisons of equipment 1 (AP-16 IF Plus) in relation to equipment 2 (Sprinter XL) and to compare titration configurations in order to optimize the productive capacity of the ANF (antinuclear factor) and Anti-dsDNA tests. **Methods:** The evaluation method adopted was to compare the performance of equipment 1 with equipment 2. Subsequently, a new set of equipments were installed that offer a microscope capable of scanning the image of the slides. At the end of the study, the procedures and workflow were reformulated in order to make better use of the new technology.**Results:** As an initial result, the equipment replacement increased the processing capacity from 142 samples to 198 samples in addition to a 25% reduction in preparation time of the slides in the screening step. The scanning of the images of the slides expedited the reading process in computers; it also increased the traceability and safety of the process. With the reformulation of the procedures and the fact that the new technology stores the images in a database we have obtained a reduction in primary titration repetition, which resulted in an increase of up to 50% in the slides´ dilution capacity during the titration step. As a final result, there was a 40% reduction in the processing time of each sample, an increase of capacity in the titration step, and also a greater traceability and safety in the overall production. **Conclusion:** The process automation of ANF (antinuclear factor) and Anti-dsDNA tests improved the production of the immunology sector, however, only the implantation of the new technology did not result in the maximum optimization of the processes, whereas a more refine evaluation of the proposed set and production flow was necessary in order to reach the optimal configuration for screening and titration of the exams. We were able to prevent a underutilization of the mechanism by 65%, bringing a real gain in productivity by 33% of sequential dilution capacity.

B-027

Accurate Detection of ANCA and Endpoint Titer Using Single Well Titer on NOVA View® Automated Fluorescence Microscope

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Objective: Automation of indirect immunofluorescent (IIF) assays has the potential to improve reproducibility and eliminate subjectivity of anti-neutrophil cytoplasmic antibodies (ANCA) testing, while improving workflow and efficiency. The purpose of this study was to compare the performance of NOVA View®, a computer-aided automated fluorescence microscope to that of the traditional manual method for ANCA detection and endpoint titer, using a clinically and analytically characterized cohort of samples from patients with ANCA-associated vasculitis (AAV) and controls. **Methods:** The study included 653 samples for positive agreement from patients with AAV (n=185), relevant disease controls (n=409), and anti-MPO and anti-PR3 positive samples, previously characterized by ELISA (n=59). All samples were tested on both NOVA Lite® DAPI ANCA (formalin) and NOVA Lite® DAPI ANCA (ethanol) kits (Inova Diagnostics, San Diego, USA). The study for endpoint titer was performed on 24 anti-MPO (P-ANCA) and 23 anti-PR3 (C-ANCA) positive samples. Slides were analyzed and interpreted by NOVA View. Subsequently, a trained technologist interpreted the digital images from the NOVA View computer monitor, and also read the slides with a manual fluorescence microscope. NOVA View software generated results and digital image interpretation results were compared to those obtained with manual microscopy, and with each other. **Results:** In the clinical cohort population, NOVA View digital image reading, manual reading, and NOVA View® output results showed a high level of agreement. Based on 47 samples, 76.6% of SWT results were within ± 1 dilution step of that of the manual titer, and 91.5% were within ± 1 dilution step of that of the digital titer, and 97.7% of SWT results were within ± 2 dilution steps of that of both the manual titer and digital titer.

Conclusion: This study demonstrates that the new ANCA module on the NOVA View automated system generates results including endpoint titer that are equivalent to ANCA testing by manual microscopy. NOVA View is an attractive option for labs who want to automate and streamline the reading and interpretation of the traditional fluorescent microscopy.

B-028

Early development of DxONE Insights, a tool to enhance data driven decision making to improve laboratory efficiency

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Background: As hospital networks face today's paradox of declining reimbursements and increased emphasis on patient satisfaction, it is difficult to find the balance between reducing costs and maintaining quality of service. We must continually seek improvement opportunities that reduce cost without compromising quality. Adventist Health laboratory network was a pilot site for a new clinical informatics tool: DxONE Insights from Beckman Coulter.

Objective: Evaluate DxONE Insights in its ability to provide important data to guide labs to improve overall efficiency. Some of the applications we evaluated were reagent waste reduction; testing consolidation; appropriate assignment of low volume testing to Adventist Regional Core Lab or Reference Lab; and better alignment of staffing to the workload.

Methods: Eighteen Adventist Health Hospitals with Beckman Coulter DxI and DxC instruments equipped with PROService Remote monitoring were provided access to their instrument data via the DxONE Insights pilot tool. After training on the tool, lab directors were challenged to evaluate their lab's data in key areas using the DxONE Insights pilot tool: reagent efficiency, instrument to instrument test menu comparison, cartridge utilization, and staffing efficiency. Recommended testing changes were coordinated with the Medical Director and Medical Staff to gain alignment.

Results: One laboratory used the Sample Count Report and made an adjustment to better align staffing to testing volumes. Several laboratories noted that low volume assays were loaded on two analyzers, and consolidated testing to a single analyzer (reducing the need for additional QC and calibration testing). Low volume tests were identified and some were moved to a centralized regional lab and other critical tests were identified to be run with QC on an as needed basis vs. routinely. Overall reagent usage is being monitored with an intent to improve efficiency; it was 78.5% in Q4 2016 & 74.5% in the current quarter.

Conclusions: The DxONE Insights pilot tool has become a catalyst to change our view of the business of laboratory testing. The visibility provided with the DxONE Insights tool has helped Adventist Health Laboratories involved in the pilot program reduce waste in their processes and increase efficiency. This leads to decreased costs, without sacrificing the quality of patient care. Routine use of this tool will provide a method of sustainment of the improvements gained and opportunity for future improvement opportunities. The data allowed us to collaborate with lab staff, and with the Medical Directors and Medical Staff to ensure that essential tests have remained available without compromise to patient care.