Wednesday, July 30, 2014

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

Management

B-124

Critical Values Reporting: The Search For an Effective Solution.

R. Khoury, P. Gudaitis, B. P. Salmon, A. Gandhi, J. Camoia, D. Pasquale, D. Gudaitis. *Aculabs, Inc., East Brunswick, NJ*

Background: Critical laboratory result according to Dr. George Lundeberg is: "A laboratory test result that represents a pathophysiologic state at such variance with normal as to be life-threatening unless something is done promptly and for which some corrective action could be taken." Although his description of critical was more than 30 years ago, critical vales received more attention when the Clinical Laboratory Improvement Amendments Clinical Laboratory implemented the importance and the concept of critical values. CLIA, CAP, State agencies and JCAHO require laboratories to have written procedure for reporting critical value, defining critical results, documentation and read back, and turnaround time for reporting critical results to the care giver. The determination of critical cutoff depends on the population, setting, and the feedback from the caregivers.

Design: data from 79,328 tests ordered on 13,579 Specimens that were collected from residents in Long-Term Care facilities were collected and included results from: chemistry, hematology, coagulation, therapeutic drug monitoring, and cardiac markers. Critical result calls and any problem with reporting the results to the caregiver (because the patients are resident in Long Term Care Facilities the results are given to the nurse in charge of that patient) were documented for every critical test. Statistical analysis was done using Analyse-it.

Results: 1,784 (2.8%) critical results were documented; the majority of the critical samples were for chemistry followed by hematology and coagulation. 616 (34.5%) values were reported immediately to the caregiver by the technologist who performed the test due to the severity of the results; 1168 values were reported by our call-in department, 22% of the calls were unsuccessful due to either no one answering the calls, nurses are busy/unable to take the calls, or nurses refuse to provide her/his name to be documented in addition to read back the result. All unsuccessful calls were followed by another call until the results were given to the appropriate caregiver. Most of the unsuccessful calls were between 10-11 AM, followed by 5-6 PM, and 7-8 PM. which coincide with morning meetings, passing medication, lunch/dinner break.

Conclusion: the majority critical values are reported to the caregiver without any delay; more than one fifth of the results took longer time to relay the result due to inability to reach the care giver. Implementing reliable communication systems will help improving the critical values reporting, such as immediate electronic notification via fax/online, automated notification system, default phone number or alternate caregiver in case of inability to reach the facility. Auditing record will help identifying any inadequate documentation, weakness, and the facilities with the most unsuccessful call to work with them to solve the problem.

B-126

Six Sigma Reagent Performance Quality Metrics for Beckman Coulter AU Clinical Chemistry Instruments

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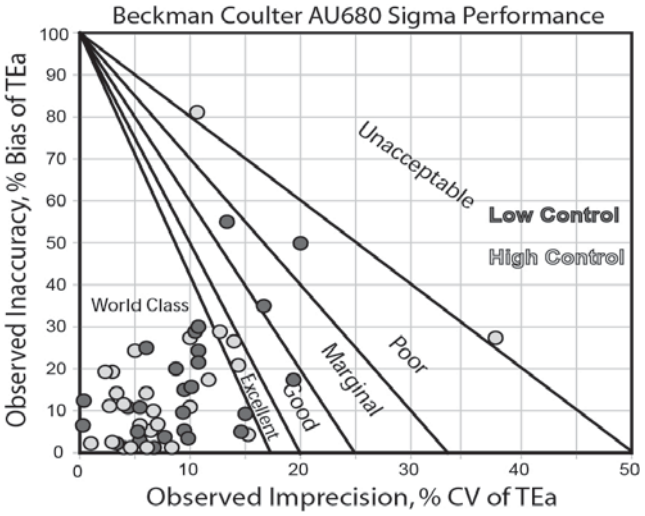
Background: Clinical chemists should be aware of the analytical strengths and limitations of their laboratory methods. Six Sigma reagent performance quality metrics are an excellent way to quantify the precision and accuracy of analytical methods. However, the literature is scant with publications describing these metrics for today's clinical chemistry instruments. Data for 26 clinical chemistry analytes on two AU platforms (AU680 and AU5800) were used to calculate sigma metrics. We display the performance of these methods on Method Decision Charts, a popular tool for portraying Six Sigma metrics.

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 the expected mean).

Results: The AU680 results are summarized on the accompanying Method Decision Chart. The majority of methods evaluated on both the AU680 and AU5800 were classified as "Good" or better with many achieving Six Sigma performance. The latter group should be easy to control with cost-effective QC practices. In contrast, a few analytes do not achieve desired status and therefore may require more rigorous QC practices.

Conclusions: Most clinical chemistry methods function at world-class specifications using the Beckman Coulter AU680 and 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 choose which analytes to focus on for method improvement. Additionally, optimal QC practices for laboratory production are implied.



B-127

The Empower project - integrated tool to evaluate the quality and effectiveness of laboratory testing.

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Background Classical external quality assessment (EQA) is well established, however, the need for integrated EQA-services recently emerged, among others to empower clinical laboratories for future tasks, e.g., contribution to the development and implementation of global health-care policies. Also, ISO 15189 accreditation requires laboratories to identify and monitor quality indicators. From this perspective, we developed the Empower project.

Methods The project comprises 4 pillars: (i) master comparisons with panels of frozen single donation sera, (ii) virtual EQA-1 and (iii) -EQA-2 based on data readily available in the laboratory, i.e., patient- and internal quality control (IQC) results, and (iv) conceptual/statistical education about analytical quality. The pillars (i) to (iii) are conducted across laboratories and manufacturers. The master comparisons aim at participation of 20 laboratories per manufacturer, and encourages the latter to include also their in-house laboratories. It is essential that the participants use homogeneous systems, i.e., instrument, calibrator and reagent from the same manufacturer. Virtual EQA-1 requires the laboratories to calculate and send the daily medians of the results for outpatients. We plot the moving median of the collected data in time. The participants can consult a graphical user-interface to monitor the mid- to long-term stability of their performance in comparison to other peer group laboratories. Virtual EQ-2 part (not operational yet, except in a few laboratories) plans a similar approach, but on the basis of the daily IQC means.

Results The value of the master comparisons is in showing the intrinsic quality of assays as performed under 'field' conditions, the performance of the individual laboratory within its peer group and the calibration fix-point and interchangeability of results between laboratories/manufacturers. Monitoring of patient- and IQC-data gives evidence about the mid- to long-term analytical variation of testing in the individual

laboratory, backed-up by information on peer group performance. It also enables to uncover biases between different instruments in a laboratory, as well as occurrence of shifts/drifts. If the cause of the aberration can be identified, the problem can be solved either by the laboratory or the manufacturer. For example, an unacceptable lot-to-lot variation may require factorizing by the laboratory or fundamental improvement of the lot stability by the manufacturer. The observation of biases may also help laboratories to understand the sometimes fluctuating flagging frequency of results.

Conclusions The Empower project reflects on the mid- to long-term analytical stability of laboratory/assay performance and enables to uncover all major bias components/sources. From this perspective, we believe it is a new integrated tool for modern quality management. Its major asset is that it works with data generated from commutable samples, and linked to observations in daily IQC practice. It strengthens the position of laboratories in their claims from manufacturers, facilitates the dialogue at the laboratory-clinician interface, and is a tool for the discipline to derive realistic quality specifications. On longer term, it might establish a constructive relationship between laboratories, manufacturers, clinicians and health policy makers, so that together they can build towards a common understanding about manageable quality of performance to the benefit of the patient.

B-128

The relevance of a computerized system for temperature and humidity control in a large Brazilian laboratory

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Background: The controls and records of temperatures and humidity are very important in many areas. In clinical laboratories, the temperature control of samples and reagents are fundamental for analytical quality. This activity can be complex and difficult when involves several areas and many instruments as refrigerators, freezers, ultra freezers, climate chambers and acclimatized rooms, resulting in 60 points of control in our DASA SP Central Lab. This Lab is currently processing around 4.5 million tests / month, with huge sample flow and local reagents stock representing a large monetary amount. This reality demanded a technical solution. The team of equipment management (SELAB) opted for a system based on thermo transmitter technology, using radio frequency, software for data analysis and creating an emergency flow.

Objectives To enumerate the main features and benefits of a computerized system for temperature and humidity control as: Capability to monitor sixty points of temperature or humidity; Standardization of our monitoring procedure - change from manually to computerized Registration and safety in storage of data in compliance with FDA title 21, CFR part 11; Analyze equipments performance; Easy submission of records in audit processes as PALC, CAP, ISO.

Methodology The laboratory acquired the DataNet System produced by Fourier Systems. This solution provides an intelligent network sensor system with assurance of reception and no data loss. The ZigBee is a standard-based protocol built around the IEEE *802.15.4 wireless protocol, providing the network infrastructure required for wireless and low power network applications. Basically the system consists of thermo transmitters, receiver, server and an integrated phone. The thermo transmitters were fixed next to the equipments. With a thirty minutes interval the measurements are sent to server. Using the software, the ranges of alarm and pre-alarms are defined for all points to be monitored. Together with The Department of Analytical Quality, different ranges were set up. When the temperature reaches the control limits, the software sends an email containing information about the area and temperatures that are outside the acceptable range.

Results: In February of 2012, the system was on line, monitoring 24 hours these instruments:

• 5 climate chambers;

• 6 ultra freezers (range: -80 to -60°C);

• 15 refrigerators (range: 2 to 8°C);

• 15 freezers (range: -30 to -8°C);

• 7 heated chambers (various intervals);

• 12 acclimatized room (range: 15 to 25°C)

Two year after implementation several risk situations were avoided for samples and reagents through the alerts emailed to areas and staff working in the lab.

Conclusion: The system has shown a good level of reliability and has helped us to avoid problems through tendency of temperature, shown in graphs. The daily registers allow us to identify low performance equipment. During this period there weren't any problems with samples or reagents.

The Company reached a high level of security for the temperature data. Now is easy the submission of records in audit processes. DataNet also keeps the traceability of all users' activities, following the regulation from The Food Drugs Administration, Title 21, Code of Federal Regulations Part 11.

B-129

Managing Good Internal Quality Control by Adopting Risk Analysis Framework

J. J. Jeyaraman, Z. Sakiman, E. B. Tan. *Sunway Medical Centre Berhad, Petaling Jaya, Malaysia*

Background: Internal Quality Control (IQC) is the heart of quality assurance and plays a pivotal role in not only ensuring accurate and reliable patient results but also ensuring high standards of quality in materials, method performance and manpower. SUNMED lab has implemented newly designed Analytical Quality Control (AQC) strategy and it could actually improve overall assays monitoring and performance. However, the question on whether the newly designed AQC strategy alone is it effective enough for managing good analytical quality? Our objectives are to determine whether applying Risk Analysis Framework could actually reduce analytical and the probability of medical error, comply with accreditation standards and further improve customers' outcomes.

Methods: We have adopted Six-Step Risk Analysis Framework and came up with Quality Control Plan (QCP). We did the following:

• Firstly we identified the potential failures in incorrect test results.

• After that we estimated the risk using the probability, severity and detectability.

• The identified risks were evaluated and prioritized using criticality matrix (for example staff competency, IQC and test algorithm)

• In addition to that we identified control plans to reduce the proritized risks

• We further implemented the mitigation plans into QCP (for example staff competency, gap analysis, training strategies, revised test algorithm and AQC strategy)

• We also reviewed the system for effectiveness of QCP

Results: The results showed

• Significant risk reduction from the average criticality rating of 35 (unacceptable) down to 12 (acceptable); hence reducing the probability of medical error.

• Marked improvement in the ISO 15189 audit nonconformance from 17 in the year 2010 to 3 in Jan 2013 assessment.

• Improved overall customer satisfaction rate by 15% in the 2013 against the year 2011.

Conclusion: By adopting Six-Step Risk Analysis Framework and implementing it in QCP enables our SUNMED lab not only to mitigate but also assist in preventing possible hazard or risk that may occur before incorrect results are reported to health care providers and clinical actions being taken.

B-130

Head, Shoulders, Knees and Toes... Baby Steps to Specimen Nomenclature & Informatics

R. Merrick[1], C. Johns[2], P. Banning[3]. *[1]Vernetzt, LLC, Sacramento, CA, [2]LabCorp, Burlington, NC, [3]3M Health Information Systems, West Linn, OR*

Objective: Applying informatics to laboratory reporting involves complex standards and terminologies. Accurate portrayal of the specimen is crucial to appropriate processing at the front end, and correct clinical interpretation by the provider. Adding layers of computerization; secondary use cases of tumor registries, public health reporting, laboratory assay research; US federal Meaningful Use mandates in future years intensifies the needs. Work has been accomplished to date to create a standardized specimen cross-mapping table using the SNOMED CT terminology. The Specimen Cross-Mapping Table (CMT)'s goals are: 1) Give guidance to SNOMED CT ® encoding for Specimen related terms in the context of HL7® v2.x messaging using the Specimen (SPM) segment, 2) Identify gaps in the existing standard nomenclature, 3) Map the existing HL7 specimen terminology to SNOMED CT and 4) Provide references about common collection methods and 5) Indicate specimen preferences for specific laboratory domains.

Methods: Local specimens terms from partner labs were collected and mapped to a single term, called the Public Health Interoperability Project (PHLIP)-preferred term. For each PHLIP-preferred term a definition is provided as well as a link to a description of the collection method, where possible. Each PHLIP-preferred term is then mapped, either one-to-one or one-to-many, to the HL7 defined SPM fields, using

SNOMED CT concepts from the appropriate hierarchies for each applicable SPM field. HL7 terms were also mapped to the PHLIP-preferred term, facilitating a HL7 to SNOMED CT crossmapping. The resulting Specimen-CMT, at this time focused on human sample types, is now being reviewed by professional associations for the accuracy of the definitions as well as to provide validation about preferred specimen types for each laboratory section (microbiology, chemistry, pathology, etc).

Results: The Specimen-CMT has been incorporated into a simple mapping tool for ease of mapping local codes to standards and across standards. Several new terms have been submitted to SNOMED CT and guidance on use of specific vocabulary forwarded to message guide authors.

Conclusion: This work is ongoing at the Laboratory Messaging Community of Practice (LMCoP), comprised of laboratory and standard experts from public health laboratories at the state and federal level, national clinical laboratories, the National Library of Medicine and professional organizations, to improve and expand beyond human samples to animal and environmental domains. The goal is to provide a starter set of specimen related vocabulary for electronic data systems in the health care arena.

B-131

Test Overutilization is an Issue That Should be Solved: Folate Studies Taken From Internal to External Laboratory Reduced the Number of Orders by 76%!

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Background: The most frequent reason for the heavy load of the routine clinical laboratories is overutilization of tests. Some of the requested parameters are not used by the clinicians in their daily practice. In addition, test turnaround times are gradually shortened by the laboratories to help the clinicians speed up their patient management. This study evaluated whether prolongation of the test turnaround times will affect the ordering frequency of the test by the clinicians.

Methods: The number of folate, vitamin B12 and ferritin test requests were counted in ten-day periods throughout January and February 2014. Between January 21st and February 2nd, folate requests were sent to an external laboratory because of the shortage of folate in the distributor's stocks. The supplier was not able to provide the folate test for about two months and our laboratory consumed its own stocks. Then we took the statistical numbers of requests of folate, vitamin B12 and ferritin for this ten-day period(TP2), before(TP1), and after this ten-day period(TP3). One-way ANOVA and Tukey post-hoc tests were used to compare the numbers of requests of the three parameters between these three ten-day periods. Statistical significance was set at $p<0.05$.

Results: There was a statistically significant difference between the three ten-day periods for folate orders as determined by one-way ANOVA($F(2.27)=173.745$,$p<0.001$). A Tukey post-hoc test revealed that the number of test requests was significantly different for folate orders between TP1(350.40±46.14), TP2(84.30±11.13) and TP3(146.40±33.06)($p<0.001$), whereas there was no statistically significant difference between the ten-day periods for B12($p=0.224$) and ferritin($p=0.155$).

Conclusion: This study indicated that there is an obvious excess of folate test request in our hospital. There was a remarkable difference between the essentially and the routinely ordered numbers of folate tests. In contrast, no such difference was observed for vitamin B12 and ferritin test requests. This remarkable gap between request numbers of parameters of even the same diagnostic panel such as anemia suggests that a limitation given to a test request may result in prevention of overutilization.

B-132

Developing, Implementing, and Validating Auto verification in the Medical University Laboratory in Thailand

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Objective: The purpose of this study is to build auto verification rules and evaluate against manual verification using historical data. Rules are optimized to match the expected outcomes from manual review.

Relevance: Instrument Manager provides a flexible middleware platform for implementing auto verification using its sophisticated rules engine, freeing the laboratory staff of other activities.

Methodology: Analysis results over a week were used to evaluate reliability of rules developed for 36 Chemistry and Immunology tests. These rules were developed to cover 3 major areas, Auto verification range, Delta check (%) and Integrity Check. Auto verification ranges were derived based on Reagent Assay Inserts, international guidelines, and laboratory experience. Delta check values were calculated as %RCV. Integrity checks were developed to ensure consistency, e.g. serum indices (HIL), contamination, etc.

Validation: Analysis results were processed through Instrument Manager based on rules developed. The same data set was compared with manual review and release. Adjustments to rule parameters were made to ensure auto verification closely matched manual review by reaching 0 % of false auto released results.

Results:

Metrics	Rules setting at the beginning		After revised rules set	
	Number	%	Number	%
Total Samples	7,676	100%	9,831	100%
Auto released Samples	6,248	81.4%	8,387	85.3%
Manual released samples	1,428	18.6%	1,444	14.7%
Released result correctly	7,259	94.6%	9,821	99.9%
False Auto released	196	2.6%	0	0%
False hold for manual released	221	2.9%	10	0.1%

Conclusion: Adoption of auto verification successfully reduced the tedious manual review process. 85.3% of test results were auto-released, and only on the remaining 14.7% required staff manual review. Of all these samples, almost 99.9% were released correctly compared to our manual review. Only 0.1% was held for review when they could not be auto-released. There is no impact on patient safety as manual check is required and no results were falsely released.

B-133

Improving Workflow in the SGC Phlebotomy Area Utilizing Front Line Co-workers and Lean Tools

J. K. Witt, B. Barksdale. *Mercy, Smith-Glynn-Callaway, Springfield, MO*

Background: The project addressed workflow in the clinic phlebotomy area utilizing lean and six sigma techniques. Workflow consisted of 6 phlebotomists working in 9 phlebotomy rooms. Phlebotomists collected 350 specimens a day with errors in collecting/receiving of the specimens in the LIS of 75 specimens a month. The area design was disjointed and inefficient, without defined roles for the phlebotomists in collecting/receiving and calling patients. No computers were in the phlebotomy rooms for collecting/receiving patient specimens.Two computers were located in the main phlebotomy area. The 6 phlebotomists used these two computers, resulting in bottlenecks, inventories and delays in specimen processing, inefficient movement, lost specimens and chaos.

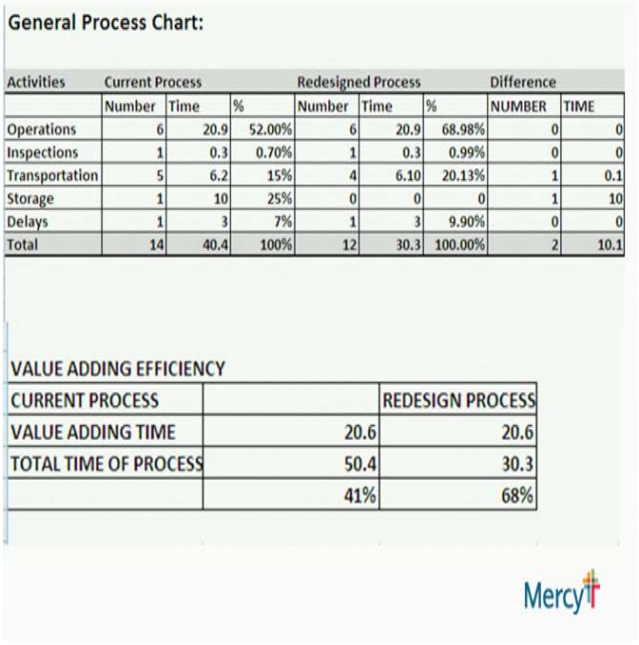
SGC Mercy clinic monitored unreceived specimen errors for 12 months. All errors are a source of patient, physician and co-worker dissatisfaction as well as an increase in cost and inefficiency.

Data was gathered to understand the current process and all phlebotomists were invited to participate. The data was placed in a 5w2h, general process, process activity, spaghetti and flow charts. Suggestions for improvement were also placed in charts for comparison.

Methods: Frontline co-worker focus groups, observation, VOC, VOP and flowcharts..

Results: The phlebotomists identified the need of computers in the main rooms and the need of better defined job roles. Unreceived errors improved by approximately 60%.

Conclusion: Involving front line co-workers to investigate and improve processes led to the 60% improvement in collecting/receiving errors. Value adding efficiency increased 27%. The phlebotomists are encouraged to make suggestions for further workflow improvements as well as debrief on each months issues and problems. Quality improvement is ongoing.



General Process Chart:

Activities	Current Process			Redesigned Process			Difference	
	Number	Time	%	Number	Time	%	NUMBER	TIME
Operations	6	20.9	52.00%	6	20.9	68.98%	0	0
Inspections	1	0.3	0.70%	1	0.3	0.99%	0	0
Transportation	5	6.2	15%	4	6.10	20.13%	1	0.1
Storage	1	10	25%	0	0	0	1	10
Delays	1	3	7%	1	3	9.90%	0	0
Total	14	40.4	100%	12	30.3	100.00%	2	10.1

VALUE ADDING EFFICIENCY

CURRENT PROCESS		REDESIGN PROCESS
VALUE ADDING TIME	20.6	20.6
TOTAL TIME OF PROCESS	50.4	30.3
	41%	68%

Mercy IT

B-134

Differences in laboratory requesting patterns in emergency department in Spain.

A. Andrade-Olivie[1], M. Lopez-Garrigos[2], J. L. Barbera[3], J. L. Quilez-Fernandez[4], J. L. Ribes[5], J. M. Gonzalez-Redondo[6], J. Sastre[7], J. V. Garcia-Lario[8], J. Asensio[9], J. I. Molinos[10], J. Molina[11], J. R. Martinez-Ingles[12], J. Diaz[13], L. Navarro-Casado[14], L. Martin-Martin[15], M. Salinas[2]. *[1]Hospital Xeral-Cies, CHU, Vigo, Spain, [2]Hospital Universitario de San Juan de Alicante, San Juan de Alicante, Spain, [3]Hospital de Manises, Valencia, Spain, [4]Hospital Universitario Reina Sofia de Murcia, Murcia, Spain, [5]Hospital de Manacor, Manacor, Spain, [6]Hospital Santiago Apostol, Miranda de Ebro, Spain, [7]Hospital Virgen de los Lirios, Alcoy, Spain, [8]Hospital Virgen de las Nieves, Granada, Spain, [9]Hospital Universitario Infantil Niño Jesus, Madrid, Spain, [10]Hospital Sierrallana, Torrelavega, Spain, [11]Hospital Comarcal de la Marina, Villajoyosa, Spain, [12]Hospital General Universitario Santa Lucia, Cartagena, Spain, [13]Hospital Francesc de Borja, Gandia, Spain, [14]Complejo Hospitalario Universitario, Albacete, Spain, [15]Hospital General de La Palma, Santa Cruz de Tenerife, Spain*

Background:Compare laboratory requiring patterns in patients admitted to emergency department (ED), in 76 Hospitals in Spain. Methods:20 tests ordered by ED physicians during 2012 were examined in a cross-sectional study. Data were collected from laboratory databases and indicators that measured every test request per 1000 ED admissions and related test requesting ratios, were calculated. Results:Table shows mean, median, range and variability index (Percentil90/Percentil10) of every indicator result. The frequency of ordering the stat tests ranged from 9.8 to 466.2 per 1000 ED patient's admissions. Procalcitonin and NT-proBNP were only measured in 61 and 49 stat laboratories respectively. Total proteins were measured in every ED. Albumin was measured in one. Also, lipase instead of amylase in one. Conclusion:Considerable variability exists in the use of stat laboratory test by physicians in 76 ED. Variability between centers was extremely high, especially in the less requested tests, despite clear indications of such request in emergency setting, indicating that can be often determined as a matter of routine or out of habit in some areas. These large variations included tests that are clearly redundant, as urea/creatinine and AST/ALT. What is really surprising is the high demand for some tests in some ED, such as procalcitonin and NT-proBNP, compared to the absence of measurement in other settings. The high variability of indicator results shows a probable stat abuse and misuse, a dangerous issue in Emergency setting. Requests not justified may lead to delays in testing for patients who have truly life-threatening conditions. Appropriateness indicators can be applied across a spectrum of laboratories, being useful for comparing requesting patterns. There is a need to unify demand by optimizing the use of appropriate tests, through interdepartmental communication to achieve a good use of diagnostic testing, on which many emergency clinical decisions are based.

	Mean	Median	Range	Variability index
Tests requesting per 1000 ED admissions				
Alanine transaminase (ALT)	147,81	127,85	0,00-607,62	50,39
Albumin	16,95	0,65	0,00-415,69	∞
Amilase	97,81	93,85	0,58-228,06	3,45
Aspartate transaminase (AST)	143,40	112,70	0,00-609,60	∞
Brain natriuretic peptide (NT-proBNP or proBNP)	14,52	1,57	0,00-96,31	∞
Calcium	66,03	30,40	0,00-425,80	45,46
Cell Blood Count (CBC)	466,21	400,40	59,15-1053,42	2,63
C-Reactive protein (CRP)	232,11	233,44	0,00-692,84	8,33
Creatine Kinase (CK)	115,61	111,89	2,03-468,67	31,98
Creatinine	438,07	395,71	33,92-999,33	2,62
Glucose	425,38	394,76	36,45-988,32	2,42
Lipase	9,87	0,00	0,00-181,85	∞
Potassium	434,37	399,15	35,44-1004,40	2,43
Procalcitonine (PCT)	18,09	10,88	0,00-145,06	∞
Sodium	427,16	398,76	25,48-1004,39	2,40
Total bilirubin	116,90	100,61	0,00-521,56	20,84
Total protein	66,54	22,21	0,11-429,67	197,05
Troponin	104,92	99,35	0,03-230,16	2,93
Urea	395,26	373,70	1,88-997,29	3,89
Urinalysis	160,49	161,07	9,29-439,74	3,14
Related test requesting ratio				
AST/ALT	8,84	1,00	0,00-537,63	∞
CK/Troponin	2,53	1,07	0,02-68,50	17,91
CRP/CBC	0,54	0,61	0,00-0,95	7,88
PCT/CRP	0,15	0,05	0,00-2,84	∞
Urea/Creatinine	0,91	1,00	0,00-1,43	1,86

B-135

Impact of Technology in Improving the Quality of Pre-analytical Phase of Laboratory Investigations in a Tertiary Care Oncology Center.

C. V. Hingnekar, H. K. V. Narayan. *Tata Memorial Hospital, Mumbai, India*

Background: This is a study to assess the impact of technology in improving the processes in the preanalytical phase of laboratory investigations as compared to the erstwhile manual method. The objective of this study is to assess the impact in terms of turnaround time, elimination of transcription and labeling errors resulting in enhanced patient satisfaction. The technologies such as Laboratory Information System for Requisitioning and Reporting, Smart card for patient identification and payments, Patient Summoning System, Automatic Phlebotomy tube Labeler (APTL) and Pneumatic Tube System have been adopted as part of the Automation.

Methods: A comparative study based on objective and subjective parameters was carried out to find out the efficacy of the automated system over erstwhile manual operations. 29 staff members from different sample collection areas and lab personnel who had experienced both the systems were interviewed and their responses were tabulated.

Results: The comparative data after automation reveals that there is a significant reduction in sample labeling time (75%), reduction in transcriptional errors (81%) and reporting errors (100%) as compared to the manual era. Sample collection per day has increased by 166%. Similarly with the use of pneumatic tube system the time required in delivering the samples has decreased (93%) so has the breakage due to mishandling (10%). The need for repeat sample collection also decreased (66%). By installation of Patient summoning system the average patient waiting time is reduced by 73%.The issues of patient identification and traffic has improved.

Conclusion: The results show that with the introduction of integrated automated systems working in tandem there has been a significant reduction in Turn around Time and elimination of errors. Staff efficiency has improved and so has the quality of care resulting in improved patient satisfaction. It is evident therefore that technology driven management can improve the quality of patient care, however the challenge of perpetual innovation and maintenance of such systems remain.

B-136

Recommendations for New QC Rules Based on Precision from 2012 Data.

d. S. plaut[1], N. Lepage[2], T. Taylor[3], W. McLellan[4]. *[1]unaffiliated, Plano, TX, [2]Children's Hosp. Eastern Ontario, Quebec, ON, Canada, [3]Ingalls Hospital, Chicago, IL, [4]unaffiliated, Hollywood, FL*

Objectives: To show that data based on current precision indicate that new QC rules be seriously considered.

Relevance: Current data indicate a significant increase in precision since the first QC rules were proposed by CAP (1974) and AACC (1981).

Methodology: Two CAP (1988 and 2012) quantified precision. Our survey of 35 analytes from chemistry, hematology and hemostasis indicated a decrease of 58%

in CV (average; range 22-83). We 'translated' the 2012 SD into a new set of rules to detect both systematic and increased random errors. Our translations indicate these rules to be quite effectively: 1 4SD, 2 3SD and R 5 SD with cumulative sum for certain analytes.

Results: The table shows representative changes.

Conclusions:

1) The improvements in precision indicate that QC rules be reevaluated. These changes significantly reduce false rejects while increasing error detection and lower patient risk.

2) Each analyte should be assessed to determine the proper rule(s).

Conclusion:

Representative Data

Analyte	CAP 1988		CAP 2012		
	Mean	%CV	Mean	%CV	% Decrease
Cholesterol	330mg/dL	5.6	217mg/dL	1.0	87
Hemoglobin	19.5gm/dL	3.8	15.1gm/dL	1.7	41
Prothrombin Time	19.0 sec.	6.4	11.5 sec	2.8	56

B-139

Changes in Primary Care Requesting patterns in a two year period in Spain

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

METHODS: 36 and 76 laboratories for the year 2010 and 2012 respectively from diverse regions across Spain filled out the number of 29 tests requested by GPs.

Two types of appropriateness indicators were calculated. Every test requests per 1000 inhabitants of the following: alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), calcium (CA), cell blood counts (CBC), C-reactive protein (PCR), cholesterol (CHOL), creatinine (CREA)erythrocyte sedimentation rate (ESR), ferritin (FERR), phosphate (FOSF), gammaglutamiltranspeptidase (GGT), glucose (GLUC), HDL-cholesterol (HDL), glycated hemoglobin (HBA1), iron (IRON), lactate dehidrogenase (LDH), prostate specific antigen (PSA), thyrotropin (TSH), total bilirubin (TBIL), triglycerides (TG), urate (URAT), urea (UREA), urinalysis (URIA). And ratio of related tests requests.

Free PSA/PSA (FPSA/PSA), aspartate aminotransferase/alanine aminotransferase (AST/ALT), direct bilirubin/total bilirubin (BILD/BIL), folate/B12 vitamin (FOL/B12), free thyroxin/thyrotropin (FT4/TSH), urea/creatinine (UREA/CREA)

RESULTS: In spite of the differences observed, CBC, glucose and urate were less requested and TSH more requested in the second period, no significant differences were found in any of the studied tests.

DISCUSSION: Our results suggest that test requesting in Primary Care in Spain have not varied in a two year period. At least achieving targets in related tests requesting ratios, as AST/ALT, is necessary. The showed figures can be used as a pillar foundation to be based in ulterior interventions to achieve appropriate requesting.

CONCLUSION: A more active Clinical Laboratory behavior is necessary to lead to a better laboratory tests appropriate Primary Care requesting.

	2010			2012			p value
	Mean	*Standard deviation*	*CI95%*	*Mean*	*Standard deviation*	*CI95%*	
Tests per 1000 inhabitants							
ALP	139,12	74,28	114,36-163,89	149,97	76,69	132,44-167,49	0,478
ALT	332,05	65,97	310,05-354,04	319,27	66,46	304,09-334,46	0,339
AST	257,58	105,85	222,29-292,87	252,69	111,90	227,12-278,26	0,825
CA	88,22	60,60	68,01-108,42	98,89	71,49	82,55-115,23	0,436
CBC	387,53	93,15	353,95-421,11	359,17	75,45	340,32-378,02	0,112
CRP	60,65	39,38	47,52-73,78	58,10	35,88	49,84-66,35	0,732
CHOL	357,10	57,41	337,96-376,24	339,88	74,74	322,80-356,96	0,220
CREA	351,73	64,38	330,27-373,20	343,05	77,96	325,23-360,86	0,558
ESR	105,53	66,85	81,42-129,63	92,91	55,77	78,86-106,96	0,333
FERR	130,91	33,73	119,33-142,50	127,79	43,68	117,67-137,91	0,710
FOSF	61,00	57,57	41,52-80,48	61,29	53,13	49,15-73,43	0,979
GGT	258,95	79,82	232,34-285,56	251,06	86,66	231,26-270,86	0,642
GLUC	372,61	61,66	352,06-393,17	361,88	72,65	345,28-378,48	0,441
HDLC	274,97	63,21	253,90-296,04	260,71	75,16	243,54-277,89	0,322
HBA1	85,04	22,53	77,53-92,55	89,14	27,59	82,83-95,44	0,435
IRON	131,66	51,13	114,10-149,23	133,53	56,96	120,33-146,72	0,869
LDH	49,69	59,16	29,96-69,41	43,90	49,98	32,48-55,32	0,588
PSA	51,08	14,19	46,35-55,81	52,81	16,52	49,04-56,59	0,586
TSH	174,38	41,71	160,47-188,29	186,58	46,01	176,07-197,10	0,176
TBIL	138,67	67,61	115,79-161,55	151,27	80,08	132,97-169,57	0,416
TG	342,36	53,57	324,49-360,22	325,05	73,80	308,19-341,91	0,206
URAT	298,46	74,06	273,77-323,16	276,77	85,15	257,18-296,36	0,189
UREA	218,25	106,80	182,64-253,86	208,65	116,09	182,12-235,18	0,673
URIA	196,71	75,37	171,59-221,84	210,07	71,50	193,62-226,52	0,363
Related test requested							
FPSA/PSA	0,15	0,10	0,12-0,18	0,22	0,68	0,06-0,38	0,545
AST/ALT	0,78	0,28	0,69-0,87	0,80	0,35	0,72-0,88	0,742
BILD/TBIL	0,11	0,19	0,05-0,18	0,12	0,23	0,07-0,18	0,822
FOL/B12	0,93	0,12	0,89-0,97	0,92	0,14	0,89-0,95	0,710
FT4/TSH	0,37	0,23	0,30-0,45	0,37	0,22	0,32-0,43	0,955
UREA/CREA	0,63	0,31	0,53-0,74	0,62	0,35	0,55-0,70	0,906

B-143

Environmental resource management of an ISO 14000 certified clinical laboratory in Brazil

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Background: Our clinical laboratory, with headquarters in Brasilia - DF, Brazil, makes 1.7 mi exams per month and it has an environmental resource management system, with ISO 14000 certification, that controls several processes in order to reduce environmental impact in our activities. The purpose of this study is to know the environmental impact that the laboratory's activities had in the ecosystem in 2013 (environmental performance) and to share the monitoring methods, treatments and control used in a health care services institution.

Methods: We measured the consumption of natural resources (water, electric energy and paper), fossil fuel for sample transportation, plastic bags, biomedical and solid waste, paper and electronic waste recycling, printing savings through exam results checked online (lab's website). In short, the biomedical waste is taken to a waste treatment facility and eliminated using pyrolysis, the effluent is treated through an oxidative process using ferric chloride and sodium hypochlorite solution and the environmental monitoring is performed through measurement of chemical oxygen demand (COD) and biochemical oxygen demand (BOD).

Results: The laboratory's environmental performance in 2013 can be seen in the table below:

Environmental performance - 2013	
Water consumption (M^3)	5497
Electric energy consumption (kW)	2.087.898
Paper consumption - white paper (unit)	12.920.000
Paper consumption - recycled paper for reports (unit)	4.191.662
Printed pages (unit)	21.126.179
Waste sorting (recycling) (Kg)	4.038
Fuel consumption (liters/year)	91.744
Plastic - plastic bags for waste (unit)	338.7
Plastic - Oxo biodegradable plastic bags (unit)	956.053
Plastic - plastic cup (unit)	3.001.800
Recycled electronic waste (Kg)	824
Chemical residue treatment (Liters/day)	2000
Biomedical waste treated (Kg)	203.166,25
Exam results checked online	794.614
Printing and paper savings (unit)	6.356.912

Conclusion Identifying the environmental performance of the clinical laboratory allowed us to see the impact of the activities in the ecosystem. This knowledge encourages all workers to engage in different processes, the involvement of service users, and it spreads the environmental resource management practices of the ISO 14000 certification. The environmental performance is assessed every semester and the results are available in the company's website and in the sustainability report published by the United Nation Global Compact every year, in their website.

B-144

Critical laboratory tests values notification according to the Internacional Patient Safety Goals by Joint Comission in a general Private Hospital in São Paulo, Brazil.

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Background: A laboratory critical value refers to an extremely abnormal laboratory test result which may be life threatening if treatment is not initiated immediately. The number of critical values results will influence laboratory workload, clinical care and patient treatment. International Paciente Safety Goals (IPSG) has been introduced in Brazil recently to reach the Joint Comission acreditation standards. The notification of the critical laboratory tests results, recommended by the goal number 2 (improve effective communication) of IPSG, is one of the most challenging surveys for the clinical laboratories.

Methods: Critical laboratory tests results of a 300 bed general hospital were analyzed from August 2013 to December 2013 using the laboratory information system. The five main tests were selected to understand the Hospital profile according with the tests results and to establish a monthly follow up of the notifications registered on the laboratory system according with the TJC recommendation.

Results: From August to December 2013, 5834 tests from a total of 441.571 (1,3%) fulfilled the definition of a critical value. The five more representative tests that showed critical results were: Prothrombin time with 580 (11%), Partial thromboplastin time with 580 (11%), pH with 285 (5%), Troponin with 216 (4%) and K with 118 (2%). The notification of these values was improved along the months reaching 87% in the last month of this series. The final objective is to reach 100% notification according to the recommendation of TJC.

Conclusion: IPSG is very important to improve the patient safety and can also be used to improve the laboratory procedures and the communication with the hospital staff. The results we have obtained in this study were compared with the ones from another Hospital that has already reached the second period of accreditation by TJC. We noticed that goal number 2 from the IPSG was improved among the months in that hospital, reaching 100% of successful communication of the critical values. The main driver that supported this goal was a very effective continuous education of the laboratory team.

B-146

Quality Assessment and Management in Clinical Diagnostic Laboratory Medicine

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Background: Laboratory results play a major role in guiding decisions in patient management. In laboratory medicine, meaningful, accurate and precise measurements are essential for diagnosis, risk management and treatment. Various strategies have been adopted to reduce laboratory errors including internal quality control (QC) procedures and external quality assessment (QA) programs. Autopsy services also play a major role in contributing to clinical knowledge, medical education and quality assurance programs. The purpose of this study was to assess Proficiency Testing (PT) programs and to determine the rate of concordance and discordance between clinical diagnoses and post-mortem findings.

Methods: Our clinical laboratory participated in two external PT programs: Provincial Health Metrx (mandated by College of Physicians and Surgeons of Saskatchewan) and College of American Pathologists (CAP) survey. The clinical laboratory tests commonly used to manage patients were examined for the period of one year for any discrepancies. We also retrospectively reviewed the records of the medical and autopsy charts for all the deceased adult in-patients admitted during 2002 to 2004 in the hospitals of Saskatoon Health Region (SHR). A total of 3416 in-patient deaths were registered during the study period. In accordance with selection criteria, 158 cases were included in this study. The mean age of subjects was 66.6 ± 15.3 years with a range of 16-94 years. The study group consisted of 92 males (58.2%) and 66 females (41.8%) with an average length of stay at the hospital of 12.9 ± 10.9 days. In addition, we evaluated the impact of diagnostic modalities such as Computerized Tomographic Scanning (CT) and Magnetic Resonance Imaging (MRI) on clinical diagnoses.

Results: In the Health Metrx PT, 5 groups of 43 analytes were analyzed and from 598 tests, 5 discrepancies resulted, yielding a total discrepancy rate of 0.84%. In the CAP survey PT, 12 groups of 58 analytes were analyzed and of 431 tests, 3 discrepancies resulted, yielding a total discrepancy rate of 0.70 %. In both surveys the remaining tests had no discrepancies. The autopsy results showed that the concordance rate between clinical and autopsy diagnosis was 70.9%. The discordance rate was 24% and in 5.1% of the study population a conclusive clinical or autopsy diagnosis was not finalized. CT scans and MRI were found to be confirmatory or diagnostic in 85% and 93% of the autopsy patients in which these modalities were used.

Conclusion: The quality in the clinical laboratory is maintained in a satisfactory manner, meet the performance criteria and requirements set up by provincial regulatory agencies. It is prudent to monitor, promote and enhance quality services for our patients. The study confirmed that the concordance and discordance rates between clinical diagnosis and post-mortem findings in SHR are consistent with those reported in the literature. Also, despite the technical advances in diagnostic modalities, diagnostic discrepancies remain prevalent in the present day health care system. The study also emphasizes the value of PT programs and autopsies as an effective quality improvement and educational tool with a strong impact on quality management.

B-148

Sigma metric's impact on analytical performance in a chemistry area of a reference clinical laboratory A case study at the clinical laboratory of Hospital Pablo Tobon Uribe " the hospital with soul "

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Sigma metric's impact on analytical performance in a chemistry area of a reference clinical laboratory A case study at the clinical laboratory of Hospital Pablo Tobon Uribe " the hospital with soul " Key words: analytical performance, sigma metrics. Background: The most frequently method used to validate analytical runs in clinical laboratories is the Levy Jennings (LJ) graph, but this tool can control only the stability of the process, not the size of the analytical errors. Lack of control on the size of the analytical error, could produce misleading or misinterpretation, resulting in wrong laboratory results. Controlling analytical errors contributes to increase the reliability and clinical utility of the results. Analytical error control is time-consuming and demands effort, causing discouragement sometimes. The sigma metrics allow control of analytical errors for a big group of analytes with different total allowable errors, contributing to the improvement of analytical performance in clinical laboratories. Methods: At the Clinical Laboratory of Hospital Pablo Tobon Uribe in Medellín, Colombia on June, 2011, the sigma metric approach was implemented to control the performance of 25 analytesof clinical chemistry by awareness concepts, personnel training, using a specialized software, implementing connectivity for quality control data and showing new graphing tools such as performance per percentiles, sigma metric and total error integrated with Levy Jennings in a specialized software . For the initial diagnosis, the sigma metric was measured using a variety of quality control specifications as biological variability, RilliBAK, CLIA and the state of the art by percentiles. After this, multiple corrective actions were implemented and quality specifications were initially selected, but later on were changed to increase the constraint with the objective to monitor analytic imprecisión. Results: From June 2011 to October 2013,the performance improvement of the analytes, controlled through sigma metricwas considerable. The decrease of the imprecision, bias and analytical total error was observed in the majority of the analytes, the percentage of the analytes with sigma metric >5 increased from 68% to 79.4% and the percentage of the analytes with sigma metric <1.96 decreased from 14% to 2.94%. The trend of performance improvement is clearly observable during these two years as a result of the homogenization of knowledge, process standardization, continuous monitoring, rigorous analysis and corrective actions. Conclusions:The implementation of sigma metricsand its graphs shows the errors as errors per million of opportunities that exceed the total error allowable defined. Additionally the behavior of analytes is displayed, through a "quick glance", contributing to a decrease in analytical errors. The diversity of situations that occur at clinical laboratories, such as differences in workloads, stabilities of reagents, adjustment or calibration times and clinical metrological requirements,influencesthe analytical performance. These situations can be controlled by sigma metric, providing a standard measure that allows for the monitoring of the performance of a large amount of analyte, even despite the diversity.

B-149

Collaboration between ER and Lab to Improve Troponin Turnaround Times

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Purpose: The purpose of this project is to improve the care of Acute Coronary Syndrome (ACS) patient by developing a collaborative relationship with the Emergency Room (ER) and laboratory staff in order to decrease the turnaround time (TAT) of door to troponin result. The goal is door to troponin result in less than 30 minutes. Early diagnosis and medical management of patients with ACS improves the overall outcome in patients presenting to the ER with a complaint of chest pain. Cardiac markers are used in the diagnosis and risk assessment of patients with chest pain.

Design: A multidisciplinary team was formed to create a process and guidelines for the ACS patient that presents to the emergency room. This team worked collaboratively to initiate change within the triage area to reduce draw times, result times, and decrease hemolysis rates.

Participants: A Chest Pain Committee encompassing physicians, registered nurses (RN), emergency room technicians (ERT) , phlebotomists, and lab representatives.

Methods: Multiple meetings were held between the lab and the ER to understand each other's processes in relation to the entire procedure from door to troponin result. Each area worked together, not in silos, to improve the time for each step. Well-defined guidelines were developed for the initial treatment of the ACS patient in triage. Based on these guidelines, the triage RN quickly determines if the patient meets Cardiac Markers guidelines and directs the ERT and phlebotomist accordingly. A phlebotomist is stationed in triage at all times. If cardiac marker guidelines are met, the cardiac markers will be drawn by the phlebotomist while the ERT is performing an EKG. The ERT or RN will be responsible for the lab draw if multiple draws are needed. The introduction of a Mint Green lab tube was added specifically for Troponin levels in the ED. Troponin specimens from this tube can be processed immediately and help us to meet the <30 min Troponin TAT goal. Following the initiation of this process, data was collected and interpreted to determine the success of our process improvement.

Results/Outcomes: Emergency Room and Lab developed a collaborative relationship of professionalism and partnership. Data was received that exemplifies how we have improved the care of the ACS patient.

Order to draw times has decreased from 55 minutes to 8 minutes.

Draw to received specimen has decreased to 3 minutes.

Our door to Troponin result time is averaging 47 minutes with data collection continuing.

Troponin hemolysis rates have decreased from 15% to 1%

Implications: A collaborative Team Approach is being utilized in the care of the ACS patient to improve both patient and associate satisfaction. The care of the ACS patient has improved significantly as evidenced by our data interpretation. Data continues to be collected to evaluate the ongoing effectiveness of our process improvement.

B-150

Designing QC Rules for Multiple Instruments: Should a QC Rule be Centered on Individual Instrument Means or on a Fixed Mean? Should a the limits be based on Individual Instrument SD's or on a Fixed SD?

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Background: Objective - Compare performance of QC strategies centered on the individual instrument mean versus a fixed mean and limits based on individual instrument SD versus a fixed SD when applied to multiple instruments testing the same analyte.

Relevance - Using a fixed mean and SD appears to be a common practice when multiple analytic units evaluate the same analyte. The comparative efficacy of this approach has not been formally evaluated. We compare the expected number of unreliable final results reported due to the occurrence of an out-of-control condition, $E(N_{uf})$, when the QC rule means are centered on the instrument means versus a fixed mean and when the QC rule limits are established based on the instrument SD's versus a fixed SD.

Methods: We consider 4 analytic units in the laboratory evaluating the same analyte. We assume each instrument evaluates 2 QC levels using a $1{:}3_s/2{:}2_s/R{:}4_s$ QC rule every 100 patient examinations. The fixed mean is set to the average of the instrument means. The fixed SD is set so the overall false rejection rate across the 4 instruments is 0.0097. We investigate a range of means and SD's for the 4 instruments. The resulting instrument CV and bias combinations have sigma values $[(TE_a - bias)/CV]$ ranging from 3 to 6. We determined the maximum value for $E(N_{uf})$ and area under the $E(N_{uf})$ curve for the 4 different cases:

1. QC rule means centered on instrument means and QC rule limits based on instrument SDs

2. QC Rule means centered on a fixed mean and QC rule limits based on instrument SDs

3. QC rule means centered on instrument means and QC rule limits based on a fixed SD

4. QC rule means centered on a fixed mean and QC rule limits based on a fixed SD

In each of the above cases we design the QC rules so the overall false rejection rate across the 4 instruments = 0.0097, which is the false rejection rate for the $1{:}3_s/2{:}2_s/R{:}4_s$ QC rule.

Results: Tables of results are computed for the simulations. In general, the maximum $E(N_{uf})$ and the area under the $E(N_{uf})$ curve were lowest for rules using a fixed mean and fixed SD for the instruments.

Conclusion: Using a fixed mean and fixed SD for the QC rule had the best performance. The fixed mean appears to balance the risk of reporting unreliable results across multiple instruments while the fixed SD allocates more false rejection rate to poorer performing instruments resulting in a lower overall risk of reporting unreliable results when individual instruments have moderate to good process capability (3-6 sigma).

B-151

Evaluating the Reproducibility of Analysis in the Clinical Laboratories. Results from a proficiency testing (PT) scheme and comparison with biological variability.

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The quality criteria for the proficiency testing (PT) schemes in Laboratory Medicine include the evaluation of the accuracy of the participating laboratories, the use of human origin commutable testing materials (sera) that minimize matrix effects, the evaluation of linearity of assays by using at least two samples per distribution and the estimation of the reproducibility of measurements.

In order to fulfill these criteria, ESEAP (the Greek PT scheme in Laboratory Medicine) introduced the measurement of reproducibility using the analysis of the same sample four times during a yearly cycle. The quality goal for the participating laboratories, is the reproducibility to be at least 50% of the biological variability for each analyte. (Ref: Ricos et al. "Current databases on biologic variation: pros, cons and progress." Scand J Clin Lab Invest 1999;59:491-500, revision 2014).

In this study we used results from the 290 laboratories of ESEAP in Greece and Cyprus and we evaluated them against the proposed limits derived from the biological variability for each of the analytes included in the "clinical chemistry" scheme.

We excluded the results from laboratories that haven't reported all the four samples, from the laboratories that where excluded from the normal bias analysis (elimination in two-passes of all results > or <2.5SD of the consensus mean value) and the laboratories that reported a method change during this cycle. We finally processed 4 results from 209 laboratories and for 21 different parameters and we calculated the mean value of reproducibility for each parameter.

These results are presented at the following table:

Analyte	Biological Variability (%)	Proposed limits (%)	Measured Reproducibility (%)
Glucose	5.60	2.80	2.31
Urea	12.10	6.05	3.36
Creatinine	5.95	2.98	***4.16***
Sodium	0.60	0.30	**1.42**
Potassium	4.60	2.30	1.78
Total Protein	2.75	1.38	***2.55***
Albumin	3.20	1.60	***2.85***
Cholesterol	5.95	2.98	2.68
HDL- Cholesterol	7.30	3.65	3.57
Triglycerides	19.90	9.95	2.89
Uric Acid	8.60	4.30	2.82
Total Bilirubin	21.80	10.90	4.14
Calcium	2.10	1.05	**2.55**
Phosphate	8.15	4.08	2.63
Magnesium	3.60	1.80	***3.60***
Iron	26.50	13.30	4.49
SGOT (AST)	12.30	6.15	3.13
SGPT (ALT)	19.40	9.70	5.30
γ-Glutamyl Transferase	13.40	6.70	4.59
Creatinine Kinase	22.80	11.40	8.90
Amylase	8.70	4.40	3.08

Our results show that all the currently used methods outperform the proposed quality goals, except for the cases of **Sodium** and **Calcium** as also as of ***Creatinine, Total Protein, Albumin*** and ***Magnesium*** where the results are below the biological variability but not below the quality goal of 50% of the biological variability.

B-152

Relational Data Modeling Approach to Demonstrate Value of the Clinical Laboratory in Healthcare Systems

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Background: Adoption of electronic health records has will likely expand over the next several years due to incentives and penalties in the American Recovery and Reinvestment Act. Furthermore, there is growing interest in mining and analyzing this data to evaluate costs, practice patterns, and clinical effectiveness. We evaluated the impact of the ability to efficiently link laboratory data to external sources for large hospital projects. We also developed an appropriate data model to facilitate such data integration.

Methods: We extracted and linked clinical and operational data from existing sources (EPIC Systems®, Cerner CoPath®) which were also joined to detailed financial data (Allscripts®) for each department as well as the hospital system as a whole as well as external data documents (e.g., external price proposals). Linked data were used prospectively to evaluate the pro forma return on investment (ROI) for hospital projects involving the laboratory as well as the impact of such projects on workflow and quality measures when applicable. Linked data were employed retrospectively to evaluate the actual ROI and impact on clinical operations. We specifically looked at two large recent projects (2013-2014): a proposal to purchase a new microbiology system (prospective) and the results of a project to streamline radiology patient flow using POCT (retrospective). In each case, we examined the impact of absent, or poor, linking of laboratory to external data sources on each project. Based on our work we constructed a relational data schema with Navicat® software to connect disparate clinical, operational, and financial data sources.

Findings: The first project was an evaluation to purchase a MALDI-TOF instrument for bacterial identification. Without efficient links to external data sources we had to rely on cost savings resulting from lower reagent costs. With only this information projected measures of ROI were: payback period = 20.6 years, net present value (NPV) = ($228,519), and modified internal rate of return (MIRR) = -22.34%. None of these measures argues financially to pursue the project and one would have to rely on non-financial factors to make the case for purchase. We then re-evaluated the project including of cost savings resulting from earlier adoption of appropriate treatment of patients with sepsis (MSDRGs 371-373) and earlier discharge (based on actual costs and volumes at our hospital system). With this linked information, measures of ROI were: payback = 12.62 weeks, NPV = $5,471,954, and MIRR = 80.79%. All of these measures are highly favorable for the project. For the second project we evaluated the impact of a joint laboratory/radiology project on net revenue for radiology contrast studies. After implementation of the POCT intervention, the annual patient volume for these studies increased by 906 resulting in a net contribution of $410,776. As a project the actual payback period was 22.1 days. Patient satisfaction measures were also demonstrably better.

Conclusion: Linking laboratory data and data from external sources allows laboratory professionals to 1) provide optimal data for making clinical and operational changes, 2) credibly demonstrate value to hospital administrators, and 3) foster collaborative projects throughout the hospital system.

B-153

Comparison of critical results frequency for point-of-care testing (POCT) vs. STAT core laboratory testing among critical care unit patients: a management review regarding POCT utilization

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Background: A point-of-care analyzer (EPOC, Epocal, Ottawa) was recently introduced into a critical care unit (CCU) at our institution to measure blood gases (pH, pO2, pCO2), electrolytes (Na, K, ionized Ca), metabolites (glucose, lactate), and hematocrit (HCT) in select patients. Because of cost considerations, POCT was originally restricted for use in patients meeting conditions either of use of extracorporeal oxygenation (ECMO), use of a ventricular assist device (VAD), need for resuscitation ("code"), or known hemodynamic instability. In a setting where STAT testing is frequently warranted, selective use of POCT raised the issue of whether uniformity of standard of care was compromised when POCT was not universally deployed. We performed a six-month review of data to compare frequency of critical values between CCU samples for which POCT was utilized (POCT) and those CCU samples for which STAT core laboratory testing (CORE) was performed instead, to assist in management evaluation of whether lesser restriction on use of POCT should be advocated in this setting.

Methods: POCT and CORE laboratory test results for CCU patients for a six-month interval were obtained from electronic records. Glucose was excluded from the analysis because of overlap with extensive use of separate POCT glucose analyzers. The number and percentage of critical results among POCT and CORE samples were determined for 8 analytes as follows (analyte (critical ranges)): pH (<7.2 or >7.6); pO2 (<40 mm Hg); pCO2 (<20 mm Hg or >70 mm Hg); Na (<120 mmol/L or >160 mmol/L); K (<2.5 mmol/L or >6.5 mmol/L); iCa (<3.3 mg/dL or >6.5 mg/dL); lactate (>3.3 mmol/L); HCT (<20).

Results: POCT data comprised 261 panels of 8 analytes (2088 measurements) from 64 patients. CORE data comprised 11711 measurements from 206 patients. 58.6% of all 261 POCT panels had one or more critical results, with an overall critical result percentage of 11.9% among the 8 analytes. CORE test results had an overall critical result percentage of 3.1%. However, the ratio (R) of absolute number of critical results for POCT/CORE was 249/367 (R=0.67). This low value for R is likely to be an upper limit (that is, R is at most 0.67), in consideration of the fact that POCT results are bundled within a panel rather than ordered independently (i.e., some number of POCT critical results are likely to be an overcount due to untargeted repeat testing).

Conclusions: CCU use of POCT demonstrated high preselection for critical results. However, absolute numbers of critical results in the CCU were substantially greater from among CORE (non-POCT) results (R<1). Given R<1, and in consideration of the difference in expected turn-around-times between POCT and CORE testing (nominally, <10 min for POCT vs. up to 60 min for certain CORE analytes), use of CORE testing in the CCU might be regarded as a lesser service to patients relative to use of POCT. These findings supported a management recommendation that use of EPOC POCT in the CCU should be less restricted in order to maintain a more uniform standard of care.

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Monitoring the Quality of Results from the ARCHITECT Analyzer Using Six Sigma Metrics Generated by EP Evaluator Software

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Quality of lab results has a direct impact on patient care. Six Sigma is a universal benchmark to measure quality. We used Sigma metrics as a quality indicator to objectively quantitate the performance of 26 chemistry assays on the Abbott ARCHITECT c8000 and c16000 instruments. We calculated Sigma metrics using the equation: Sigma Metric = (TEa - Bias ^{observed}) / CV ^{observed} Total allowable error (TEa) was obtained from either CLIA or the RICOS database, our bias compared to our peers was derived from the BioRad Unity database and CV's were calculated periodically from our lab results. We have been monitoring Sigma metrics quarterly for over a year using the EP Evaluator software. This software is user-friendly and allows the user to input specific TEa goals. We currently compare sigma metrics between 3 analyzers to monitor performance across the instruments. Using laboratory Quality

Control (QC) data generated for the chemistry assays on the ARCHITECT c8000 and c16000 instruments, we observed on average, 97% of the assays were greater than 4 Sigma and 71% were greater than 6 Sigma. None of the assays were less than 3 Sigma and 3% of the assays were between 3 to 4 Sigma. As an example, Sigma metrics for 26 chemistry assays from a quarterly monitoring check on one of the ARCHITECT c16000 instrument is shown in Table 1. In conclusion, the Abbott ARCHITECT instruments provide high quality results for 97% of the chemistry assays. Our next step is to implement streamlined Westgard rules to assist us in reducing the amount of QC checks currently performed in our lab. We plan to further automate the monitoring of Sigma metrics when EP Evaluator would have the capability to automatically download the bias values from the BioRad Unity database.

Table 1. Six Sigma Metrics assays on one of the ARCHITECT c16000 analyzer (April-June 2013)

Test	TEa%	Bias%	CV%	Sigma	Test	TEa%	Bias%	CV5	Sigma Metric
Albumin	10	0.4	2.2	4.5	Creatinine	37.28	-0.3	1.8	20.4
Alk.Pkos.	30	2.9	2.0	13.7	GGT	22.7	-7.9	1.9	8.0
ALT	20	5.3	1.7	8.6	Glucose	10	-0.2	1.4	7.1
Amylase	30	-1.3	1.1	25.4	HDL	30	0.7	2.2	13.4
AST	20	2.4	2.4	7.3	Lipase	37.88	-1.4	2.2	16.6
Bili D	45	4.1	5.0	8.1	Magnesium	25	-2.1	3.5	6.6
Bili T	30.69	1.0	4.1	7.2	Phosphorus	10.11	-0.2	2.1	4.7
Calcium	8.29	-2.2	1.4	4.4	Potassium	12.71	0.7	1.4	8.8
Chloride	5	0.4	0.9	5.3	Total Protein	10	0.0	1.3	7.9
Cholesterol	10	-0.1	0.7	13.5	Sodium	3.25	0.7	0.7	4.4
D-LDL	12	-1.4	2.5	4.3	Triglycerides	25	-1.4	1.4	17.4
CK	30	2.2	1.0	27.2	Urea (BUN)	9	-1.7	2.0	3.7
CO2	25	0.4	4.3	5.7	Uric Acid	17	-1.9	1.3	11.4

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Managing Emergency Department Add-on Laboratory Orders

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Background: Laboratory test orders placed on specimens after the initial orders have been placed (addedon orders) can tax resources and are impacted with reporting delays which may impact patient care. These added-on orders disrupt normal workflow and can also impact staffing needs.

Methods: We examined 31 days of Emergency Department (ED) orders at two institutions to explore differences between initial ordering patterns and the add-on orders to determine if automation storage and laboratory processes could decrease these delays. We assessed time to results for both initial orders and add-on orders on Troponin, Magnesium, and Lipase orders. “Time to result” for add-on orders was defined as the time from order electronically placed to results sent electronically, since the specimen had already been received. “Time to result” for initial orders was defined as the time from specimen receipt to results sent electronically. We compared “time to result” for add-on orders at the two institutions to determine if automated storage decreased reporting delays.

Results: Over the 31 days, there were 35,840 ED orders at the two institutions and 627 (1.7%) of these were addon orders. Most of the laboratory add-on orders were chemistry tests (62%). The following three tests totaled 45% of the addon orders: Troponin, Magnesium, and Lipase. For each of these three tests, add-on orders were significantly delayed. One institution had refrigerated storage on the automation line (Hospital #1) while at the second institution sample storage was off-line (Hospital #2). For Troponin, an off-line test at both institutions, no difference was observed. For Magnesium and Lipase, both on-line tests, there was an additional 0.36 to 2.21 hour delay in result reporting for add-on when the sample storage was off-line. For example, Magnesium addon median time to result at Hospital #1 was 0.57hr (IQR 0.38, 1.07) while at Hospital #2 it was 2.37hr (IQR 1.00, 3.38) $p<0.0001$. The second approach to improving addon time to results was a cost-benefit analysis of adding Magnesium to all comprehensive metabolic panels and only reporting the result in instances where it was ordered. Depending on the institution, it was estimated $100 - $200 a month in unbillable results would be incurred in order to eliminate the approximately 1-2 hour delay in result reporting..

Conclusion: In our assessment, the addition of automated storage is the optimal approach to decrease reporting delays of addon test orders.

B-157

Strategies to Improve Staff Competency and Turnaround Time in Haematology Slide Review

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Background: Turnaround time (TAT) is one of our laboratory’s key performance indicators. We noticed that majority of our Full Blood Count (FBC) tests that exceeded our 1 hour TAT target were related to manual slide reviews. There seemed to be little correlation among the complexity of cases or seniority of staff.

Method: We reviewed all manual slide reviews for April 2012 (n=651) and grouped the degree of difficulty into easy, moderate and difficult categories. In each of the categories, we further analyzed the time taken by our staff based on their job grades: New hire, Junior Medical Technologist, Medical Technologist and Senior Medical Technologist. In July 2012, we proposed a “recommended” slide reading time based on the complexity of cases and the seniority of staff. All cases exceeding the new slide review time target were reviewed and retraining given to concerned staff.

Results: In August to October 2012, the TAT for FBC is 96.4% (78 cases out of 2175 exceeded TAT target). In November 2013 to January 2014, the TAT for FBC is 99.2% (22 cases out of 2846 exceeded TAT target). We applied chi square test and demonstrated a p-value (2-tail) of <0.0000001.

Conclusion: We were able to objectively guide staff competency and set slide reading time according to case complexity and seniority of staff, and propose specific and targeted retraining. More importantly, we realized a definite and sustained improvement in our FBC TAT, ultimately providing better patient care.

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Evaluation of Quality OptimiZer quality management software (Awesome Numbers Inc.) to minimize patient risk, reduce clinical cost and implement EP 23 recommendations.

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Objectives to evaluate the efficacy of Quality OptimiZer™ software to assess analytical process quality, verify clinical effectiveness of Q.C. processes and recommend a comprehensive Q.C. strategy, to quantify the impact of OptimiZer Q.C. processes on patient risk, clinical and laboratory costs, and to compare Quality OptimiZer reports to EP 23 recommendations.

Relevance: Ineffective quality control practices expose patients to the risk of incorrect or delayed diagnosis and/or treatment. CLSI EP23 requires labs to “ensure test result quality is appropriate for clinical use;” validate “the ability of the QC procedures to detect medically allowable error;” and assess “potential costs both in terms of the patient’s well-being and financial liability.”

Methodology: We examined analytical processes, Q.C. processes, patient volumes and costs from two laboratories x two instruments x five analytes. For each Q.C. sample, we gathered : A. The four numbers required to evaluate analytical process quality: **1.** Measured mean; **2**. Measured SD; **3**. Peer mean; **4**. TEa limit, and B. The three numbers that determine Q.C. process effectiveness: **5.** Q.C. Chart assigned mean; **6.** Assigned SD; and **7.** Q.C. rule(s) Quality OptimiZer: - rated analytical process quality based on Total Error and Margin for Error recommended a 5-part Q.C. strategy - simulated a shift that would cause 5% of results to fail TEa limits. - compared the effectiveness of current and recommended QC processes to detect this significant shift - quantified patient risk, clinical and laboratory costs of each QC process. We selected one sodium control to illustrate the importance and interaction of the seven numbers required to manage quality.

Results For the selected sodium example: - Laboratory practice for all controls on all tests was to use a 1-2 and 9x rule as warnings, and 1-3, 2-2, 2/3-2, R4 rules as rejects. - The assigned mean was 0.7 SD below the measured mean; the SD was assigned at 2.1 x the measured SD. - The OptimiZer Q.C. strategy would detect a clinically-significant change sooner, prevent risk to 1330 patients, save 66 patients from clinically-misleading results and result in a net saving of $1,062.00. Quality OptimiZer reports satisfied EP 23 recommendations to: - ensure test result quality is appropriate for clinical use, - determine statistical limits that will identify unacceptable changes in performance of the measuring system, - prove effectiveness of quality control - quantify patient risks and costs of control quality, - implement and modify a 5-part Q.C. strategy.

Conclusions OptimiZer Q.C. processes met EP23 requirements, decreased patient risk, and reduced clinical costs. Error detection is impeded by the common practice of assigning mean and SD values from inappropriate sources and using outdated Q.C. rules. Laboratory quality would benefit from increased staff focus on clinical quality and the interaction of the seven numbers that drive and assess that quality.

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Generation of statistical protocols derivated from sigma metric in a clinical laboratory

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OBJECTIVE: To demonstrate the usefulness of the sigma metric to generate statistical protocols to control the analytical performance of measurement systems in clinical laboratories.

KEY WORDS: statistical protocols, sigma metric, clinically useful results, analytical performance.

BACKGROUND: Historically, the clinical laboratory has used different strategies for evaluating the performance of analytical runs since Levy Jennings graphs, statistics rules on the same graphs and analytical performance limits (CLIA, RilliBAK, Biological variation, etc.). However, standardizing the selected strategy into a daily routine becomes a challenge for the clinical laboratory.Recently, some laboratories in Colombia have invested resources and efforts for the implementation of the sigma metrics as an indicator of measurement systems efficiency, with the benefit of including the automatic generation of statistics from the sigma metric protocols, which has helped to increase the safety of delivering clinically useful results.

METHODS: 1,192 statistical protocols, corresponding to 437 analytes from chemistry, hormone and coagulation areas from a network of 12 clinical laboratories, were designed over a period of 12 months with specialized software. At the end of this period the protocols were ordered and grouped in ranges according to their sigma metric, defining the protocols most commonly used in each range and finally generating algorithms to select the protocol to implement.

RESULTS: 6 sigma metric ranges were obtained. The most commonly protocols obtained for each range of sigma metric were ≤3σ sigma: $1_{3s}/2_{2s}/R_{4s}/4_{1s}/8_X$ (55%) and $1_{3s}/2_{2s}(2_{of32s})/R_{4s}/3_{1s}/6_x$ (43%) of cases, for the range 3σ to 3.9σ :$1_{3s}/2_{of32s}/R_{4s}/3_{1s}/6_x$ (38%) and $1_{3S}/2_{2S}/R_{4S}/4_{1S}/8_X$ (25%), for the range 4.0 σ-4.6σ: $1_{3s}/2_{2s}/R_{4s}/4_{1s}$ (34%), $1_{3s}/2_{2s}(2_{of32s})/R_{4s}/3_{1s}/6_x$ (38%), $1_{3s}/2_{2s}(2_{of32s})/R_{4s}/3_{1s}/8_x$ (25%), for the range 4.6σ-4.9σ: $1_{2.5s}$ (72%), 1_{3s} (23 %) y $1_{3.5s}$ (5%), for the range 5.0σ -5.9σ: $1_{2.5s}$ (39%), 1_{3S} (51%) and $1_{3.5S}$ (10%) and finally for ≥6σ: $1_{3.5s}$ (94%).

CONCLUSIONS The use of statistical protocols contributed to the improvement of performance in laboratory tests achieving an increase of 93% to 96% in the number of measurements with sigma metrics > 1.96 over a 12 month period. These protocols were automated in correlation with the sigma metric, thereby decreasing the investment of time, false rejections and false acceptations produced by inadequate protocols and poor timing. Additionally, the retrospective analysis led to the conclusion that for analytes with < 4.7σ multi-rules protocols are required and for > 4.7σ a single rule is applicable.

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Sigma metrics to assess analytical quality: Importance of allowable total error (TEa) target.

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Background. Six Sigma metrics were used to assess the analytical quality of automated clinical chemistry tests in a large clinical laboratory and examine the impact of different allowable total error (TEa) goals on the metric. Clinical laboratories are challenged to maintain the highest analytical quality but it is difficult to measure it objectively and quantitatively. Methods. The Sigma metric is estimates quality based on the traditional parameters used in the clinical laboratory: allowable total error (TEa), bias, and precision. Sigma metrics were calculated for 41 clinical chemistry and immunoassay tests, including serum and urine matrices, on five ARCHITECT c16000 chemistry analyzers. Controls at two analyte concentrations were tested to calculate precision, bias was estimated as the difference between observed results and the control target values, and Sigma metrics were calculated using three different TEa targets (Ricos biological variability, CLIA, and RiliBÄK) using the following equation: Sigma = (TEa – bias)/CV (all values expressed as %) Results. Sigma metrics varied with the analyte concentration, TEa target, and between/among analyzers. Sigma values identified assays that are analytically robust and require minimal QC rules and those that exhibit more variability, requiring more complex QC rules. Analyzer-to- analyzer variability was also assessed using Sigma metrics. As an example, Fig. 1 demonstrates the effect of the TEa target on the Sigma metrics for albumin.Conclusions. The Sigma metric is an efficient means to measure quality and optimize QC rules based on observed quality. Lack of TEa targets for some analytes and the variability of TEa from different sources can cause inconsistent estimates of Sigma for the same anlayte. Architect analyzers demonstrated generally high Sigma values and comparable analyzer-to-analyzer performance. Sigma metrics are a valuable means for comparing the analytical quality of two or more analyzers to ensure the comparability of patient test results.

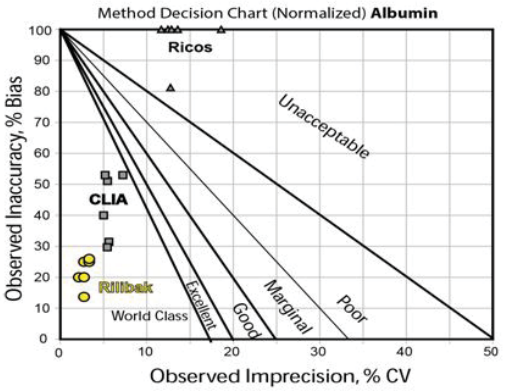

Figure 1. Normalized method decision chart for albumin comparing Sigma metrics calculated using biological variability (▲), CLIA (■) and RiliBÄK (●) TEa targets. Data points represent the Sigma value for controls at two concentrations and from three different analysers.

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Performance of Analysis Teams of Blood Collection after Training in Pre-Analytical phase and Phlebotomy

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Background: Pre-analytical conditions are the key factors in maintaining the high quality of tests results. They are necessary to accurate reproducibility of laboratory tests for clinical diagnosis. In research at private's clinical laboratories, we evaluated the impact of some pre-analytical drivers before and after training, in the team of blood collection.

Objective: Analyze the points of improvement during the process of phlebotomy, and proposing a tool for continuous improvement that can aggregate in the preparation of this professionals working in this area. Promote the training of these phlebotomists and assess how this continuing education can impact not only on the quality of the tests report, but also the performance of these professionals to the client.

Methods: Pré-Analytical errors are attributed to a lack of patient preparation, care, collection and identification. Their becoming frequent because, of the low training and the existence of different degrees of involvement of several people in the process. The study conducted quantification in percentage of errors (points of improvement) committed in the collection procedure in three clinical pathology laboratories, in the South, Midwest and Northeast regions of Brazil, before and after the theoretical and practical training in venipuncture, following the most current practices described in the literature. The data were divided into three phases: pre-collecting, collection and pos-collection.

Results: The request of the patient's identity, verification of the test request form, preparation of client and antisepsis had opportunities of improvement raging from 6-31% before training and 1-7% after the training. The blood collection in a closed system totaled 75% of the punctures before the training and 86% in the post training, had 13% and 44% respectively of opportunity for improvement. The time using tourniquet and homeostasis showed 17% and 60% of errors before training, versus 1% to 4% after. The overall mean compliance before training was 75% and after the educational activity was 98%.

Conclusion: We conclude that the improvement of the team after the training was considerable and has an evident gain in the pre-analytical process and the quality of the request report result.

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Disclosure of Medical Errors: An Approach towards Improving Quality in Laboratory Medicine

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Background: The quality of healthcare is an emerging concern worldwide. Despite the advancement in medical field, adverse events resulting from medical errors are relatively common in healthcare system. We have previously reported a non-punitive,"no-fault" model for reporting medical errors in clinical laboratory medicine. There are several barriers to disclosure including the risk of legal action faced by the physicians and often strained physician-patient relationship. It also jeopardizes the opportunity to enhance quality improvement in health care, as many medical errors are the result of systemic problems that are difficult to detect unless the errors are reported. However, an appropriate disclosure is vital to overcome these barriers and manage the consequences of an adverse event**.**

Methods: In order to analyze the progress made in the area of medical error disclosure and to understand the rationale for effective error disclosure policies, we reviewed and evaluated various error disclosure initiatives across Canada and other parts of the world (Australia, New Zealand and United States of America).

Results: The majority of provincial regulatory bodies in Canada have adopted some form of disclosure policy. However, these Canadian provincial initiatives remain isolated because of their non-obligatory nature and absence of federal or provincial laws on disclosure. In Australia, disclosure policy integrates the disclosure process with risk management analysis towards investigating the critical events. In New Zealand, in any adverse event, patients are rehabilitated and compensated through a no-fault state funded compensation scheme. This disclosure model supports the health care providers and strengthens the policy of honest disclosure. The United States Joint Commission on Accreditation of Healthcare Organizations mandated an open disclosure of any critical event during care to the patient or their families. By following an open disclosure policy, patient's autonomy can be preserved and malpractice claims can be reduced effectively. The complexities of medical error disclosure to patients present ideal opportunities for medical educators to probe how learners are balancing the ethical complexities involved in error disclosure with other related fields.

Conclusion: The correction of flaws in the healthcare system and the subsequent protection of patients' health should be the industry's top priority, rather than applying punitive measures to physicians and health care providers who make inevitable errors. We believe that the disclosure policies can provide framework and guidelines for appropriate disclosure which can lead to improved quality care and more transparent practices in clinical laboratory medicine and overall healthcare system. We suggest that disclosure practice can be improved by creating a uniform policy, centered on honest disclosure and addressing errors in a non-punitive manner.

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Improvement of pneumatic tube system specimen submission from the Emergency Department to the Core Laboratory using Lean Six Sigma tools

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Background: Pneumatic tube systems (PTS) can eliminate the need for clinical staff to leave the ward to deliver specimens and can save time in transporting specimens to the laboratory. However, once the PTS carrier arrives in the lab, the onerous for submission compliance rests heavily on lab staff. Implementation of a hospital-wide PTS resulted in many specimens arriving in the lab without proper order entry. Review of the PTS usage records indicated that the Emergency Department (ED) submitted the greatest number of specimens overall and the greatest number of specimens missing test orders. In addition, ED staff felt that delays in specimen processing were increasing the overall wait time for ED patients. This management project focused on strengthening the relationship between the ED and Core Laboratory to both meet the College of American Pathologist's requirement for orders for all lab tests and to decrease the specimen processing time for ED samples.

Objective: To assess and improve the ED's process for submission of specimens to the Core Lab via PTS.

Methods: The define-measure-analyze-improve-control (DMAIC) tollgates of a Lean Six Sigma (LSS) project were used to identify and implement solutions for the ED to submit specimens with electronic orders. Data captured by lab staff estimated the error defect rate for ED specimens missing test orders. Process and value-stream mapping identified the extra steps both lab and ED staff took when samples were missing orders. A root cause analysis was used to identify critical factors relating to the delay in processing ED samples. Solutions were selected and a new process was defined. Pilot studies tested the proposed solutions to ascertain improvement significance and full-implementation potential. Finally, a control/response plan was initiated to sustain the gains obtained in this management project.

Results: The test orders defect (missing + partial orders) rate of ED specimens submitted by PTS to the Core Lab was 16.8%. Reworking of ED specimens missing orders between the ED and Core Lab staff accumulated to one full-time equivalent (FTE) ED clerk/medical laboratory technician. Value-stream mapping identified some quick wins in the submission process such as a change in the default setting for label printers in the ED. The root cause analysis generated three solutions: 1) lab order entry granted to ED medical support assistants, 2) new employee orientation revised to ensure new ED staff received the proper laboratory information system (LIS) signature class, 3) "rainbow" specimen draw SOP initiated for the ED. These solutions reduced the specimens submitted by PTS without orders defect rate down to 3.5%.

Conclusion: The LSS structure to this management project provided a forum for open communication and buy-in from end-users in both the ED and Core Lab. Leadership support from both departments fostered a culture of change which resulted in a cost avoidance of one FTE, an enhanced process for specimen submission, and improved CAP compliance for lab test orders. Lessons learned from this management project can be applied to other clinics and wards in the medical center.

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Inventory Automation for the Lab and Cost Savings Using an Inventory Management System

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Today's laboratories share similar inventory management problems spending too much time ordering and managing inventory. Low volume usage products, like calibrators, expire unnoticed requiring urgent orders with overnight shipping expense. Manual check-in and check-out processes lead to errors. Physical inventories are required to reconcile discrepant levels. Managing expiration dates and sequestering new reagent lots requires constant vigilance. Most laboratories are also resource-limited and technical staff is needed for complex testing issues.

We introduced the Abbott Inventory Manager at Saint Francis Health System to automate our inventory management. Each item is assigned a Serialized Global Trade Item Number (SGTIN) tag that is tracked using Radio Frequency Identification (RFID) technology. This system combines the use of RFID, electronic connectivity with Abbott and software management to track inventory starting from Abbott's warehouse to the hospital. Electronic Data Interchange (EDI) connectivity with Abbott enables our lab to access product catalog, create purchase orders, receive order acknowledgement and advance shipping notices. The software monitors on-hand stock levels, lot numbers, expiration dates with critical alerts and triggers auto-replenishment suggestions. It configures user roles and approval levels and also maintains an audit trail. Since Inventory manager is an open system, we are able to include non-Abbott items as part of the inventory.

Post implementation, our hands-on time of unpacking, labeling and logging-in our inventory has been reduced by 60% and our error rate has declined from 27% to 1.1%. Table 1 reflects the annual lab staff labor savings of $21,606.47 as documented during pre and post implementation. We anticipate, after one year, to see additional savings due to reduction of expiring reagents and emergency overnight orders.

In conclusion, automation of inventory management in our lab has minimized manual intervention of labeling, counting, tracking and ordering inventory. We reduced our error rate and realized both time and cost savings.

Table 1. Lab Staff Labor Savings Pre and Post Implementation of the Inventory Management System

Dept.	Activity	Pre IMS		Post IMS		Savings	
		Annual Labor Hours	Annual Labor Dollars	Annual Labor Hours	Annual Labor Dollars	Annual Dollars	%
Receiving Dock	Physical Count	57.4	$969	8.2	$138	$831	86%
Receiving Dock	SAP Goods Receipt	12.2	$206	18.3	$309	($103)	-50%
Lab	Receive Product into Lab	306.5	$9,195	121.4	$3,642	$5,553	60%
Lab	Consume Products	27.0	$809	22.5	$675	$135	17%
Lab	SAP Decrement	44.9	$1,347	12.0	$359	$988	73%
Lab	Physical Inventory	261.7	$7,850	24.9	$746	$7,104	91%
Lab	Check/Order Products	65.5	$1,965	33.2	$996	$969	49%
Lab	Yellow Sticker Generation	204.3	$6,130	0.0	$0	$6,130	100%
Receiving Dock	Transport to Main Lab (CC-IA)	19.4	$328	19.4	$328	$0	0%
Receiving Dock	Transport to Lab Storage (Heme)	6.9	$116	6.9	$116	$0	0%
Total Annual Hours and Dollars		1,218.5	$28,915	254.76	$7,308.53	$21,606.47	75%

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Re-engineering Critical Laboratory Testing for Timely Chemotherapeutic Management.

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Background: Delivery of cytotoxic therapy is a complex multifaceted process that involves harmonized collaboration between all systems involved. Laboratory assessment is an essential component of assuring that patient care is efficient, timely, and accurate. As the volume of oncology patients is increasing, providers and patients are faced with long wait times until laboratory results are available before chemotherapy can be safely administered. Optimizing laboratory turn-around time (TAT) assures timely delivery of chemotherapy, which would subsequently translate into improved outcomes and satisfaction. In this study, we aimed to investigate how to reduce the laboratory TAT for key laboratory tests so as to optimize the timely administration of chemotherapy. **Method**: The TAT can be affected by several factors including phlebotomy, clinical laboratory distribution, and test operation. We collected time data in each step in this process, including the time from specimen collection to specimen receiving in the central laboratory (Col-Rcv), specimen receiving to result release (Rcv-Res), and the overall TAT from specimen collection to result release (Col-Res). **Results**: The median TATs before our process re-engineering were: 31 min (Col-Rcv), 40 min (Rcv-Res) and 74 min (Col-Res) for a comprehensive metabolic panel (CPNL), and 34 min (Col-Rcv), 9 min (Rcv-Res) and 50 min (Col-Res) for a complete blood count (CBC). After reconfiguring the specimen transfer and analytical workflows to have specimens tubed directly to the central laboratories and assayed immediately, the CBC showed a significant reduction in the median (Col-Res) TAT of 20 min ($p<0.0001$). For CPNL, by processing all specimens as STAT samples, the median (Col-Res) TAT was significantly reduced from 74 min to 54 min ($p< 0.0001$). To investigate if we can further improve on the (Col-Res) TAT for chemistry tests, we engaged our clinical colleagues who identified 2 key CPNL analytes, total bilirubin (TBil) (to monitor liver toxicity) and creatinine (Creat) (to monitor renal toxicity), that, if we are able to deliver the results within the same timeframe of the CBC, would allow for faster decision-making for drug infusions. We evaluated the suitability of the whole blood ABL 8000 analyzer (Radiometer, OH) for this purpose and found that both whole blood TBil (WB-TBil) and Creat (WB-Creat) can be routinely resulted within 2 min of sample introduction. Correlation studies (Passing-Bablok and Bland-Altman plots) between whole blood and plasma samples from this cancer population showed: [ABL WB-TBil] = 2.00 [Roche plasma TBil] – 0.60, (range 0.1-2.1 mg/dl, n=164) and [ABL WB-Creat] = 1.08 [Roche plasma Creat] – 0.04 (range 0.4-3.1 mg/dl, n=166). There was 90% concordance of WB-TBil results when compared to plasma TBil results <1.1 mg/dL. The CV for WB-Creat was <10 % (0.43 mg/dL), and WB-TBil was 20% (0.5 mg/dL). **Conclusion**: Careful workflow analysis and re-engineering of transport and analytical process for key laboratory tests significantly reduce median overall TAT to a ~20 min that will facilitate timely delivery of chemotherapy.

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The Effect of Patient Immune Status on QuantiFeron Test Results: An Investigation

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Background: Our laboratory tests patient specimens for latent tuberculosis using a test kit to measure cell mediated immune response. Latent tuberculosis is non-communicable and asymptomatic, but can develop into active tuberculosis at a later time and therefore is important to diagnose to prevent disease development.

The test is a two-part process. The patient's blood is drawn into a series of three tubes: a tube containing tuberculosis antigen, a tube containing nothing, which serves as a negative control, and a tube containing mitogen, which is a non-specific stimulator of T-cells to trigger a gamma interferon response and serves as a positive control. The tubes are incubated at 37°C for 16-24 hours and then the plasma is analyzed using an ELISA test. There is a software calculation against a standard curve that determines IU/mL of the nil, TB antigen and mitogen tubes. The results are then analyzed compared with a variety of permutations to determine if the results are positive, negative, or indeterminate. Infectious disease providers are interested in tracking the individual IU/mL results that the software uses in the interpretation and therefore the nil, TB antigen minus nil, and mitogen minus nil results are reported in addition to the qualitative interpretation.

New lots of kits are checked for similar reactivity with specimens that have already been tested with the kit currently being used prior to patient testing.

It was noticed in June of 2013 that, although the lot-to-lot check had been acceptable, the newer lot of kit being used was yielding more indeterminate and low-reactive results. It was important to determine if this was due to a problem with the testing kit or the immune status of the patients.

Methods: All results over a nine month period were tracked. Any patient with an indeterminate or low-reactive result (mitogen minus nil of less than 1.0) was checked for a diagnosis suggesting immunocompromised status.

Results: From May 2013 until January 2014, a total of 1648 samples were tested. Of those, there were 44 (2.67%) indeterminate results and 14 (0.85%) negative results due to low mitogen reactions. Case histories of these patients revealed that in fact, they were immunocompromised and the test results were concordant with clinical findings. All but one result were explained by the patients being immunocompromised due to various disease states. The one that could not be explained was a pre-employment sample with no charted information.

Conclusion: In conclusion, it has been determined that the increase in indeterminate results that was observed was due to immunocompromised patients and not sub-optimal test kits. For patient safety and quality of results, it has been decided that we will continue our practice of tracking the indeterminate and low-reactive results to ensure that the immune status of the patient is the cause and not a problem with kit or sample tube integrity, particularly because infection disease providers are using the calculated values in their clinical decision-making.

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Use of a Decision Matrix and Positivity Rates to Substantiate Test Scope: Propoxyphene - A Case in Point

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Background: Any toxicology test ordered should have value to the individual requesting the test and to the patient. It is, therefore, critical to optimize analytical scopes so that relevant testing is performed. Otherwise, there is consumption of resources with little value added. Since reference laboratories often serve wide client bases with competing needs, it is advantageous to have an objective means of determining if an analyte should be maintained in a particular test. A decision matrix (DM) was created to quantify the considerations involved, and used to evaluate the necessity of maintaining propoxyphene in limited-scope immunoassay panels.

Propoxyphene was approved by the US FDA in 1957 for use as an opioid analgesic, but was withdrawn in Nov 2010 due to risk of serious or fatal heart rhythm abnormalities.

The drug was frequently prescribed, and associated with abuse, overdoses and lethal outcomes. While past toxicological relevance cannot be argued, is it appropriate to now remove propoxyphene from immunoassay tests or should the practice continue? To address this question, the DM was used in conjunction with a multi-year positivity rate evaluation.

Methods: The toxicology panels evaluated were immunoassay based (ELISA or EMIT) and used for several matrices. DM assessment criteria with the associated factors were: a) legal availability in the US [yes:5; no:1], b) legal world-wide availability [yes:5; no:1], c) length of time unavailable [>10 yrs:1; 5-10 yrs:2; 2-4 yrs:3; 1-2 yrs:4; <1 yrs:5], d) illicit drug sources [yes:5, no;1], e) current positivity rate [75-100%:5; 50-74%:4; 25-49%:3; 1-24%:2; <1%:1] and f) other testing means within the laboratory [yes:1; no:5]. The factors for propoxyphene were entered for each matrix type to obtain the Total Score (TS). Using the DM, the minimum and maximum possible TS are 6 and 30, respectively. The recommendations based upon the TS are: 6-9 (remove from scope), 10-19 (monitor) and 20-30 (maintain in scope). An evaluation of positivity rates over a 3.5 year period was also performed.

Results: The TS for propoxyphene was 8 out of 30 in blood, serum/plasma, urine, tissue, hair, stool and meconium, and 9 out of 30 for fluid. Positivity rates by matrix type by year, from 2010 to mid-2013, were: blood (2.03%, 0.32%, 0.18%, 0.10%); serum/plasma (1.79%, 0.21%, 0.13%, 0.0%); urine (2.65%, 0.56%, 0.28%, 0.22%); tissue (1.48%, 0.86%, 0.0%, 0.0%); fluid (3.86%, 1.62%, 1.56%, 2.32%); hair (1.19%, 0.81%, 0.0%, 0.0%); stool (7.5%, 0.0%, 0.0%, 0.0%); meconium (19.62%, 22.45%, 9.53%, 0.0%).

Conclusion: Using the above determinations, our working group made two recommendations: 1) remove propoxyphene from the immunoassay panels and 2) treat propoxyphene in a similar fashion to most other drugs by using a broad-spectrum screening approach (TOF or GC/MS) or a directed analysis when warranted by case history. The severe decline in positivity rates suggests that the continual need to monitor the drug is no longer required. When the challenge of assessing scope relevancy arises, it is prudent to consider all available data including positivity rates and to employ a DM to substantiate any operational decisions.

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Comparison of Inpatient and Outpatient Genetic Test Utilization in a Pediatric Tertiary Care Center

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Background: Increasing rates of send out testing represent a growing financial burden for hospital laboratories. In the pediatric tertiary care setting, genetic testing for rare inherited diseases is costly, and many such tests are infrequently ordered, which increases the probability of an order error. In addition, these tests are occasionally ordered on inpatients, so their cost is not reimbursed. In an effort to better utilize resources, some medical centers are actively monitoring test utilization for tests fulfilling certain criteria such as cost. The goal of this work was to analyze the data in a laboratory utilization database and compare genetic tests ordered in both inpatient and outpatient settings to determine if inpatient genetic test orders should be treated differently than outpatient orders.

Methods: A laboratory-generated test utilization database maintained by faculty and genetic counselors containing over 750 orders for genetic tests over a period of more than 2 years was analyzed. Send out tests were recorded in the database if they met the following criteria: 1) cost > $1000, 2) multiple genetic tests on one requisition, 3) request to send to nonpreferred laboratory, or 4) request to send out a test performed in-house. At the time of order, patient demographics (including inpatient vs. outpatient), test information, ordering provider specialty, and test cost were recorded. After review by the appropriate staff, the approval or modification of a test (including indications for doing so), cost savings, and the results of the tests were also entered into the database. Based on the indication for ordering the test, results were classified as positive, negative, uncertain significance, or pending. For tests cancelled or modified after review, orders determined to be non-indicated or ordered incorrectly were recorded. Data on inpatients and outpatients was compared and the proportions of test approvals, positive results, cost, cost savings, and error rates were compared, with tests for equality of proportions applied when relevant.

Results: Data from 147 inpatient and 632 outpatient genetic test orders was analyzed. The rate of test approval without modification was similar for both groups, at 66% for inpatient orders and 71% for outpatient orders (p=0.27). The proportion of positive results was also similar between the two groups, at 29% for inpatients and 27% for outpatients (p=0.78). The mean cost for inpatient genetic tests reviewed was $660 higher and the mean cost savings per order reviewed was $120 higher in inpatients (cost savings of $550 vs. $430 per order reviewed). The error rate, which was calculated as a percentage of tests that were either cancelled or modified because an incorrect test was ordered, was not significantly different, at 6.8% for inpatient and 5.1% for outpatient genetic test orders (p=0.52).

Conclusion: The rate of test approval and proportion of positive results was similar between inpatient and outpatient genetic tests orders, although cost savings per inpatient order was higher. The order error rate of greater than 5% for both patient groups, however, suggests that maximizing the proportion of genetic test orders under review would prevent errors in diagnosis and patient management.

B-169

QC Rules for High Sigma-Metric Processes

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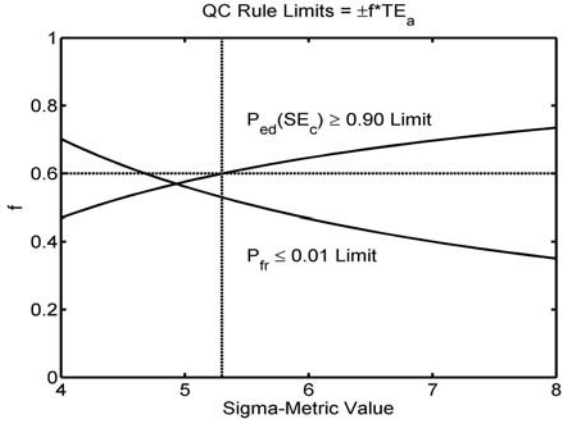
Background: Objective: Define a simple, yet effective QC rule for high sigma-metric processes and determine the minimum sigma-metric threshold for the rule.

Relevance: High sigma-metric processes are generally easy to quality control. A simple effective QC rule that can be confidently applied in all high sigma-metric situations would be valuable.

Methods: QC rejection limits are defined as $\pm f*TE_a$ (a fraction of the allowable total error specification for the analyte). Probabilities of false rejection, P_{fr}, and critical systematic error detection, $P_{ed}(SE_c)$, were derived assuming either 2 or 3 QC concentration levels are evaluated. SE_c is defined as an out-of-control condition that would produce 5% patient results containing measurement error exceeding TE_a. QC rule rejection limits were required to provide $P_{fr} < 0.01$ and $P_{ed}(SE_c) > 0.90$.

Results: Validation: Mathematically derived probabilities were validated by computer simulation. Conclusion: The range of values for f that meet the false rejection and error detection constraints when 2 QC concentration levels are evaluated as a function of sigma-metric value is shown in the figure. A QC rule with rejection limits given as $\pm 0.6*TE_a$ provides as least 90% critical systematic error detection with a false rejection rate less than 1% for any process with sigma-metric value greater than 5.3. The false rejection rate of the QC rule will decrease and the error detection probability of the rule will increase for sigma-metric values greater than 5.3.



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Total Laboratory Automation (TLA) to Improve Efficiencies: Before and After study at a 2,941 Bed Medical Center in Taiwan.

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Objective: To assess the increase in efficiency of TLA by implementing the ACCELERATOR APS to replace multiple separate work processes including better Turn Around Time goal achievement, optimized workflow, reduction in FTE, reduced consumables and increased space utilization.

Relevance: ACCELERATOR APS is an automated track system that manages pre-analysis, analysis, as well as post-analysis operations. It centralizes all these operations.

Methodology: This study analyzed one month's data of % that achieved the TAT goal and consumables usage of 29 clinical chemistry assays for STAT outpatient

sample from laboratory information system. The number of working steps and staff requirements were obtained by workflow observation and space require, all metrics performed before and after implementation.

Validation: The facility has a TAT goal of 60 minutes for 29 STAT Chemistry assays for outpatient sample. The percentage of TAT achievement and consumables usage were analyzed using LIS data. Working steps and personnel required were collected via workflow observations. Space utilization is from the calculations done by engineers.

Results:

Metrics	Before Implementation	After Implementation	% of increase and decrease
No. of tests	27,866	32,286	15.8%
% Achieved TAT goal	96	99.3	3.3%
Working steps	21	5	-76.0%
Personnel	10	4	-60.0%
Sample tube usage	26.058	25,608	-1.7%
Aliquot tip and cup usage	5,211	0	-100%
Space required (sq. meter)	1,397	597	-57.2%

Conclusion: The implementation of the ACCELERATOR APS to combine pre-analysis, analysis and post-analysis in one platform, resulted in an improvement of laboratory efficiencies in all key metrics. This was achieved despite the 15.8% increase in testing volume observed after implement of the ACCELERATOR APS.

• 3.3% increase in tests achieving their TAT goal

• 76%, 60%,1.7% and 52.7% are reduction in working steps, personnel, sample tubes and space required respectively

• 100% elimination of aliquot tips and cups due to consolidate testing.

B-171

Use of Technological Advances to Improve Laboratory Turn Around Times

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Background: Timely laboratory results can be essential for quality patient care. As such, laboratory turnaround times (TAT) are often cited as performance measures and quality indicators. We sought to tabulate changes in TAT observed after the implementation of new processes and technologies into our laboratory. These included personalized productivity reports, status display monitors, result autoverification, preanalytical automation, and the use of plasma instead of serum.

Methods: The TAT of basic chemistry profiles were determined before and after each change was implemented. The TATs of samples analyzed from 0700-1530 weekdays only were tabulated as per institutional review board approval at the University of Mississippi Medical Center, Jackson, MS. Each experimental group included over 4000 samples collected during a given eight week period. A minimum of two weeks were allowed to pass in order for technologists to adapt to each change, whereas three months were allowed for the acclimation to new instrumentation. After baseline measures were collected, the first change involved daily dissemination of individualized performance reports. Each report included the number of samples analyzed and average TAT of STAT and routine results of each technologist. Secondly, an LCD monitor was installed within view of the technologists. The LCD monitor displayed the status of all pending samples. Next, the results of autoverification was recorded where only normal patient results were autoverified. The TAT changes associated with preanalytical automation and use of plasma were also tabulated.

Results: The greatest reduction in TAT, 13.6 minutes, was obtained after the implementation of preanalytical automation. Reductions of 6.81, 6.65, and 5.99 minutes, respectively, were noted with implementation of autoverification, the status display monitor, and productivity reports. Autoverification resulted in the best cost:benefit ratio at no cost, whereas autoverification was the most costly at hundreds of thousands of dollars.

Conclusion: Preanalytical automation afforded the greatest reduction in TAT, but also came with significant monetary and space requirements. Laboratories can significantly reduce their TAT via several methods inexpensive methods. Solutions include autoverification, personnel productivity reports, LCD displays, and alternate sample collection tubes.

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Eliminating non-value added pre-analytic processes to improve laboratory turnaround time and patient safety for emergency room patients

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Background: Our hospital system has been looking at various ways to eliminate non-value added processes to improve patient care and decrease costs. One cause of emergency department (ED) patient dissatisfaction is extended length of stay (LOS) from delays in test ordering to test result availability time. A joint ED and laboratory team sought to decrease LOS by utilizing value stream mapping (VSM). VSM is a lean manufacturing method to analyze and improve the flow of information and materials across a process. We focused on an ED with no stat lab: all specimen testing outside of a very limited ED point-of-care menu was sent via pneumatic tube to the main lab. In the main lab, we utilized VSM to optimize the flow of ED specimens from pneumatic tube receipt to automated chemistry or hematology line log-in time.

Methods: The measuring timeframe criteria for the laboratory portion of the project were established. The tests tracked were the basic metabolic panel, complete metabolic panel, hepatic panel, lipase, and complete blood count. Measurements were (1) laboratory pneumatic tube station receipt to stat specimen log-in (SL) time, (2) SL to automated chemistry line log-in (CL) or hematology line log-in (HL) time. Percent of ED relabeled (%R) tubes was determined by manually tracking relabeled specimens over 24 hour periods. Specimen processing personnel motion was observed and spaghetti charts were made. After corrective interventions, times for (1) and (2), %R, and spaghetti chart walk paths were reassessed.

Results: The initial state showed that SL was 2:00 minutes, CL was 13:20 minutes, HL was 05:20 minutes, and %R was 46%. Major causes of pre-analytical phase delay were lack of prioritization for stat specimens, issues with label placement on specimen tubes, and work interruptions and non-value added motion by specimen processing personnel. The intervention for ED personnel was training on correct label positioning techniques using visual aids to demonstrate the spatial relationship between specimen label, automated line bar code reader, and specimen puck. The specimen processing area interventions included establishment of a STAT bench, establishment of a separate Problem bench to eliminate unnecessary interruptions, and designated specimen tube runners. After intervention, SL was 00:48 minutes (60% decrease); CL was 09:20 (30% decrease); HL was 03:44 (30% decrease); and %R was 0 (100% decrease). A comparison of the initial state spaghetti chart to that of the confirmed state showed an 87% decrease in walk paths. The projected annual monetary savings for the laboratory portion was $33,396.

Conclusions: Small yet significant interventions implemented via this VSM project by ED and laboratory personnel improved the specimen flow from the ED to the laboratory automated lines. The interventions in the current study decreased pre-analytical phase delays, improved patient safety and satisfaction, and resulted in potential monetary savings.

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Quantifying of the Cost of Unnecessary Clinical Laboratory Testing for Hospital Systems and Healthcare Payers

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Background: Diagnostic laboratory testing represents the largest source of structured medical information in most healthcare systems. Testing with little or no diagnostic value is a significant source of unnecessary cost to the health care system. Using data available from two hospital systems (>15 hospitals) and four large regional payers (>6 million covered lives) we evaluated testing patterns for several diagnostic test scenarios to quantify the cost of unnecessary testing.

Methods: Using available evidence-based medical knowledge we determined test scenarios for which at least one test was largely unnecessary. We aggregated 14 test scenarios into 7 diagnostic categories: thyroid (e.g., concurrent free T3 and/or free T4 given TSH within the reference range), liver function (e.g., concurrent GGT and alkaline phosphatase given ALKP within the reference range), suspected pancreatitis (e.g., concurrent serum amylase and lipase), vitamin D status, iron status, general inflammation (e.g., concurrent CRP and erythrocyte sedimentation rate), and myocardial injury (e.g., concurrent troponin and CKMB).

Combining laboratory, operational, and detailed financial data we calculated costs based on available cost accounting categories for each hospital system. We also queried claims databases for four US regional payers and extrapolated ordering

patterns from hospital data. Hospital data and payer data covered at least 12 months (24-48 months in most cases) during the period 2008-2013 for hospitals and 2009-2012 for payers.

Findings: The mean annual volume of unnecessary testing in the hospital systems was 270,517 tests representing variable plus labor costs of $1,824,805 and total costs of $2,514,822. For payers, the mean annual volume of the same unnecessary testing was 1,261,817 tests worth $30,497,028 in net paid out claims (see table).

Conclusion: The cost of unnecessary testing is substantial to both hospitals and payers. There is great opportunity for laboratory professionals to quantitatively demonstrate value by improving test utilization patterns.

Annual volume and cost of unnecessary testing for hospitals (a) and payers (b)

Diagnostic Category	Volume(a)	Variable Cost(a)	Total Cost(a)	Volume(b)	Paid Claims(b)
Thyroid	109,209	$645,389	$913,858	536,097	$12,252,830
Liver Function	17,542	$80,989	$109,361	30,963	$458,420
Suspected Pancreatitis	23,179	$118,793	$164,338	172,798	$3,606,089
Vitamin D Status	4,610	$175,018	$229,000	33,864	$2,166,743
Iron Status	27,292	$145,967	$202,811	145,186	$4,503,433
General Inflammation	31,108	$194,863	$298,743	196,372	$1,868,772
Myocardial Injury	63,077	$463,786	$596,711	146,537	$5,640,741
TOTAL	270,517	$1,824,805	$2,514,822	1,261,817	$30,497,028

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Sample Size Requirements for QC Lot Cross-Over Studies

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Background: Objective: Determine the number of QC results required in a cross-over study to provide a good estimate for the mean (and possibly SD) for a new lot of QC material.

Relevance: Establishing the mean concentration for a new lot of QC material is an important laboratory activity. A major concern is that a poorly estimated QC mean will lead to a QC rule that gives too many false rejections. Designing cross-over studies that provide good estimates with a minimum number of replicates is important.

Methods: Simulations were employed to estimate the influence of cross-over study sample size on a QC rule's false rejection rate when the QC rule is based on estimates obtained from the cross-over study. Three cases are considered; 1) the QC mean is estimated, but the SD is known, 2) the QC mean is estimated and SD is computed as estimated mean * known CV, and 3) both QC mean and SD are estimated. The outcome metrics evaluated are the expected probability of false rejection, $E(P_{fr})$, when cross-over study estimates are used in the QC rule, and the probability the false rejection rate is not greater than twice the false rejection rate of the QC rule with known QC mean and SD. One million simulations were employed to obtain estimates.

Results: The table shows some of the results.

Conclusion: If the SD or CV are known and only the QC mean is estimated, then a cross-over study based on N=10 results can provide a QC rule that has at least an 80% chance that the false rejection rate of the rule will be no greater than twice the false rejection rate using the true QC mean and SD. If SD must be estimated from the cross-over study, then at least 60 QC results are required.

1-3s/2-2s/R-4s QC Rule (Using known mean and SD, $P_{fr} = 0.01$)

Case	N	$E(P_{fr})$	$P(P_{fr} < 2 * 0.01)$
SD known	7	0.017	0.75
SD known	**10**	**0.015**	**0.86**
SD known	14	0.013	0.93
SD known	21	0.012	0.98
CV known (10%)	7	0.018	0.73
CV known (10%)	**10**	**0.015**	**0.83**
CV known (10%)	14	0.013	0.90
CV known (10%)	21	0.012	0.96
SD estimated	20	0.025	0.55
SD estimated	40	0.016	0.71
SD estimated	**60**	**0.014**	**0.81**
SD estimated	80	0.013	0.86

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Investigation on Causes and Impact of Specimen Rejection in Clinical Chemistry Laboratory

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Background: Accurate results are critical to patient management and quality care. Errors occurring in the pre-analytical phase account for up to 90% of total laboratory errors. Of those, inappropriate specimen due to quality and quantity account for 70%. Pre-analytical specimen integrity and quality are extremely important to the final result reported by the laboratory. Specimen rejection is conducted to ensure accurate identification and quality of samples as well as the accurate results. Unlike quality control systems widely applied to ensure the quality of the analytical phase, quality improvement intending to reduce pre-analytical errors as part of total quality management has not been fully implemented and achieved. This study was conducted to investigate the frequency, causes, and impact of specimen rejection in clinical chemistry laboratory.

Methods: Rejected chemistry specimens in our laboratories recorded in LIS during a 4-month period were collected. The number of rejected specimens, reason, and location for rejection were analyzed.

Results: Of the 245,058 chemistry specimens received to the laboratories during the data collection period, 647 (0.26%) were rejected. The most common reasons for specimen rejection were contamination (IV fluid or TPN) (227, 35.1%), unacceptable specimen (wrong collection tube, unlabeled, mislabeled, or inappropriately labeled specimen) (n=179, 27.7%), quantity not sufficient (QNS) (n=98, 15.1%), hemolysis (n=61, 9.4%), clot (n=60, 9.3%), and patient ID error (n=14, 2.2%). The most commonly affected analytes due to specimen rejection occurring after collection were glucose (n=192, 8.82%); calcium (n=153, 7.0%), magnesium (n=148, 6.8%), potassium (n=138, 6.3%), creatinine (n=101, 4.6%), and BUN (n=96, 4.44%). Inpatient areas had the most rejections occurring after collection (45.3%), followed by outpatient areas (24.6%), adult Intensive Care Units (ICUs) (17.2%), and ER (11.0%). When compared with the respective frequency with which they collect specimens, laboratory personnel (phlebotomists) submitted significantly fewer rejected specimens than other in-hospital personnel groups (at a rate of 0.22% vs. 1.34% for floors often collected by other in-hospital personnel groups. Total recollected specimens (n=230, 0.09%) during a 4-month period added an average of 108 minutes delay (from recollect order placed to results completed) to the turnaround time per test. The cost for total of 230 specimen recollection was $5510.80 USD.

Conclusions: Specimen rejection criteria should be followed and specimen rejection should be monitored on a regular basis. Those frequent factors that are associated with rejection and have a great impact on patient results and patient care should be identified. Actions and education should be taken for quality improvement. Efforts should be made to standardize laboratory manuals and procedures as part of continuous quality improvement program. Policy and procedures specifically to specimen requirement, collection, transportation, and preparation should be strictly followed.