Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0001

SIX SIGMA: IS IT APPLICABLE IN LABORATORY MEDICINE?

L.N. Velazquez-Jimenez [3], S. Quintana-Ponce [3], R.G. Hernández-Nava [2], M. Maruris-Reducindo [3], R. Sierra-Amor [1], M. Calixto-Gálvez [3], N.R.E. Barlandas-Rendón [3]
[1]*Colegio Mexicano de Ciencias del Laboratorio Clínico, México.*
[2]*Escuela Superior de Nutrición y Ciencia de los Alimentos, Universidad Autónoma de Guerrero, México*
[3]*Facultad de Ciencias Naturales, Universidad Autónoma de Guerrero, México.*

BACKGROUND-AIM

Within the analytical quality system of clinical analytical laboratories, the six sigma metric has become a useful tool for all parts of the quality control design process. Analytical performance can be evaluated with this scale, quality control rules have been suggested depending on the sigma value obtained.The aim of the present work was to analyse the six sigma model and its application in quality control planning in laboratory medicine

METHODS

This is an observational, longitudinal and analytical study, 22 analytes from the area of clinical chemistry were evaluated. The following formula was used for the calculation: Six sigma = [ETa (%) - Bias (%)] /CV (%); 12 month internal control (ICC) and external quality control (EQC) data and analytical quality specifications (AQS) based on minimum biological variability (MBV), desirable biological variability (DBV) and optimal biological variability (OBV), Clinical Laboratory Improvement Amendments (CLIA) and Rilibak (Guideline of the German Medical Association for Quality Assurance of Laboratory Medical Examinations) in clinical chemistry methods on three different analysers were used.

RESULTS

The sigma values obtained per analyte and per method varied depending on the selected AQS, the same analyte presented sigma values with world-class performance and sigma values with unacceptable performance, depending on the AQS used, consequently, the recommended quality control rules varied depending on the selected AQS.

CONCLUSIONS

The application of the six sigma model in the selection of QC rules should be applied with reservation, as it depends on the AQS used, there is currently no international consensus on its selection. Clinical laboratories should identify the appropriate AQS for the analyte evaluated and the technical capability of the equipment used to efficiently apply the six sigma model in their QC planning.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0002

VERIFICATION OF PERFORMANCE SPECIFICATIONS FOR FSH AND PROLACTIN ASSAYS ON THE MAGLUMI X3 IMMUNOASSAY PLATFORM

L. Mino [3], M. Lika [2], E. Kapllani [3], A. Bulo [1]
[1]*Laboratory Department, University of Medicine, Tirana*
[2]*Laboratory Networks, "Mother Teresa" University Hospital Centre, Tirane*
[3]*Pegasus Med Laboratory, Tirane*

BACKGROUND-AIM

Verification of examination methods is a key requirement of ISO 15189:2022. It mandates that laboratories verify the performance of new instruments or tests before incorporating them into routine use. This process ensures that the new tests meet the performance characteristics declared by the manufacturer under the specific conditions of the laboratory. The objective of this study was to verify the performance specifications for Follicle-Stimulating Hormone (FSH) and Prolactin (PRL) assays on the Maglumi X3 immunoassay platform, as claimed by the manufacturer.

METHODS

We followed the CLIA EP15-A3 guideline to verify the precision and accuracy/bias of the FSH and Prolactin assays on the Maglumi X3 platform. To evaluate method precision, we used two levels of third-party controls (Randox), testing each control in five replicates daily over five consecutive days for both FSH and Prolactin. The results were analyzed using Analyse-It and compared with the manufacturer's claims for precision (within-run and within-laboratory precision). For accuracy/bias evaluation, the same controls were used, and a t-test was applied to assess the significance of any error, as no manufacturer-declared bias was available. In cases of significant bias, the EFLM database for biological variation was consulted to compare our results with the allowable total error.

RESULTS

For both assays, the standard deviation (SD) and coefficient of variation (CV) for precision showed no significant differences compared to the manufacturer's claims ($p > 0.05$). Bias (error) was found to be significant ($p < 0.05$) for both FSH and Prolactin, but the observed bias was smaller than the allowable total bias according to the EFLM biological variation database. Specifically, the bias at level 1 for both FSH and Prolactin was lower than the optimal bias, and the bias at level 2 was lower than the desirable bias.

CONCLUSIONS

The FSH and Prolactin assays on the Maglumi X3 platform meet the manufacturer's claims for precision (within-run and within-laboratory) and fall within the allowable total error specifications as outlined in the EFLM biological variation database.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0003

ANALYTICAL PERFORMANCE EVALUATION OF THE HEMOLYSIS LEVEL OF LIQUICHEK™ SERUM INDEX (BIO-RAD) ON THE AU5800® (BECKMAN COULTER®)

B. Izquierdo Alarcón [1], R. Ramos Corral [1], C. Castillo Pérez [1], P. Jurado Parras [1], J. Guillén Reyes [1], M. Mayor Díaz [1], R. Millán Guirado [1], M. Martínez-Novillo González [1]
[1]*Clinical Analysis Department, Laboratory Medicine Institute, Hospital Clínico San Carlos, Madrid, Spain*

BACKGROUND-AIM

Hemolysis is probably the most frequent source of interference in clinical laboratory. For some time now, many analyzers incorporate detection systems for this interferent called hemolysis index (H). Quality assurance of H should be regularly monitored before using data of this measure for purposes of accepting or rejecting results. However, quality control of such index is infrequently implemented neither not verified by the difficulty in obtaining appropriate reference materials.

METHODS

Bio-Rad Liquichek™ Serum Index product (Hemolysis Level) was evaluated in our AU5800® analyzers (Beckman Coulter®). The measurement of H was measured automatically by spectrophotometry. The absorbance readings were converted into indices which were expressed on a unitless ordinal scale corresponding to a range of haemoglobin concentrations (1: 50-99 mg/dL, 2: 100-199 mg/dL, 3: 200-299 mg/dL, 4: 300-500 mg/dL, 5: >500 mg/dL).
Performance was monitored over a 5-day period in the three AU5800® of the biochemistry department at the beginning and end of the analytical series (N=30). On the other hand, it was processed 10 times in the same equipment to evaluate intraserie precision.

RESULTS

The results obtained were H=3 in both the interseries and intraseries studies for all measurements.
Target value published in the control insert was 200 mg/dL, while the value published by the manufacturer report for peer group participants was H=2 in 80% and H=3 in the rest. The peer group variability is consistent with the small number of participants (2 laboratories).

CONCLUSIONS

- In our study H value of Liquichek™ Serum Index control remains constant compared to peer group data provided by Bio-Rad.
- In our Laboratory measurements with H=3 (lactate dehydrogenase, potassium, total and direct bilirubin) were rejected, being indispensable to ensure the quality of H with a third range control.
- It would also be interesting to evaluate a higher degree of hemolysis level since H=6 is a reason for serum container rejection in our Laboratory.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0004

MAJOR UPDATE OF THE HORIZONTAL GUIDELINES FOR THE ASSESSMENT OF CLINICAL/MEDICAL LABORATORIES: ESYD G-CLINLAB 2024 OF THE HELLENIC ACCREDITATION SYSTEM

P.N. Kanellopoulos [1], I. Sitaras [2]
[1]*Biochemistry Department, General Hospital of Athens "Laiko"*
[2]*Laboratories Accreditation Division, Hellenic Accreditation System ESYD*

BACKGROUND-AIM

Accreditation under ISO 15189:2022 promotes high standard heath care services for patients and health care providers, through the assessment of the technical competence of medical laboratories and its consistency assured by a suitable management system. With the view of assisting this process both on the side of the laboratories but also the assessment teams, ESYD, the Greek Accreditation Body, issues Guidelines for a long period of several years, taking into account particular features of Greek Laboratories.

METHODS

The major update of 2024 spans a large variety of laboratory test types (Biochemistry, Hematology, Blood Transfusion, Microbiology, Genetics, Cytogenetics, Molecular Diagnostics, Immunology, Flow Cytometry, Cytology, Pathology) and deals with specific topics (Primary Sampling, Multisite Accreditation, Point-of-Care Testing, and Umbilical Cord Blood Banks). At least ten distinguished Greek Scientific Societies participated in a consultation process before the final draft.

RESULTS

The Guidelines refer to either approved standardized methods which require verification, or laboratory-developed tests, modified approved methods and Research Use Only methods which require analytical validation and clinical verification. For each main category of testing and relevant subcategories, extensive guidance is offered related to analytical verification or validation methods, as well as estimation of measurement uncertainty, some of which are quite innovative alternatives, with focus not only on the initial evaluation of laboratories, but also the extension and re-evaluation of the accreditation. Guidance for the overall assessment of the suitability of the method may be extremely helpful in determining the performance specifications and its fitness of purpose. Priority is also given on guiding all testing categories on up-to-date Quality Assurance methods with detailed suggestions on Internal and External Quality Control.

CONCLUSIONS

Ensuring consistency and reliability, simplifying decision making, setting recommendations for best practice, and cost-effectiveness are some of the benefits of these Guidelines along with the main initiative which was the promotion of laboratories accreditation in the medical sector. They are available on the Hellenic Accreditation System site (www.esyd.gr).

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0005

SHORT-TERM ANALYSIS OF REAGENT LOT VARIATION: A PILOT STUDY COMPARING QC AND PATIENT SAMPLES

K. Narayan [1], S. Gangopadhyay [2], A. Yadav [2]
[1]*POST GRADUATE RESIDENT, DEPARTMENT OF BIOCHEMISTRY, VMMC AND SAFDARJUNG HOSPITAL, NEW DELHI*
[2]*PROFESSOR, DEPARTMENT OF BIOCHEMISTRY, VMMC AND SAFDARJUNG HOSPITAL, NEW DELHI*

BACKGROUND-AIM

A clinical chemistry laboratory must ensure consistent, reliable test results, adhering to quality control (QC) protocols during reagent lot changes. Such changes can introduce variations, especially for frequently tested analytes. ISO 15189:2022 recommends using patient samples over QC material to compare new and previous reagent lots, avoiding possible commutability issues with use of QC. While compliance with NABL 112 requires running either patient sample or QC material on both old and new lots, with acceptability limits of ±1 SD or ±10% (2019) or within the analyte's measurement uncertainty (2024).
This pilot study has been undertaken as an attempt to analyze the difference of variation using QC material and patient sample for reagent lot verification.

METHODS

The reagent lot verification was studied using both QC materials and Patient samples on Beckman AU 680 platform for closed system reagents between June to Dec 2024 for the parameters Phosphorus, LDH, Amylase, and Lipase using non enzymatic chemical methods. The QC lot did not change during this period.

RESULTS

QC materials at Levels 1 and 2 were tested in duplicate for both kits, old and new and their average results were calculated. Pre-existent patient samples were also tested in duplicates for both lower- and higher-range values and the differences (log delta QC, log delta patient value) compared using Mann Whitney U test (https://www.socscistatistics.com/tests/mannwhitney/default2.aspx) with p value significance at < 0.05. The z-score was calculated at -0.21429 with p-value = 0.83366, thus indicating a non-significant variation.

CONCLUSIONS

These preliminary results indicate that there is no difference in tracking lot to lot variation of reagents with the use of either QC material or patient sample. This is in contrast to the findings of another Indian study based in 2021. However, more reagent lot variations need to be analyzed over a larger period of time to give any conclusive evidence of variations including long term drifts.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0007

RESULTS OF THE EXTERNAL QUALITY ASSESSMENT (EQA) PROGRAM IN HEMOSTASIS AT HEMATOLOGY LABORATORY -RABTA, TUNIS (2023-2024)

A. Ben Messaoud [1], H. Baccouche [1], A. Ben Hmed [1], A. Chakroun [1], S. Mahjoub [1]
[1]*Hematology laboratory, Rabta Hospital, Tunis,Tunisia*

BACKGROUND-AIM

External quality assessment (EQA) of laboratory analyses is a crucial part of the quality system of medical laboratories in accordance with ISO 15189 requirements.
Our laboratory has registered for the external control program.
Our goal was to make a global analysis of hemostasis parameters one year after the registration of the program.

METHODS

Twelve lyophilized samples were obtained from BIO-RAD (Hercules, California, United States) between April 2023 to April 2024 and one sample was analysed per month.
Eight parameters were evaluated: Activated partial thrombin time (APTT), D-Dimer concentration (DD), Antithrombin activity (ATIII), Fibrinogen concentration (FIB), Prothrombin activity (PT), International normalized ratio (INR), Quick time (QT), Factor VIII activity . All of them were determined by STA R Max3 (Stago, France) except D-Dimer concentration with mini VIDAS (Biomérieux ,France) .

RESULTS

For each parameter, the results were divided in number N according to the z-score value obtained into two categories: satisfied (Z-score in absolute value < or equal to 2) and questionable or unsatisfied results (Z-score in absolute value > 2).
Only 5 parameters had shown results with Z-score >2 :
-DD (N=12) : 1 non-conformity
-APTT (N=12) : 2 non-conformities
-INR (N=12) : 1 non-conformity
-PT (N=12) : 1 non-conformity
-QT (N=12) : 1 non-conformity
For each non-conformity found, we looked for reasons and actions taken :
-DD : Input error
-APTT : 1) Input error 2) Check next sample
-INR :Recalculation of Quick Time (QT)
-PT : Recalculation of Quick Time (QT)
-QT : Internal quality control verification

CONCLUSIONS

The interest of external quality control in the evaluation of the accuracy of the method and the reagents used. It can serve to highlight non-conformities at the origin of unsatisfied results in order to identify possible reasons and put the necessary corrective actions.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0008

IMPLEMENTATION OF A SELF-ASSESSMENT TOOL IN MEDICINE LABORATORY: DRIVING IMPROVEMENTS ALIGNED WITH ISO 15189:2022

E. Catry [1], F. Mullier [1], L. Moreno Y Banuls [1]
[1]*Department of Laboratory Medicine, CHU UCL Namur, UCLouvain, Belgium*

BACKGROUND-AIM

Unlike conventional internal audits that quantify non-conformities, a self-assessment approach avoids numerical scoring to encourage open and transparent reporting. Instead, it identifies opportunities for improvement (OFIs). In this regard, we developed a comprehensive questionnaire to evaluate compliance with the ISO 15189:2022, such as risk management, patient-centered processes, and staff competency, compatible with all medical laboratory departments.

METHODS

The questionnaire encompasses all ISO 15189 requirements. It is designed for collaborative completion, allowing input from multiple stakeholders, including the specialist in laboratory medicine responsible, senior and junior medical laboratory technologists. Furthermore, each department is asked to evaluate its level of satisfaction with the aforementioned criteria using the emoticon system. Prior to its implementation, the questionnaire was tested by departments with a relatively high level of familiarity with ISO 15189 (i.e., biochemistry, hematology-hemostasis, and immuno-hematology) to ascertain its alignment with expectations and its ease of completion. The time required for completion was evaluated and reviewed.

RESULTS

The initial version of the questionnaire was overly theoretical and difficult for the senior technician to interpret, particularly with regard to vague sentences. The second version was more practical and better received, but still required approximately one day to complete correctly. The third and currently applicable version has been revised and summarized to reduce completion time to approximately half a day.

CONCLUSIONS

Key OFIs include improvements to documentation workflows, enhanced intradepartmental communication, and the integration of risk-based thinking into routine operations. These findings allow for targeted corrective actions that ensure transparency and encouraging the discovery of systemic issues. By shifting the focus from non-conformities to constructive improvements, it encourages staff engagement, proactive participation, and cultivates a culture of continuous quality enhancement through constructive dialogue and actionable outcomes. The methodology provides a scalable framework for other laboratories seeking to align their practices with ISO 15189:2022.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0009

EXTERNAL QUALITY ASSESSMENTS IN CLINICAL BIOLOGY FOLLOWING THE ISO17043 STANDARD.

B. China [1], S. Whathlet [1], S. Broeders [1], A. Capron [1]
[1]*Sciensano*

BACKGROUND-AIM

Efficient, rapid, and accurate diagnostic methods are essential for providing quality information to clinicians, establishing a reliable diagnosis, and effectively managing patients. The Sciensano service "Quality of Laboratories" organizes external quality assessment (EQA) programs in medical diagnosis following the ISO17043 standard. According to Belgian legislation, Belgian medical laboratories must register with the Sciensano EQA to benefit from the reimbursement of their tests.

METHODS

The process involves several key steps. First, the laboratories must register online for the EQA programs. Second, Sciensano prepares or selects samples that are as close as possible to clinical samples. The homogeneity and stability of the samples must be guaranteed. The samples are sent to the participants by complying with the law. Instructions for sample handling are provided to the participants. The participants have, in general, two weeks to analyze the samples and submit their results. Shortly after the submission deadline, the laboratories obtain a preliminary report to evaluate their proficiency. The global results are then discussed with an expert committee and summarised in an online global report. At the end of the cycle, an annual report per domain is also produced, and finally, a global annual report, including all the domains, is produced. The data submitted can be qualitative or quantitative, and the further processing of the data may, for example, be different in terms of statistical processing.

RESULTS

In 2024, Sciensano organized 46 EQA surveys under the ISO17043 standard. The results of individual participants and the global results per method were evaluated. The results can also be compared with those of previous years. Overall, the results are excellent and constantly improving. Nevertheless, specific problems have been highlighted, and our inspectors will monitor the laboratories concerned.

CONCLUSIONS

Participation in EQA programs allows laboratories to evaluate their techniques and compare them to those of other participants. An incorrect result is a non-conformity in their quality system, which involves preventive and corrective actions.The final objective is to improve the quality of medical diagnosis in Belgium to benefit the patient.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0010

INTERNAL QUALITY CONTROL AUDIT: APPLICATION TO THE DETERMINATION OF 25OH-VITAMIN D AND PARATHORMONE

M.A. El Mehdaoui [3], N. Ould Bessi [3], L. Abib [1], A. Kemache [3], A. Lakhdari [1], B. Ait Abdelkader [2]

[1]*Hormonology Laboratory, Pierre and Marie Curie Center, Algiers, Algeria*

[2]*Hormonology Laboratory, Pierre and Marie Curie Center, Algiers, Algeria. Biochemistry Laboratory, Department of Medecin, Faculty of Medecin, University of Health Sciences, Algiers, Algeria. Cytogenetic and Oncological Genetics Research Laboratory,Universi*

[3]*Hormonology Laboratory, Pierre and Marie Curie Center, Algiers, Algeria. Biochemistry Laboratory, Department of Pharmacy, Faculty of Pharmacy, University of Health Sciences, Algiers, Algeria. Cytogenetic and Oncological Genetics Research Laboratory,Univer*

BACKGROUND-AIM

Internal quality control (IQC) is one of the key technical requirements for the accreditation of medical laboratories according to the ISO 15189. It's used to check the efficiency of the analytical system. However, to detect a trend or drift in the system, continuous monitoring of the CIQ using Levey-Jennings (LJ) charts is essential.We report in this work our experience of internal quality control of two parameters: 25 OH Vitamin D (VitD) and parathormon (PTH), in the hormonology laboratory of Pierre and Marie Curie specialist hospital of Algiers.

METHODS

We used COBAS® Precicontrol Varia multiparametric serum (2 levels) for Vit D and Precicontrol Universal multiparametric serum (2 levels)for PTH.The measurement was processed on Roche COBAS® module e411 for PTH and module e601 for VitD, using the 4th generation electrochemiluminescence immunoassay method. 22 values of each level for 25OH Vit-D have been collected and 20 values of each level for PTH . The results were plotted on LEEVEY JENNINGS diagrams and interpreted according to WESTGARD rules. The results were processed using SPC version 6.0 software for EXCEL.

RESULTS

25OH VIT-D : Level 1: 90.90% of the values in (0S-1S), 4.54% of the values in (1S-2S), 4.54% of the values in (2S-3S), all the rules (1 2S,1 3S, 2 2S, 41S et R4S) were respected apart from the violation of rule10S followed by curative maintenance.
Level 2: 81.81% of values in (0S-1S), 9.09% of values in (1S-2S), 9.09% of values in (2S-3S), all rules (1 2S,1 3S, 2 2S, 41S, R4S et 10S) complied without exception.
PTH :Level 1: 80% of values in (0S-1S), 20% of values in (1S-2S), 0% of values in (2S-3S) ,all rules have been respected without exception
Level 2: 75% of the values in (0S-1S), 25% of the values in (1S-2S), 0% of the values in (2S-3S),all rules have been respected without exception

CONCLUSIONS

The audit of quality control ofthe analytical activity of our hormonology laboratory revealed the absence of systematic errors and random errors linked, among other things, to the quality of the reagents and calibration sera. As a result, the analytical process for the two parameters tested was well managed.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0011

ROLE OF LABORATORY PROFESSIONALS IN IMPROVING PATIENT SAFETY

R. Escobar Conesa [1]
[1]*UGC Laboratorio. Hospital Universitario Torrecárdenas (Almería)*

BACKGROUND-AIM

In vitro diagnostic tests include all the procedures that work on samples and not on patients directly. The Patient Safety Strategy of the Public Health System of Andalusia establishes in its 3rd strategic line of Safe Comprehensive Care, a specific section for the safe use of in vitro diagnostic tests; and for this reason, the Hospital Safety Commission has requested the formation of this working group.

METHODS

The multidisciplinary composition is established, made up of 9 members, including doctors and nurses who carry out their healthcare activities both at the hospital level and in Primary Care, which allows for the collection of all views on the safety of in vitro diagnosis by the specialties linked to the Clinical Laboratory with a bi-monthly meeting frequency. They are set as lines of work:SWOT analysis of patient safety in vitro diagnostic testing,Unequivocal identification of patient and samples,Training to reduce the percentage of hemolyzed samples during the blood collection procedure,Communication of critical values, Analysis of security notifications received quarterly and Promoting a safety culture among professionals.

RESULTS

The first meeting to establish the working group will be held in March 2024.
A review has been carried out of the parameters included in the procedure for communicating critical values based on the latest recommendation of the SEQC of 2023, potassium is modified from 6.2 to 6.5 mEq/L.
Monthly training is scheduled for nursing staff on the extraction and proper identification of blood culture samples, as well as the importance of the pre-analytical phase in hemolysis, which has significantly influenced the reduction in the percentage of hemolyzed samples received.

CONCLUSIONS

The patient is at the centre of healthcare and therefore, safety is a fundamental aspect, making it necessary to be aware of trying to avoid or at least minimise the risks associated with healthcare activity.
In the field of Clinical Laboratory, this premise is reflected in the safe use of in vitro diagnostic tests and therefore, these established actions are aimed at achieving this.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0012

SHOULD PANIC VALUE RESULTS BE REPEATED?

Y. Hajisoy [1], A. Zuleykha [2]
[1]*Azerbaijan Medical University, Baku, Azerbaijan*
[2]*Baku Health Center, Baku, Azerbaijan*

BACKGROUND-AIM

A panic value is a laboratory result that could be life-threatening if not treated. It is undesirable for such an important result to be caused by an analytical problem and lead to inappropriate treatment for the patient. For this reason, panic values are often remeasured for control purposes.

METHODS

The initial and repeated results of glucose, INR, Troponin I, and procalcitonin (PCT) tests of samples with panic values from the samples received by our laboratory during 2024-2025 were studied. The absolute difference and percent change between the two values, the mean percent change, and the mean amount of change were calculated. These changes were compared with the CLIA total allowable error percentage (TEa).

RESULTS

144 results with panic values were analyzed. 26 glucose, 40 INR, 63 troponin I, 15 PCT results were analyzed and the average percentage change and amount of change were calculated as follows.
Glucose 0.07-3.0%
INR 1.07-0.28%
Troponin I 1.56-0.98%
PCT 1.23-0.76%

CONCLUSIONS

None of these tests were found to exceed the overall permissible limit for CLIA. It was considered unnecessary to repeat the panic value results.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0013

VERIFICATION OF THE ANALYTICAL PERFORMANCE OF THE SERUM CRP ASSAY ON THE ABBOTT® ARCHITECT CI8200 IN THE BIOCHEMISTRY LABORATORY OF THE MOHAMMED VI UNIVERSITY HOSPITAL, OUJDA.

O. Kharkhach [1], D. Elmoujtahid [1], E. Sebbar [1], M. Choukri [1]
[1]*Biochemistry, central laboratory, CHU Mohammed VI, Oujda*

BACKGROUND-AIM

In the field of clinical diagnostics, measuring C-reactive protein (CRP) plays a crucial role as a key biomarker for inflammation and infections. Analytical method verification is therefore essential to ensure optimal precision and reliability.
The aim of this work is to evaluate an immunoassay method using chemiluminescent microparticles (CMIA) immunoassay of serum CRP on an Abbott Architect® ci8200 automated system.

METHODS

Based on the recommendations of the protocol of the technical guide for accreditation in human health, SH GTA 04 COFRAC according to ISO 15189, we carried out the verification of a verification of a CRP immunoassay method (CMIA) on the Abbott® ARCHITECT ci8200 analyser. The repeatability test consisted of analysing the same sample 30 times under the same set of conditions.The data were analysed using the method validation module method validation module EVM.

RESULTS

The study assesses the reproducibility of measurements, analyzing the impact of variations due to different experimental factors. The results reveal low coefficients of variation (CV), compliant with quality standards: CV1: 3.42%, CV2: 1.83%, CV3: 3.28%. These results highlight the method's reliability under varied conditions.
Simultaneously, repeatability assessment demonstrates similarly low CV values, reflecting remarkable stability and precision under controlled conditions: CV1: 7.67%, CV2: 4.77%, CV3: 1.96%. These performances meet the criteria of established standards, confirming the robustness of the method on the ARCHITECT ci8200 analyzer.

CONCLUSIONS

The results validate the relevance of this method for CRP measurement, offering precision and reproducibility tailored to the demands of modern diagnostics, while adhering to the standards set by professional societies.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0014

VERIFICATION OF THE ANALYTICAL PERFORMANCE OF THE SERUM B2M ASSAY ON THE ABBOTT ALINITY CI® IN THE BIOCHEMISTRY LABORATORY OF THE MOHAMMED VI UNIVERSITY HOSPITAL, OUJDA.

O. Kharkhach [1], D. Elmoujtahid [1], E. Sebbar [1], M. Choukri [1]
[1]*Biochemistry, central laboratory, CHU Mohammed VI, Oujda*

BACKGROUND-AIM

In the realm of clinical diagnostics, the quantification of Beta-2-Microglobulin (B2M) has emerged as a critical tool for assessing kidney function, monitoring immune disorders, and evaluating certain malignancies. Ensuring the accuracy and reliability of B2M measurements is essential for effective patient management.
This study focuses on the verification of B2M assay performance using the Abbott Alinity ci® analyzer.

METHODS

This prospective study was conducted in the biochemistry laboratory of Mohammed VI University Hospital over a 30-day duration. The investigation focused on the reproducibility and repeatability of B2M dosage. The study was conducted in two phases: first, daily control measurements at three levels (low, medium, high) over 30 days assessed reproducibility and consistency. In the second phase, serum samples with varying B2M concentrations were grouped into three levels, and 30 replicates per sample were performed to evaluate repeatability.The data was processed using the validation module of the
validation module of the EVM middleware method.

RESULTS

The reproducibility of the B2M assay was evaluated across multiple concentration levels, demonstrating low coefficients of variation (CV), all within acceptable quality standards: CV1: 2.36%, CV2: 2.94%, CV3: 2.44%. These findings highlight the robustness of the method under varying analytical conditions.
Additionally, repeatability assessments under controlled conditions revealed equally low CV values, reflecting the method's stability and precision: CV1: 2.55%, CV2: 1.68%, CV3: 1.00%. These results confirm the reliability of the B2M assay on the Abbott Alinity ci® analyzer.
By meeting the stringent criteria set by recognized professional societies, this study validates the analytical performance of the B2M assay, underscoring its suitability for clinical use. The method offers high precision and reproducibility, aligning with the demands of modern diagnostics for accurate and reliable patient care.

CONCLUSIONS

The verification of the analytical performance of the serum Beta-2-Microglobulin (B2M) assay on the Abbott Alinity ci® is a critical step in ensuring the accuracy, reliability, and clinical utility of this diagnostic tool.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0015

GUIDELINES FOR THE FREQUENCY OF PARTICIPATION TO EXTERNAL QUALITY ASSESSMENT FOR ANALYSES FOCUSED ON RARE DISEASES IN THE BELGIAN MEDICAL CENTERS OF HUMAN GENETICS

j. Lantoine [8], V. Benoit [9], A. Brysse [1], K. Claes [5], A. Corveleyn [6], V. Dideberg [1], W. Coucke [8], M. De Rycke [7], L. Van Laer [4], X. Peyrassol [3], M. Philippeau [2], M. Ravoet [2], S. Rombout [9], S. Seneca [7], S. Symoens [5], K. Van Den Bogaert [6], F. Wilkin [3], W. Wuyts [4], A. Capron [8], N.M. Vandevelde [8]

[1]*Centre de Génétique Humaine (UNILAB) - CHU Sart-Tilman, Domaine Universitaire du Sart Tilman (Bâtiment Tour 6, +1), B-4000 Liège, Belgium*

[2]*Centre de Génétique Humaine - Cliniques Universitaires Saint-Luc UCL, Avenue Hippocrate 10, 1200 Brussels, Belgium*

[3]*Centre de Génétique Humaine – ULB Erasme, Route de Lennik 808, 1070 Anderlecht, Belgium*

[4]*Centrum Medische Genetica - UZ Antwerpen, Prins Boudewijnlaan 43 Bus 6, 2650 Edegem, Belgium*

[5]*Centrum Medische Genetica - UZ Gent, Corneel Heymanslaan 10, 9000 Gent, Belgium*

[6]*Centrum Menselijke Erfelijkheid - UZ Leuven, Herestraat 49, 3000 Leuven, Belgium*

[7]*Centrum voor Medische Genetica - UZ Brussel Vrije Universiteit Brussel, Laarbeeklaan 101, 1090 Brussels, Belgium*

[8]*Department of Quality of Laboratories, Sciensano, rue Juliette Wystman 14, 1050 Ixelles, Belgium*

[9]*Institut de Pathologie et de Génétique, Avenue Georges Lemaître 25, 6041 Gosselies, Belgium*

BACKGROUND-AIM

In order to support the Belgian Medical Centers of Human Genetics (BMCHGs) in the development of a Quality Management System and the participation to External Quality Assessment programs (EQAs), the Belgian National Institute for Health and Disability Insurance in collaboration with the Belgian Institute for health, Sciensano has developed a funding for the participation of the BMCHGs to EQAs focused on genetic tests performed in the context of hereditary rare diseases and hereditary rare cancers. Indeed,
participation to external quality assessments (EQAs) is required for the ISO15189 accreditation of the Belgian Medical Centers of Human Genetics (BMCHGs). However, no directives on the minimal frequency of participation to genetic EQAs exist and European recommendations in this field are heterogeneous and it potentially impacts healthcare quality.

METHODS

In order to address this lack, genetic EQA schemes offered by accredited providers and focused on analyses used for rare diseases' diagnosis were analyzed by a working group in order to propose minimal frequencies of participation to EQA schemes with reference to international recommendations and national laboratory practice. Recommendations for dealing with poor performances and change management were also formulated.

RESULTS

Our guidelines recommend to assess annually all methods if possible through EQAs covering the technique, genotyping and clinical interpretation. A triennial assessment of performance of individual diagnostic tests is also recommended. In case of poor performances impacting the diagnosis of the patient, centers should participate to an EQA the following year and implement actions to avoid future errors.

CONCLUSIONS

These first Belgian guidelines help the BMCHGs to improve their quality management system. Moreover, they help the Belgian healthcare authorities to estimate the budget required to cover the participation of the BMCHGs to EQAs. Therefore, we are convinced that these guidelines could be used as a starting point for discussion at a broader level.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0016

EVALUATION OF CAPABILITY PROCESS FOR THE MEASUREMENT OF WHOLE BLOOD COUNT

M. Stamouli [2], I. Leimoni [1]
[1]*Affidea Greece, Country Quality Safety Manager*
[2]*Department of Biochemistry, Naval and Veterans Hospital of Athens, Athens, Greece*

BACKGROUND-AIM

The performance of a process is evaluated by calculating the Cpk index, which shows how capable the process is, in producing products that meet specification limits. The purpose of this study is to calculate the Cpk index for the whole blood count measurement, and thus evaluate the performance of the hematology laboratory.

METHODS

In the study we included the results from the 3 levels of internal quality control materials (low, medium and high). Measurements were performed on the SYSMEX hematology analyzer. For each test, the Cpk index was estimated with the MINITAB 19 statistical package. The assessment of laboratory performance in 6-sigma scale was calculated by means of the formula [3*Cpk+1.5].

RESULTS

The process performance for each test, expressed in 6-sigma scale was: RBC 5,61; HB 5,37; HCT 13,11; PTL 12,48; WBC 10,74; NEUTRO 7,26; LYMPH 8,82; MONO 9,54; EOS 7,26; MCV 5,49; MCHC 9,24; MCH 12,24; PDW 5,98 ; MPV 6,81

CONCLUSIONS

The application of the method contributes significantly to the improvement of laboratory quality and the detection of errors. The formula that was applied has been proposed by MOTOROLA, a company that was a pioneer in processes quality control. The laboratory's performance is very satisfactory. Tests with performance lower than 3 sigma are unacceptable, while tests with performance between 3 and 6 sigma need further improvement.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0017

ANALYSIS AND STRATEGIES TO ADDRESS HEMOLYSIS IN A TERTIARY HOSPITAL

J. Cabanes Madrid [1], R. Mateos Pablos [1], M.d.V. Romero Real [1], S. Peral García [1], J. Sanz Gómez [1], R. Vidal Lambán [1], D. Párraga García [1], E.A. López Jiménez [1]
[1]*Hospital 12 de Octubre, Madrid*

BACKGROUND-AIM

Hemolysis is one of the main causes of sample rejection in clinical laboratories, affecting the quality of results and patient safety. At our tertiary hospital, an analysis of hemolyzed samples was conducted over the course of one year, revealing that the neonatology service, neonatal intensive care units (NICU), and the emergency service had the highest rates of hemolysis. Given this issue, the primary objective of this study was to propose specific strategies aimed at reducing the incidence of hemolysis in these critical areas.

METHODS

A descriptive analysis identified factors associated with hemolysis in the services with the highest rates, using previously collected data from the laboratory. Based on this, potential intervention strategies were proposed.

RESULTS

The analysis highlighted key areas for intervention, resulting in several proposals. In neonatology, it is suggested to improve the handling of smaller gauge needles and extraction techniques for premature neonates, minimizing risks associated with manipulation. In the neonatal intensive care units, practical simulations could improve coordination and handling of catheters and intravascular devices. In the emergency service, training should focus on executing fast yet precise procedures, with particular attention to the pressure applied during sample extraction.
Additionally, it is proposed to review and standardize sample handling and transport protocols to minimize the risk of hemolysis. The possibility of evaluating innovative technologies, such as vacuum extraction systems with pressure regulation and specially designed tubes to reduce erythrocyte rupture, is also considered.
Another proposal involves the design of a continuous feedback system, based on monthly reports detailing hemolysis rates by service and periodic meetings between the laboratory and clinical services to discuss progress and adjust strategies based on the results obtained.

CONCLUSIONS

The proposed strategies address hemolysis from a comprehensive approach, including staff training, process optimization, and the incorporation of technological resources. Although these measures require joint effort between the laboratory and clinical services, they represent a crucial first step toward reducing hemolysis and sustainably improving the quality of processed samples.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0018

STUDY OF THE ACCURACY FOR THE SERUM CALCIUM MAGNITUDE IN A CLINICAL LABORATORY.

E. Martínez Rua [1], S. Esteve Poblador [1], F. De La Fuente García [1], S. Gorriz Pintado [1], P. Estela Burriel [1], M. Ortuño Alonso [1]
[1]*Hospital Universitario de la Ribera*

BACKGROUND-AIM

In the clinical laboratory, it is necessary to verify the accuracy of the measurement procedures available by estimating the systematic error (SE%) in order to apply the appropriate corrections.

METHODS

The experimental design is based on the recommendations for the study of accuracy using reference materials with assigned values, as outlined by the Spanish Society of Clinical Chemistry. A two-level reference material from BioRad is used, one at a physiological level and the other at a pathological level. Total calcium measurements in serum are performed in 4 series on different days, with duplicates in each series, resulting in a sample size of 40 determinations. The biochemical analyzers used are two Atellica CH Analyzers from Siemens Healthineers, one for emergency use and the other for routine use.
Once the measurements are taken, and after detecting no outliers in the dataset, the mean, standard deviation, and coefficient of variation (CV) are calculated. The CVs obtained in each analyzer are lower than the imprecision calculated in our laboratory, so the systematic error (SE%) is then calculated for each level in both analyzers. The SE% is compared to the expanded uncertainty provided by the manufacturer, which is 1.79%.

RESULTS

The SE% for the physiological and pathological control levels were 0.88% and 0.24%, respectively, for the routine analyzer, and 0.45% and 0.17%, respectively, for the emergency analyzer. The SE% in each analyzer was lower than the expanded uncertainty.

CONCLUSIONS

Since the SE% is ≤ the expanded uncertainty, there is no significant difference between the obtained mean and the assigned value. As the measurement procedure has no SE%, no corrective actions, such as calibration adjustments, are necessary.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0020

SETTING-UP AN EXTERNAL QUALITY CONTROL SYSTEM FOR MEDICAL LABORATORIES. AN EXPERIENCE AT ALGIERS' AREA.

Y.K. Souami [2], A. Zemerline [1], A. Abdelaziz [4], S. Djeziri [4], H. Ould Amara [4], S. Nekkal [3], D. Yala [2]

[1]*central laboratory of hospital university Beni Messous.Algiers Algeria.*

[2]*Department of Medecine. Faculty of medecine of Algiers.Algeria.*

[3]*Department of Medecine. Faculty of medecine of Algiers.Algeria. and blood center. univesity hospital Beni Messous.Algiers.Algeria.*

[4]*Faculty of biological sciences. University of Houari Boumediene (USTHB). Algiers.Algeria.*

BACKGROUND-AIM

The external quality control program is an asset to ensure the quality of medical analysis results. However, its accessibility is a limitation. Our aim was to set-up an external quality control in biochemistry in local conditions.

METHODS

Blood donors have accepted to participitate to the project. Their blood collection was made on heparinized lithium. After verification of their exemption from contagious infectious diseases (HIV1+2, Viral Hepatitis B and C and syphillis) by the mandatory blood donor screening, all the plasma were pooled. It was tested six times (06) on Cobas (Roche) for the targeted parameters (glycemia, creatinine, uree, protein, albumin, acide urique, triglyceride, cholesterol, HDL-cholesterol, LDL-cholesterol, ASAT, ALAT, Gamma GT, phosphatases alkaline, Bilirubine total, LDH and CRP). We have invited ten (10) medical laboratories at Algiers'area, we know they are interested in the quality of their results. The plasma pooled was distributed to these laboratories regarding the biosafety rules. The transportation was offered by the team project and, was done regarding a planning made by the project team and the medical laboratories' contacts. Once, the sample arrived, the contact confirmed the reception. To avoid paper issues, we have sent the response format directly to each contact member of the medical laboratory. The responses were sent also by e-mail. The analysis was made by Levey-Jenning.diagram and on Excell (Microsoft version 10).

RESULTS

Ten medical laboratories (10/10, 100%) have participated. They have asked to follow-up it in long term and to add more parameters. The rate of participation to each biochemical parameter was between 50% to 100 % : 50% (LDL-cholesterol), 67% (Bil direct, Gamma GT), 83 % (glucose, LDH, CRP, Bil total), 100% (creatinine, urea, protein, albumin, uric acid, triglycerides, cholesterol, HDL-cholesterol, alkaline phosphatase). The techniques were automatised and manual also. Almost of the participants had had biochemical measures between one to two standard deviations for each parameter. Once laboratory had had results between 2 and 3 standard deviations

CONCLUSIONS

The design was successful and have to be continued.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0021

PERIODIC EVALUATION OF INVESTIGATIVE PROCEDURES

M. Zavrsnik [1]
[1]*Department for Laboratory Diagnostics, General Hospital Ptuj, Ptuj*

BACKGROUND-AIM

Medical laboratories prioritize the use of validated investigative procedures recommended by equipment manufacturers. These procedures must be verified prior to implementation and periodically reassessed to ensure ongoing suitability.

METHODS

At the Laboratory Diagnostics Department (LDD) of General Hospital Ptuj, annual Periodic Assessments of Standard Operating Procedures (SOPs, form ZK 5.5_10) are conducted as part of the quality management system (QMS). This evaluation encompasses all 118 accredited investigative procedures in biochemistry, immunochemistry, coagulation, hematology, urinalysis, and blood gas analysis. Key evaluation criteria include measurement uncertainty (I-IV quarter, annual average MU), sigma 6 metrics (I-IV quarter), orientation reference values (ORVs), internal quality assessment (IQA), external quality assessment (EQA), trend analysis, and compliance with SOPs. For the evaluations, the LDD uses the Periodic Method Assessment module, which is part of the Laboratory Information System (LIS).

RESULTS

Data required for assessments, including IQA, EQA, MU, and sigma 6 metrics, are automatically stored in the Laboratory Information System (LIS). The Periodic Method Assessment module of the LIS compiles this data into form ZK 5.5_10, enabling the LDD head to provide a comprehensive evaluation.

CONCLUSIONS

Since the initiation of this process in 2013, significant improvements have been observed in procedural quality. The consistent monitoring of IQA, EQA, MU, sigma 6, trend analysis, and ORVs ensures robust control over investigative procedures. These efforts uphold the quality of procedures for analyzing patient biological materials, contributing to superior patient care and reinforcing the department's commitment to excellence in laboratory diagnostics.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0022

MEDICAL WASTES MANAGEMENT AND RECYCLING: THE CASE OF BETHLEHEM GOVERNORATE

R. Abuzayyad [1]
[1]*Palestinian ministry of health laboratories / Jerusalem directorate*

BACKGROUND-AIM

Medical waste management (MWM) is a crucial issue in healthcare due to its potential health risks. Rapid population growth increases the demand for disposable medical equipment and supplies, leading to more Medical Waste (MW). The aim of the study is to investigate the current MWM process in Bethlehem governorate. Then addressing the required steps needed in order to implement recycling program, and highlight its impact on health and economy. It assesses current MWM practices, the feasibility of recycling, and the effects of MW on health and the environment.

METHODS

The study was conducted in Bethlehem governorate, targeting healthcare facilities. Data was collected through structured interviews and site visits, along with secondary data from annual reports by the Joint Services Council. The study focused on facilities, which generates significant amount of MW, in order to explore supplies and used items that is helpful to identify and classify wastes materials to be recycled.

RESULTS

There is a relationship between MW volume and healthcare services provided. The largest hospitals in Bethlehem governorate produced the most waste in 2021 and 2022, with plastic waste making up 66% of the total. This presents both environmental challenges and opportunities for economic benefits through recycling. The Palestinian plastic recycling market is constrained by insufficient investment. Medical sharp wastes 14% of MW pose safety risks but can be recycled with proper treatment. Other materials 20% of MW, that mainly consist of fabrics, offer economic value when recycled 140-199$/ton. The annual cost of medical waste management 242000–292000$ highlights the potential economic benefits of recycling, which can reduce costs, extend landfill lifespan, conserve energy, and protect public health. Establishing a medical waste recycling facility in Bethlehem is both feasible and beneficial. It promises to reduce the environmental impact of MW, provide economic gains through revenue generation, and support circular economy.

CONCLUSIONS

Medical waste recycling positively impacts health, the environment, and the economy. Investing in recycling infrastructure and technology is essential to realize these benefits and reduce the costs associated with inadequate waste management practices.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0023

IMPORTANCE OF LABORATORY ASSAY PRECISION IN LIVER DISEASE DIAGNOSTICS UTILIZING ENZYMES: GAMMA - GLUTAMYL; ASPARTATE -AMINO AND ALANINE - AMINO TRANSFERASE

H. Ampova [1], M. Emin [1], I. Kostovska [1], K. Tosheska-Trajkovska [1], S. Cekovska [1], J. Brezovska-Kavrakova [1], J. Bogdanska [1], D. Labudovic [1], S. Topuzovska [1]

[1]*Institute of Medical and Experimental Biochemistry, Faculty of Medicine, Ss. Cyril and Methodius University in Skopje, Republic of North Macedonia*

BACKGROUND-AIM

Many various triggers like viruses, alcohol, autoimmune diseases can cause liver malady in acute or chronic form. Valuable tool for proper diagnose are the liver enzymes that normally should be inside the hepatic cells, but due to the damage and cell membrane destruction, their concentration increases in the circulation. In our evaluation of laboratory test precision we included Gamma-glutamyl transferase(GGT), Aspartate- amino transferase (AST) and Alanine-amino transferase (ALT).

METHODS

For the evaluation we used two pools of control serums, with normal and pathological values, provided by manufacturer. We measured the serums five days in a row in triplicate measurements, three times per day, using Roche Cobas c311 analyzer and particle-enhanced immunoturbidimetric method. We compared the intra-assay coefficient of variation (CV), and the inter-assay coefficient of variation (CV) between replicates with the precision values claimed from the manufacturer.

RESULTS

For the enzyme GGT: normal pool (NP) intra-assay CV- 0.4. Manufacturer's claimed value 0.9. The inter-assay CV was 0.4, while value claimed from the manufacturer being 1.8. For the pathological pool (PP) values, intra-assay CV from our measurements was 0.3 in comparison to the manufacturer's intra-assay CV 0.7. As for the inter-assay CV, our measurements showed 0.2 and the manufacturer claimed value is 1.7. For AST: NP intra-assay CV 0,5 and CV inter 0,4 while manufacturers claimed 0,8 for the intra and 1,3 for the inter-assay. PP values showed intra-assay CV 0,8 and CV inter 0,6 while manufacturers claimed 0,4 for the intra and 0,8 for the inter-assay. For the enzyme ALT: for NP intra-assay CV- 0.6. Manufacturer's claimed value 0.6. The inter-assay CV was 0.5, while value claimed from the manufacturer being 1.4 and for the PP values, intra-assay CV from our measurements was 0.7 in comparison to the manufacturer's intra-assay CV 0.4. As for the inter-assay CV, our measurements showed 0.3 and the manufacturer claimed value is 1.

CONCLUSIONS

In our precision evaluation, the intra- and inter-assay coefficients of variation were in the target range of 5% and 10% respectively. The results for the liver enzymes assay on the ROCHE Cobas c311 platform demonstrate that it is a reliable immunoturbidimetric assay.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0024

A STUDY ON IMPACT OF INTERNAL QUALITY CONTROL LOT CHANGE ON MEASUREMENT UNCERTAINTY ON ROUTINE BIOCHEMISTRY PARAMETERS IN A CLINICAL BIOCHEMISTRY LABORATORY.

P. Asia [1]

[1]*Department of Biochemistry, Homi Bhabha Cancer Hospital & MPMMCC, Varanasi, India. A Unit of Tata Memorial Centre, Mumbai, India*

BACKGROUND-AIM

The concept of measurement uncertainty represents an advanced approach in quality assurance, although the identification and measurement of errors have long been fundamental aspects of quality management in clinical biochemistry laboratories. Defining and calculating uncertainty ranges offers valuable insight into the extent of variation in measurements. According to ISO 15189:2012 standards, uncertainty calculations shall focus solely on sources of uncertainty during the analytical phase. The imprecision data obtained from the routine application of internal quality control is recommended as the quantitative estimate of the uncertainty of measurement. Uncertainty may be influenced by routine changes like reagent batches, internal quality control (IQC) lots, different operators, new operators, scheduled instrument maintenance. In case of all these scenarios it is important to recalculate it. This study evaluated the impact of IQC lot change on expanded measurement uncertainty(MU) on routine biochemistry parameters.

METHODS

The MU of Routine clinical biochemistry parameters was estimated using the topdown approach using (IQC) data. IQC data of bilevel control material which were run consecutively in one year duration for six months each were observed. The mean, standard deviation (SD), Coefficient of variation percentage (CV%) were retrieved from quality control data software. The MU was calculated from CV % using the formula MU = CV% * 1.96. The mean, SD and MU was compared for the two different lot control material with the combined MU obtained from whole data set.

RESULTS

The variation in MU was significant for most of the analytes when MU of both lots was compared separately with combined MU. The variation of MU was also evident when data from two different lots of IQC was evaluated.

CONCLUSIONS

MU calculated by using IQC data is one of the practical approaches used in clinical biochemistry laboratories to measure the uncertainties associated with the analytes. However, it is important to consider the lot changes of IQC material to estimate reliable MU.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0025

ASSESSMENT OF THE ANALYTICAL QUALITY OF SOME HORMONAL PARAMETERS IN A BIOCHEMISTRY LABORATORY USING THE 'SIX SIGMA' APPROACH

Y. Neifar [1], A. Ba [4], G. Khammassi [3], M. Ayoub [3], S. Aboulkacem [2], C. Mazigh [4]
[1]*Faculty of medicine of Sfax*
[2]*Faculty of medicine of Tunis*
[3]*Faculty of Pharmacy of Monastir*
[4]*Military Hospital of Instruction of Tunis,Departement of Biochemistry*

BACKGROUND-AIM

Quality control is a crucial step in ensuring the reliability of analysis results.As part of the accreditation process,a number of method performance management tools have been developed,including the 'six sigma' approach,a performance management tool designed to improve the precision and accuracy of results.The aim of our study was to evaluate the quality of a number of hormonal parameters based on the six sigma approach and the CLIA requirement criteria.

METHODS

This is a cross-sectional study in which the results of internal and external quality control of 12 hormones (free thyroxine FT4,thyroid stimulating hormone TSH,parathyroid hormone PTH,luteinizing hormone LH,follicle stimulating hormone FSH,prolactin,testosterone,prostate specific antigen PSA,cortisol,ferritin,folate and vitamin B12) were collected over a 9 month period from January 2024 to September 2024,using the'six sigma' approach and CLIA requirements.The assay of these hormones was performed using two BECKMAN COULTER DxI analyzers(1and2).

RESULTS

On DxI1,the 6 sigma score for level 1(4.04) of PSA,level 3 ferritin(3.29) and vitamin B12(3.56) and on DxI 2,level 1(3.14) prolactin,levels 1(3.53) and 3(3.02)ferritin,level3 FT4(4.52) and LH(4.04) were between 3 and 5.
The 6 sigma score for the remaining levels of the various DxI1 and 2 parameters ranged from 1 to 3,with the exception of cortisol level1,which was 0.78 on DxI1.
Three parameters were tested on both analyzers:FT4,TSH and ferritin.
For ferritin,the 6 sigma scores for levels1 and 2(3.53 and 2.78)on DxI2 were higher than those obtained on DxI1(2.32 and 2.51),whereas for level 3,the 6 sigma score on DxI1 was 3.29 and on DxI2 was 3.02.
For TSH,the 6 sigma scores for levels 2 and 3(2.39 and 2.58)on DxI2 were higher than those obtained on DxI1(1.74 and 1.79)whereas for level1,the 6 sigma score with DxI1 was 2.49 and with DxI2 2.25.
For FT4,DxI2 presented higher 6 sigma scores than DxI1 for the 3 levels (2.46, 2.8 and 4.52) compared with 2.13, 2.34 and 2.69).

CONCLUSIONS

The application of the 'Six Sigma' approach in medical biology aims to significantly enhance the analytical quality of results.Despite significant progress,the ultimate goal of achieving a Sigma score of 6 remains a challenge.Implementing robust quality control plans is an essential step toward achieving this ideal.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0026

ANALYTICAL PERFORMANCE EVALUATION OF THE ACL TOP 550® ANALYZER FOR ROUTINE COAGULATION TESTING

m. Belhedi [1], W. Lazzem [1], H. Bargaoui [1], I. Chaaben [1], N. Mahdaoui [1], S. Chouaieb [1]
[1]*laboratory department, Habib Thameur hospital in Tunis, Tunisia*

BACKGROUND-AIM

Hemostasis analyzers are highly complex systems combining different techniques : coagulometric, chromogenic, and immunological. Our study aimed to evaluate the analytical performance of the ACL TOP 550® analyzer for routine coagulation tests.

METHODS

We evaluated the following coagulation parameters: prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen (Fg), and D-dimer (DD). In accordance with Cofrac's SH GTA 04 recommendations, analytical performance was analyzed in terms of repeatability; reproducibility; accuracy; and measurement uncertainty. The results were compared to the acceptability limits defined by the French Study Group on Hemostasis and Thrombosis (SGHT) , the supplier, and the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM).

RESULTS

The coefficients of variation (CV%) for repeatability were <2% for PT and APTT, <10% for DD, and <4% for Fg. Reproducibility and accuracy were acceptable for all parameters according to SGHT recommendations. Reproducibility CV% for normal APTT and PT exceeded EFLM acceptability limits. Our study demonstrated acceptable accuracy per SGHT for all parameters. Bias exceeded EFLM recommendations for PT and APTT. The measurement uncertainty calculated for both levels was acceptable.

CONCLUSIONS

The results confirm that the ACL TOP 550 meets the required analytical performance criteria for routine coagulation testing.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0027

VERIFICATION OF BIOCHEMICAL REFERENCE INTERVALS PROVIDED BY BECKMAN COULTER IN THE TUNISIAN POPULATION

m. Belhedi [1], w. Lazzem [1], N.e.h. Gnounou [1], S. Chouaieb [1]
[1]*laboratory department, Habib Thameur hospital in Tunis, Tunisia*

BACKGROUND-AIM

The verification of the reference intervals (RI) proposed by the suppliers for the biochemical parameters is a normative requirement according to ISO 15189. The objective of our work was to verify the IR proposed by the supplier for 25 biochemical parameters analyzed by the DxC700 AU in the Tunisian population

METHODS

A descriptive study was carried out in accordance with the recommendations of the International Federation of Clinical Chemistry (IFCC). Twenty local reference samples are collected and compared to a reference interval published by the supplier. If a maximum of two of the twenty samples are outside this interval, it can be used, otherwise redo on 20 new samples. If, during the initial check, five samples or more than two samples from a repeat set of samples are outside the published interval, the published interval cannot be used as a reference for local patients. The parameters of the renal assessment, ionogram, calcium, lipid assessment, liver assessment, nutritional assessment and thyroid assessment were checked.

RESULTS

The results revealed that, for the majority of parameters, the IRs provided by the manufacturer were consistent with the data observed in our population. However, significant differences were noted for certain parameters, notably cholesterol, triglycerides and lipases , where the proposed IRs were not representative of the measured values.

CONCLUSIONS

Rs proposed by suppliers should not be systematically adopted without verification. Local validation is necessary to ensure relevant results and improve the quality of care.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0028

ANALYTICAL PERFORMANCE EVALUATION OF CEPHALIN-KAOLIN COAGULATION TIME MEASUREMENT ON THE ACL TOP 550® ANALYZER

M. Belhedi [2], W. Lazzem [2], A. Ba [1], H. Berguaoui [2], A. Machraoui [2], S. Chouaieb [2]
[1]*department A, univerity of pharmacy of Monsatir, Tunisia*
[2]*laboratory department, Habib Thameur hospital in Tunis, Tunisia*

BACKGROUND-AIM

The ACL TOP 550® is an advanced fully automated multi-parameter analyzer designed to assess a range of both common and specific coagulation parameters through coagulometric, chromogenic, or immunological techniques. This study aimed to evaluate the analytical performance of the cephalin-kaolin coagulation time measurement method utilizing the CK-Prest® reagent on the ACL TOP 550® analyzer, in accordance with the method validation requirements outlined in ISO 15189:2022.

METHODS

According to the recommendations of Cofrac's SH GTA 04 accreditation guidelines, the performance criteria assessed included precision, accuracy, hemolysis interference, measurement uncertainty calculation. The evaluation results were compared to the acceptability limits proposed by the Hemostasis and Thrombosis Study Group and by the supplier.

RESULTS

The coefficients of variation (CV) for repeatability were 0.51% and 0.66% for the normal and pathological levels, respectively. The CVs for intermediate precision were below 3.7% at both levels. Inaccuracy was less than 6% for all external control samples. No significant interference was detected up to a hemoglobin concentration of 1 g/L. The expanded measurement uncertainty was 5.58 seconds for the normal level and 5.77 seconds for the pathological level. Overall, the results were satisfactory relative to the GEHT and supplier recommendations.

CONCLUSIONS

The ACL TOP 550® analyzer demonstrates excellent performance for the measurement of cephalin-kaolin coagulation time.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0029

ANALYTICAL PERFORMANCE EVALUATION OF DXC700 AU ANALYZER TESTS USING SIX SIGMA METRICS.

M. Belhedi [2], Z. Chedly [2], W. Lazzem [2], A. Ba [1], H. Bargaoui [2], I. Benrejab [2], S. Chouaieb [2]
[1]*biochemistry laboratory, main military hospital of Tunis ,Tunisia*
[2]*laboratory department, Habib Thameur hospital in Tunis, Tunisia*

BACKGROUND-AIM

Analytical performance assessment is a fundamental requirement of ISO 5189, which aims to ensure the reliability of laboratory results. Among the methods proposed in recent years to manage quality controls, the "Six Sigma" methodology is experiencing increasing adoption. This study aims to evaluate the performance of tests in DxC 700 AU analyzers using the Six Sigma approach.

METHODS

This is a cross-sectional descriptive study focused on the evaluation of 15 biochemical parameters analyzed on the DxC700 AU analyzer: sodium, potassium, chloride, calcium, urea, glucose, transaminases, phosphate, total cholesterol, total bilirubin, creatinine, creatine kinase, amylase, and total proteins. The sigma level was calculated based on several criteria: the coefficient of variation (CV) of internal quality controls, the bias calculated from the results of the external control, as well as the total allowable errors recommended by CLIA (Clinical Laboratory Improvement Amendments). For parameters with a sigma level less than 3, the Quality Goal Index (QGI) was calculated to identify the origin of gaps and performance problems.

RESULTS

Our study showed that low sodium, as well as both potassium and calcium levels, presented a sigma lower than 3. Amylase, on the other hand, presented the best sigma index, indicating optimal analytical performance. The calculated QGI revealed that inaccuracy was the major problem associated with sodium and calcium. As for potassium, the QGI was 1.1, suggesting a mixed error of accuracy and imprecision.

CONCLUSIONS

These results highlight the need for constant monitoring and strengthening laboratory control systems to achieve effective levels of Six Sigma for the laboratory.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0030

ANALYSIS OF NON-CONFORMITIES IN THE PREANALYTICAL PHASE AT THE MICROBIOLOGY LABORATORY OF CHARLES NICOLLE HOSPITAL OF TUNISIA

A. Ben Messaoud [1], L. Kanzari [1], S. Sabbagh [1], M. Fliss [1], A. Fakhfekh [1], A. Ferjani [1], I. Boutiba-Ben Boubaker [1]
[1]*Microbiology laboratory, Charles Nicolle Hospital, Tunis, Tunisia. University of Tunis El Manar, Faculty of Medicine of Tunis, Research laboratory « Antimicrobial Resistance » LR99ES09, Tunis, Tunisia*

BACKGROUND-AIM

In clinical microbiology, the preanalytical phase is a complex phase covering all the stages that take place from the medical prescription to the handling of the samples for analysis. In 60 to 85% of cases, errors in this phase can lead to incorrect results. This study aims to analyze the preanalytical non-conformities (NCs) recorded in the laboratory of microbiology of Charles Nicolle Hospital of Tunisia in order to implement appropriate corrective actions.

METHODS

According to the ISO 9000 definition, a NC corresponds to non-satisfaction of a requirement. In the laboratory of microbiology of Charles Nicolle Hospital, all the identified NC related to the preanalytical phase of all the specimens intended for bacteriological analysis were recorded in the laboratory NC paper sheets. In this retrospective study, we used an excel sheet in order to record and analyse, from the existing files, the NC related to the last 8 months (from Mai to December 2024).

RESULTS

Over the 29,060 samples received at the laboratory (1.2%), 359 NCs affecting the preanalytical phase. were noted. The majority of the NCs is correlated to the medical prescription and the analysis request form (n=277; 77.1%). The errors were in the patient identification numbers in more than 38% of the cases, duplicate test orders (14.8%), inappropriate test requests (13.1%), and unpaid requests (7.94%). Problems in the quality of samples were detected in 22.8% of cases. These NCs were mostly found in the Surgery, Gynaecology, and Emergency departments.

CONCLUSIONS

The control of the preanalytical NCs detected in our laboratory requires, at first, a close collaboration between administrative agents, prescribers, samplers, and biologists to implement effective corrective actions starting with education and training.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0031

ASSESSING QUALITY ASSURANCE PERFORMANCE FOR HIV VIRAL LOAD AND EARLY INFANT DIAGNOSIS IN ZAMBIA: 2022

D. Chisompola [3], C. Mfula [1], G. Chishinji [3], M. Mulasikwanda [2]
[1]*Association of Public Health Laboratories, Lusaka, Zambia*
[2]*Ministry of Health, Ndeke house, Lusaka, Zambia*
[3]*Pathology Laboratory Department, Arthur Davison Children's Hospital, Ndola, Zambia.*

BACKGROUND-AIM

Accurate and reliable HIV diagnosis is essential for the effective management of individuals living with HIV who are receiving antiretroviral therapy (ART). Providing high-quality HIV diagnostic services ensures the accuracy of test results and enables appropriate patient care. Successful treatment outcomes for people living with HIV/AIDS depend heavily on the precise measurement of HIV viral load (VL) and Early infant diagnosis (EID). This study aimed to assess the performance of laboratory platforms used for HIV VL and EID testing in Zambia, using data from the National Health Laboratory Service (NHLS) proficiency program.

METHODS

A retrospective cross-sectional study was conducted in Virology laboratories in Zambia enrolled in the NHLS external quality assurance program. The study reviewed the quality assurance performance for the year 2022, utilizing data from the NHLS database and from Virology laboratories.

RESULTS

Out of 25 laboratories, 24 (96%) participated in HIV VL quality assurance for both the first and second testing cycles. For EID, 14 out of 19 laboratories (74%) in the first cycle, while 17 out of 19 (90%) in the second cycle. When assessing the performance of diagnostic platforms for HIV VL testing, participants using the Hologic Panther, 50% achieved an average score of 100%, compared to 60% for those using the Cobas 4800 and 67% for those using the Cobas Ampliprep Cobas Taqman. In EID testing, 94% of participants scored a perfect 100% in the first cycle, while 71% achieved the same in the second cycle. Corrective actions were required for 42% of VL and 18% of EID testing cases to address performance issues.

CONCLUSIONS

The study revealed high participation in quality assurance programs among laboratories in Zambia for HIV VL and EID testing but noted variability in platform performance. Improvements in quality management, standardization of platforms, and staff training are needed to enhance diagnostic accuracy for HIV testing services.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0032

MALE HYPOGONADISM AND REPRODUCTIVE SUCCESS: A CASE REPORT

S. Garcia Chileme [1], L. Papay Ramírez [1], P. Torralbo Martín [1], T. De Haro Muñoz [1]
[1]*Hospital Universitario Clínico San Cecilio, Granada, Spain*

BACKGROUND-AIM

A 32-year-old male patient comes to the Reproduction Unit with his partner for a fertility study.As personal history, he has a BMI of 37.2. He has no toxic habits and denies the use of steroids or anabolic steroids.

METHODS

Additional studies and tests: A blood test was performed, which revealed FSH 0.9 mIU/mL (1.5-12.4 1 mIU/mL), LH 2.8 mIU/mL (1.7-8.6 mIU/mL), testosterone 201 ng/dL (249-836 ng/dL), free testosterone 8.57 pg/mL (15-50 pg/mL), with normal serial prolactin and serology. A testicular ultrasound was requested with the following report: incipient left varicocele.
A first seminogram was performed, which showed hypospermia (volume 0.6 mL) and azoospermia. Given these results, a karyotype was requested, which was normal, and a second spermiogram, with the same results.

RESULTS

The study is extended with a pituitary MRI which is normal, directing the diagnosis towards hypogonadotropic hypogonadism.
Male hypogonadism may be due to a dysfunction of the testicles or to an alteration of the hypothalamus-pituitary axis, producing a decrease in the concentration of testosterone, which may cause infertility problems.

CONCLUSIONS

At 7 months, a control semen analysis was performed with a count of 14 million spz/mL, with 20% progressive mobility and a motile sperm count of 1 million spz/mL. Given the recovery of sperm, we called the couple to schedule the first ICSI cycle, where pregnancy was achieved.
Treatment with HCG, which has biological activity of LH, produces a stimulation of spermatogenesis, acting at the testicular level stimulating Leyding cells and secreting testosterone. In men with hypogonotrophic hypogonadism who desire fertility, HCG is an effective replacement treatment to restore sperm production and initiate assisted reproduction techniques with their own gametes.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0033

RISK ASSESSMENT OF LESIONS DETECTED DURING COLONOSCOPY FOLLOWING A POSITIVE RESULT IN COLORECTAL CANCER SCREENING IN THE PROVINCE OF GRANADA.

J.C. Alcalá Escamilla [1], C. Campos Moreno [1], M. Cifuentes Flores [1], T. De Haro Muñoz [1]
[1]*Clinical Laboratory, Clinical Analysis, San Cecilio, University Hospital, Granada*

BACKGROUND-AIM

Colorectal cancer screening, using the fecal occult blood test (FOBT), is a key strategy for the early detection of malignant or premalignant lesions. Following this, colonoscopy allows for clarification of the positive result and aids in potential diagnosis. The aim is to conduct a retrospective analysis of the colonoscopy results performed after a positive screening in the province of Granada, classify the detected lesions according to their risk level, and evaluate the proportion of patients without significant lesions compared to those with low, medium, and high-risk lesions.

METHODS

A total of 1,510 samples with results for the FOBT were analyzed over the course of one month (July 2023), processed using Pledia equipment (Palex).
Samples were selected to ensure that, following a positive result, the colonoscopy and corresponding report had already been completed. The data were processed using the Modulab software.

RESULTS

Of a total of 1,510 cases, 121 tested positive (>20 µg/g), and of these, 50 colonoscopies were performed. Among these 50 colonoscopies, 34% were negative (no lesions), while the remaining 66% yielded positive results. Regarding lesion risk, 28% were classified as low-risk lesions (hyperplastic polyps or tubular adenomas). Additionally, 36% were categorized as medium-risk lesions (tubulovillous adenomas or tubular adenomas with advanced dysplasia), and only 2% were identified as high-risk lesions (lesions with malignant characteristics or invasive carcinoma).

CONCLUSIONS

The colorectal cancer screening program in the province of Granada proves to be an effective tool for identifying high-risk lesions at early stages. Although 34% of patients showed no significant findings, 64% presented lesions requiring follow-up and clinical management. The percentage of high-risk lesions (2%) highlights the importance of colonoscopy as a key tool to prevent progression to advanced stages of colorectal cancer. These results underscore the need to maintain and optimize screening programs in our population.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0034

MAXIMUM SURGICAL BLOOD ORDERING SCHEDULE OF PACKED RED BLOOD CELLS FOR ELECTIVE GENERAL AND THORACIC AND CARDIOVASCULAR SURGERY PROCEDURES BASED ON BLOOD UTILIZATION DATA FROM JANUARY 2019 TO DECEMBER 2019

S.M. Delos Reyes [1]
[1]*Batangas Medical Center*

BACKGROUND-AIM

Maximum Surgical Blood Ordering Schedule (MSBOS) is defined as the recommended maximum number of blood donor units to be ordered prior to surgery. Establishment of institution-based MSBOS is based on the local circumstances, clinical practice and patient's variables; and thus, should be reviewed and adjusted regularly. This study aims to optimize rational use of blood products by calculating the recommended MSBOS derived from current transfusion practices of selected elective surgical procedures.

METHODS

All elective General Surgical and TCVS procedures from January to December, 2019 were gathered. Deferred procedures and pediatric procedures were excluded in the study. Blood utilization of these procedures were tallied. The recommended MSBOS were calculated using Mead's criterion for each surgical procedure.

RESULTS

A total of 1021 elective GS and TCVS were included in the study, out of which, 58 procedures requested for PRBC. The total number of blood units crossmatched were 76 in which 47 were transfused. Overall crossmatched-to-transfused (C/T) ratio (1.62), transfusion probability (66%), and transfusion index (TI) (0.5) signify appropriate ordering and utilization of blood products.

CONCLUSIONS

Blood utilization of this institute is comparable with most of the recommended MSBOS from other institution. Surgeons' expertise and understanding of the procedures, as well as the knowledge and perception of the rational blood use by the Blood Bank section is implicated by the overall good blood utilization of this institution.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0035

AN INTERNAL AUDIT TO ASSESS THE POSITIVITY RATE OF URINE METANEPHRINE ASSAY TO REDUCE UNNECESSARY REQUESTS AT A TERTIARY CARE HOSPITAL, SRI LANKA

M. Denipitiya Withanage Dona Dinithi [1], R. Samarasinghe [1]
[1]*Department of Chemical Pathology, National Cancer Institute, Maharagama, Sri Lanka*

BACKGROUND-AIM

The urine metanephrine assay constitutes a pivotal diagnostic modality for the screening and subsequent monitoring of catecholamine-secreting neoplasms, notably pheochromocytomas, and paragangliomas. At the institute where audit was performed, the prevailing methodology employed for the quantification of urinary metanephrines is the competitive enzyme-linked immunosorbent assay (ELISA).Though this assay provides high specificity and sensitivity, its limitations include high cost, time consumption, and the need for specialized training.
This audit aims to assess the possibility of reducing urine metanephrine requests to improve cost-effectiveness, operational efficiency, and accessibility.

METHODS

A retrospective, cross-sectional analysis of a total 76 urine metanephrine requests received by the chemical pathology laboratory, for three months duration with regards to age, sex, indication, and positivity rate for each indication.

RESULTS

Amongst 76 request forms reviewed 96.05% were outstation requests with only 3.94% requests from the same hospital. 97.36% of requests were for screening purposes and 2.63% were for follow-up. 57.9% of the requests were from female patients while 42.1% were from males. The commonest indication was young hypertension (65.79%) followed by adrenal mass (10.52%), resistant hypertension (9.21%), palpitations (7.89%), episodic sweating (2.63%), headache (2.63%), fluctuating blood pressure (2.63%), weight loss (1.31%), and generalized lymphadenopathy (1.31%) respectively. However, the positivity rate was highest in patients with palpitation (20%) followed by adrenal mass (14%). Patients with young hypertension, resistant hypertension, episodic sweating, headache, fluctuating blood pressure, weight loss, and generalized lymphadenopathy didn't have positive results.

CONCLUSIONS

Young hypertension itself appears to be a poor indication for urine metanephrines. The rationalization of urine metanephrine requests following thorough clinical evaluation,
is pivotal in enhancing the cost-effectiveness of healthcare delivery, optimizing resource allocation, and mitigating the workload burden on diagnostic laboratories.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0036

QUALITY ASSURANCE UTILITY STREAMLINES ISO 15189 COMPLIANCE

W. Donohue [1], J. Smith [1], T. Koshy [1]
[1]*CarePoint Solutions Inc.*

BACKGROUND-AIM

Due to a recent revision to ISO 15189, over a million diagnostic laboratories and point-of-care programs accredited to International Standards Organization standards will now be required to perform comprehensive risk assessments for each test platform they operate.
CarePoint Solutions has developed Pro-QCP™, a first-of-its-kind QA utility for diagnostic testing that leverages expert guidance, machine learning, and proven risk mitigation strategies to streamline regulatory compliance, mitigate diagnostic error, and implement a more effective quality control plan.
CarePoint Solutions asked an industry quality expert, Westgard QC, and a US-based medical center in Memphis TN to evaluate Pro-QCP in terms of optimizing workflows and effectiveness at identifying and preventing sources of diagnostic error.

METHODS

CLSI document EP23-A. Wayne PA. Clinical and Laboratory Standards Institute. 2011
Pro-QCP: CarePoint Solutions, Inc. (Beverly, MA) www.pro-qcp.com
Westgard QC (Madison, WI) compared the QC plan generated by Pro-QCP for a moderately complex blood gas analyzer to one currently in use at a major academic teaching hospital.
Baptist Memorial Hospital (Memphis, TN 38120) performed a study of the time and resources required to design a risk-based quality control plan for a moderate complexity blood gas analyzer, following CLSI EP-23 protocols, with and without the aid of the of the Pro-QCP utility.

RESULTS

Westgard QC determined that the QC plan delivered by the Pro-QCP utility identified and mitigated 97 potential sources of errors or failure modes, as compared to 30 identified in the academic hospital's QC plan.
The Baptist Memorial Hospital study demonstrated that 77 hours of labor was required to develop a spreadsheet-based QC plan following CLSI EP23A protocols for a moderate complexity analyzer. In comparison, the QC plan designed using Pro-QCP required only 27 hours. For a lab operating 20 test methods, this represents 1000 hours of time savings. The investigators also identified further opportunities to mitigate risk in each phase of their testing process.

CONCLUSIONS

Pro-QCP produces a superior QC plan and significantly lowers the ISO 15189 regulatory compliance burden.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0037

ENSURING ANALYTICAL QUALITY IN ELECTROLYTE TESTING: A VERIFICATION STUDY OF THE COBAS C311 ANALYZER

M. Emin [1], H. Ampova [1], I. Kostovska [1], J. Brezovska Kavrakova [1], S. Cekovska [1], S. Topuzovska [1], J. Bogdanska [1], D. Labudovic [1], K. Tosheska Trajkovska [1]

[1]*Institute of Medical and Experimental Biochemistry, Medical Faculty, University "Ss Cyril and Methodius", Skopje*

BACKGROUND-AIM

The aim of this study was to evaluate the analytical performance of the cobas c311 analyzer in measuring serum electrolytes, sodium (Na#), potassium (K#), and chloride (Cl#) to ensure its accuracy, precision, linearity, and suitability for routine clinical applications.

METHODS

Following Clinical and Laboratory Standards Institute (CLSI) guidelines, method verification was performed using two levels of quality control (QC) materials (normal and pathological) provided by the manufacturer. These QC materials were tested three times daily as triplicates over five consecutive days using the Roche/Hitachi Cobas c311 analyzer. Intra-assay and inter-assay coefficients of variation (CV) were calculated and compared with the manufacturer's specifications. Data were analyzed using standard statistical methods to assess compliance with clinical and manufacturer requirements.

RESULTS

1. Sodium (Na#):
-Normal QC: Average = 105.31, intra-assay CV = 0.19% (vs. claimed 0.2%), inter-assay CV = 0.27% (vs. claimed 0.6%).
-Pathological QC: Average = 127.33, intra-assay CV = 0.18% (vs. claimed 0.2%), inter-assay CV = 0.21% (vs. claimed 0.4%).
2. Potassium (K#):
-Normal QC: Average = 3.32, intra-assay CV = 0.18% (vs. claimed 0.8%), inter-assay CV = 0.15% (vs. claimed 1.0%).
-Pathological QC: Average = 6.78, intra-assay CV = 0.27% (vs. claimed 0.6%), inter-assay CV = 0.22% (vs. claimed 0.7%).
3. Chloride (Cl#):
-Normal QC: Average = 79.04, intra-assay CV = 0.18% (vs. claimed 0.3%), inter-assay CV = 0.14% (vs. claimed 0.6%).
-Pathological QC: Average = 98.0, intra-assay CV = 0.26% (vs. claimed 0.3%), inter-assay CV = 0.14% (vs. claimed 0.4%).

CONCLUSIONS

The cobas c311 analyzer achieved the predefined criteria for precision, accuracy, and linearity across all electrolyte measurements. Precision studies showed low CV values, reflecting excellent repeatability and reliability. Accuracy evaluations demonstrated strong agreement with reference values, confirming the analyzer's capability to deliver results within acceptable limits. These findings affirm the suitability of the analyzer for routine clinical testing, providing dependable data for patient management.

Keywords: Electrolytes; cobas c311 analyzer; method verification; precision; clinical laboratory.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0038

SURVEY OF EXTERNAL QUALITY ASSESSMENT PROGRAMS CURRENTLY OPERATING IN MONGOLIA

T. Enkhjargal [3], S. Badmaarag [8], C. Batjargal [4], B. Munkhtsolmon [5], G. Naran [2], B. Oyun-Erdene [6], B. Solongo [7], M. Tserendejid [1]
[1]*IHNEQAP, NCTM, Mongolia*
[2]*MEQAS, Sysmex*
[3]*Mongolian Association of Health Laboratorians*
[4]*NEQAP, NCCD, Mongolia*
[5]*Oneworld Accuracy EQA, 1WA Group*
[6]*Prevecal, Biosystems*
[7]*RCPAQAP*
[8]*RIQAS, Randox*

BACKGROUND-AIM

Laboratory test results play a crucial role in patient diagnosis, treatment, and monitoring, underscoring the importance of obtaining high-quality results. To ensure analytical accuracy, clinical laboratories implement Internal Quality Control (IQC) and participate in External Quality Assessment (EQA) programs. EQA facilitates the evaluation of laboratory performance over time, assessing trueness, interlaboratory variation, and differences between methods. The aim of this survey was to evaluate the current state of EQA programs in Mongolia and assess the need for standardization or improvement of their implementation.

METHODS

Seven EQA programs currently operating in our country were included in this survey. A questionnaire consisting of thirty-six questions based on standard requirements for EQA programs, was developed and used for the assessment.

RESULTS

Among the seven EQA programs, four were international and two were national programs. The highest participation of laboratories was found in two national programs and one program run by Sysmex. Most programs conduct EQA twice a year, while two international programs do so on a monthly basis. Most EQA programs ensure commutability of control samples, with sample stability ranging from 3 days to 12 months, depending on the analyte type.

CONCLUSIONS

Overall, the implementation of EQA in medical laboratories is adequate. However, this survey highlights the need for greater educational efforts on the significance of EQA for decision-makers and training on new technologies for national EQA providers.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0039

ROLE OF THE COMMUNICATION UNIT IN THE CLINICAL LABORATORY

R. Escobar Conesa [1]
[1]*UGC Laboratorio. Hospital Universitario Torrecárdenas (Almería)*

BACKGROUND-AIM

In the Laboratory,it is essential to have a Communication Unit(CU)that is responsible for the management and dissemination of information.It is necessary to have a communication strategy aimed at both professionals and users with the aim of disseminating the operation, developing a visibility plan and participating in the training of professionals in Communication.The CU's internal and external communication plan must establish how to send information to healthcare professionals,patients and professionals of the Unit and how the institution addresses the general population and other external entities

METHODS

A CU is created,made up of the Supervisor and the Quality Manager of the Laboratory.The recipients of the information are established,both for patients and for health professionals(external users) and the Laboratory's own professionals(internal users),as well as the different forms of communication depending on the recipient

RESULTS

The main recipients and forms of communication:
1)External user communication(patients):User satisfaction surveys,Information brochures such as the one on sample collection in several languages with QR codes,Suggestion box and Web application queries analytical results
2)External user communication(primary care and specialized care health professionals):Virtual Clinical Analysis Consultation for clinical advice regarding analytical reports,Surveys on satisfaction,Inter-service meetings to reach consensus on decisions affecting common protocols and Information circular regarding planned changes in the operation of the Unit
3)External user communication(general population):Participation in informative days,training workshops and Publications of news of interest in local press
4)Internal user communication(laboratory professionals):Corporate email,Video conferencing application for telematic meetings,Bulletin board,Suggestion box, Annual survey of work environment, Meetings,Corporate intranet and WhatsApp group for instant communication

CONCLUSIONS

The creation of a CU has meant a significant improvement in the dissemination of information of interest to both internal and external users of the Laboratory,as well as the way of channeling information and promoting the visualization of the work carried out by Laboratory professionals.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0040

ASSESSING ANTI-BCMA THERAPY EFFICACY IN MULTIPLE MYELOMA THROUGH CIRCULATING BIOMARKERS

K. Fatima [2], E. Pingitore [2], S. Mimmi [6], D. Maisano [4], A.M. Zimbo [2], C. Valentina [2], M. Martino [5], A.M. Tolomeo [1], A. Quinto [3], S. Ciavarella [3], E. Iaccino [2]

[1]*Department of Cardiac, Thoracic and Vascular Science and Public Health, University of Padova, Padua, Italy*
[2]*Department of Experimental and Clinical Medicine, University Magna Graecia of Catanzaro, Catanzaro, Italy*
[3]*Haematology and Transplant Unit, IRCCS - Istituto Tumori "Giovanni Paolo II", Bari.*
[4]*Harvard Medical School, Boston, MA, USA*
[5]*Hematology and Stem Cell Transplantation and Cellular Therapies Unit (CTMO), Department of Hemato-Oncology and Radiotherapy, Grande Ospedale Metropolitano "Bianchi-Melacrino-Morelli", Reggio Calabria, Italy.*
[6]*Neuroscience Research Center, University Magna Graecia of Catanzaro, Catanzaro, Italy*

BACKGROUND-AIM

Multiple myeloma is a hematological malignancy characterized by the uncontrolled proliferation of plasma cells in the bone marrow, resulting in significant clinical complications. Despite recent therapeutic advancements, including monoclonal antibody conjugated with a cytotoxic agent, bispecific antibodies and CAR-T cell therapies, the disease remains incurable. The absence of reliable biomarkers as alternatives to paraproteins underscores the necessity for innovative tools to monitor the clinical progression of multiple myeloma. B-cell maturation antigen (BCMA) is selectively overexpressed on the surface of myeloma cells and is shed into the circulation as part of the extracellular vesicle (EV) cargo. This study aims to investigate the expression levels of soluble BCMA (sBCMA) and BCMA-associated EVs in the context of anti-BCMA therapies.

METHODS

A cohort of 20 patients with multiple myeloma, treated with anti-BCMA therapy, was recruited for this study, with serum samples collected prior to and during therapy. Extracellular vesicles (EVs) were isolated and purified from each sample and subsequently analyzed for their BCMA expression levels in comparison to sBCMA using advanced analytical technologies.

RESULTS

The analysis revealed a notable variation in the expression levels of both sBCMA and BCMA-associated EVs throughout the course of anti-BCMA therapy. Preliminary findings indicate that changes in the levels of these biomarkers correlate with therapeutic responses, suggesting their potential utility in monitoring treatment efficacy.

CONCLUSIONS

The data obtained from this study indicate that the analysis of circulating BCMA and BCMA-expressing vesicles may serve as a valuable tool for assessing response to target therapy in patients with multiple myeloma. However, given the limited number of patients in this cohort, further investigation is warranted to reinforce these findings. Importantly, the integration of novel analytical technologies for the examination of individual vesicles could enhance the depth of our understanding and support the promising direction indicated by our results.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0041

CONTROL OF ANTICOAGULANT THERAPY WITH BIVALIRUDIN IN A PATIENT UNDERGOING CARDIAC SURGERY ALLERGIC TO HEPARIN

C. Pascual Escrivà [1], M.Á. Férez Martí [1], L. Sahuquillo Frías [1], M.A. Elía Martínez [1], S. Dolz Guimenez [1]
[1]*Hospital General Universitario de Valencia, Valencia, España*

BACKGROUND-AIM

Since the beginning of cardiac surgery, the use of heparin/protamine complex with thromboelastography has been the gold standard method for safe anticoagulation control. Among the limitations of its use are allergies, so different alternatives have been sought, such as direct thrombin inhibitors like bivalirudin. His anticoagulant activity depends on dose and plasma concentration, prolonging all coagulation times, with aPTT (activated partial thromboplastin time) and its Ratio being the fundamental parameter that evaluates its anticoagulant activity.

METHODS

A 69-year-old woman was admitted to the hospital for scheduled surgery due to mitral insufficiency. Her medical history included hypertension, diabetes mellitus, dyslipidaemia, overweight, peripheral venous insufficiency, and congestive heart failure. The patient was allergic to heparin and after evaluation by the hospital's Allergology and Haematology departments; it was decided to use bivalirudin and monitored her coagulation with basic coagulation studies every 10-15 minutes in the Emergency Clinical Laboratory department, reporting the aPTT and its Ratio value, given that most most emergency laboratories do not have a specific method for monitoring it.

RESULTS

The results of the monitoring tests were (being the normal range for aPTT and its Ratio 25.1-36.5 seconds (s) and 0.8-1.2 respectively):
• Initial: aPTT 191s and Ratio of 7
• At 10 minutes: aPTT 216s and Ratio of 7
• At 2 hours: aPTT >300s and Ratio >20
• At 5 hours: aPTT 90s and Ratio of 2.9

CONCLUSIONS

Bivalirudin can be used as an alternative to heparin for use in cardiac surgery when heparin is contraindicated. It presents some advantages like rapid effect, short half-life and low immunogenicity.
The use of this type of drugs implies a change in the usual techniques for the control of anticoagulation therapies during these surgeries, and it should be approached from a multidisciplinary perspective where the clinical laboratory expert plays a crucial role.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0042

COMPARATION BETWEEN MANUAL AND AUTOMATED COUNTING WHITE BLOOD CELL AND RED BLOOD CELL IN CEREBRO SPINAL FLUID IN SYSMEX XN-1000 AND BECKMAN COULTER DXH- 900

S. Imširagić-Zovko [1], D. Babić-Maksimović [1], A. Divković [1], E. Trnačević [1], I. Hadžić [1], S. Mustafić [1]
[1]*Department of Clinical Chemistry and Biochemistry, Clinical Center University of Tuzla , 75000 Tuzla, Bosnia and Hercegovina*

BACKGROUND-AIM

Cerebrospinal fluid (CSF) is important part of the workload in clinical laboratories.By setting manual microscopy analysis as reference method, total WBC counts were determined by using Fuchs-Rosenthal counting chambers and descriptive metod for RBC.Nowadays, automated hematology analysers are employed for counting white blood cell (WBC) and red blood cell (RBC) in CSF and other body fluid.

METHODS

In this study we compare manual counting CSF cells in Fuchs-Rosenthal chamber and hematology, analysers Sysmex XN-1000 and Beckman Coulter DxH-900.

RESULTS

This study was performed on 35 randomly selected CSF samples.Statistical analysis was performed using Pearson coefficient of correlation for WBC. Statically significance coorelation between F.R. chamber and Sysmex XN-1000 for WBC r=0.999 , P< 0.001. Stastical significance coorelation between F.R. chamber and Beckman Coulter DxH-900 for WBC r=0.888 , P< 0.001. Stastical significance coorelation between Beckman Colter DxH-900 and Sysmex XN-1000 for WBC r=0.889, P< 0.001.For RBC we had some difficulties because RBC are not normal constituents of CSF.

CONCLUSIONS

Comparison showed excellent correlation for counting WBC in CSF.Our result indicates a good agreement between new automated hematology analysers and manual reference method.We have to established criteria for RBC.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0043

INTERNAL QUALITY CONTROL AUDIT : APPLICATION TO THE DETERMINATION OF CORTISOL AND ADRENOCORTICOTROPIN ACTH

A. Kemache [2], F. Rabet [1], L. Abib [1], A. Lakhdari [1], M.A. El Mehdaoui [2], N. Ould Bessi [2], B. Ait Abdelkader [2]

[1]*1: Hormonology Laboratory EHS Pierre and Marie Curie. Algiers*

[2]*1: Hormonology Laboratory EHS Pierre and Marie Curie. Algiers 2: Cytogenetics and Oncology Genetics Research Laboratory. Algiers Faculty of Medicine. University of health sciences.*

BACKGROUND-AIM

Introduction :
Internal quality control (IQC) is a statistical tool used to monitor and evaluate all stages of an analytical process, the purpose of which is to produce reliable results. Long-term monitoring is necessary to detect any breaches of this requirement via internal quality control audits.
The aim of this CIQ audit is to verify the reliability of the results of cortisol and ACTH assays in our laboratory and to assess the effectiveness of the quality control system in place in order to propose corrective measures if necessary.

METHODS

Our study consists of an audit of CIQ applied to 2 parameters: cortisol and ACTH, this was done through a prospective monitoring spread over a period of one year(2023).
We use 2 immunoanalysis techniques : electrochemiluminescence on Cobas e411 and chemiluminescence on IMMULITE 2000XPi.
The quality control used are :
Lyphochek Immunoassay Bio-Rad on IMMULITE.
PreciControl MultiMarker PCMM for ACTH and PreciControle Universel PCU cortisol on Cobas.
The results were processed, monitored and expressed using SPC for EXCEL version 2020.

RESULTS

1- ACTH: On IMMULITE : It was found that 97.22% of the values are between the mean and ± 2SD.100% of the level 1 and 2 values on Bio-Rad were below the mean, resulting in a violation of the 10x law on two occasions.
On Cobas : It was found that 94.43% of the values are between the mean and ± 2SD.The 41S rule was violated only once by combining the two control levels, indicating the presence of a systematic error.
2- Cortisol: On IMMULITE : 98.81% of the values observed on all three levels are between the mean and ± 2SD.The 12S rule was observed only once, indicating the occurrence of a random error.
100% of the control values for the third level were below the mean, so the 10x rule was violated on two occasions.
On Cobas :100% of the values observed were between the mean and ±2 SD.The majority of values were below the mean.

CONCLUSIONS

All of the analytical processes used to measure cortisol and ACTH on the two automated instruments used in our laboratory comply with the standards and requirements of Good Laboratory Practice. Audits must be objective and rigorous in order to detect any errors that could affect the quality and reliability of results

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0044

UTILITY OF CAPABILITY INDEX AND QUALITY GOAL INDEX RATIO AS DETERMINANTS OF QUALITY ADHERENCE IN A CLINICAL BIOCHEMISTRY LABORATORY

S. Kundu [1], A. Mishra [1], K. Nandi [1], B. Goswami [1]
[1]*DEPARTMENT OF BIOCHEMISTRY, MAULANA AZAD MEDICAL COLLEGE, NEW DELHI, INDIA*

BACKGROUND-AIM

The fundamental aspects of quality assurance in a clinical laboratory are accuracy and precision which can be checked by measurement of coefficient of variation(CV) and bias.Indices like capability index (Cp and Cpk) and quality goal index ratio (QGI) which takes into account both CV and bias in order to categorize the results of various parameters so that required actions can be taken to improve the outcome of poorly performing parameters.

METHODS

This is a retrospective study, and data required for the study were extracted between January 2024 and June 2024 from a Tertiary Care Government Hospital in New Delhi,India.The Cp, Cpk and QGI were calculated and six months average of these indices were taken to categorize the parameters.

RESULTS

For level 1 of IQC the Cp showed that sodium, chloride, urea and low density lipoprotein(LDL) performed marginally well and potassium performed poorly, while Cpk showed poor performance of sodium, potassium, chloride, urea, LDL, amylase and lactate dehydrogenase(LDH).Sodium, potassium, chloride, urea and creatinine had a QGI of <0.8 showing that the bias was due to imprecision while LDL had a QGI of > 1.2 showing that the bias was due to inaccuracy. For level 2 of IQC Cp showed that sodium, chloride, LDH and LDL are in marginal range and potassium performed poorly while Cpk showed sodium, potassium, chloride,urea, protein, LDL and LDH performed poorly.

CONCLUSIONS

A dip in the value of these indices inspite of ‘normal’ control charts; indicates the urgent need to examine the instrument, reagent, quality control and human factors in order to institute corrective measures.Thus Cp, Cpk and QGI helps the lab manager to bridge the gap between these two so as to take appropriate and timely steps towards improving the reliability of the results reported by the lab and enhancing the robustness of quality assurance programs in clinical laboratories.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0045

AI-DRIVEN AUTOMATED BLOOD ANALYSIS: IMPROVING DIAGNOSTIC ACCURACY AND EFFICIENCY

X. Leng [1]
[1]*Traditional Chinese medicine hospital.TongLiang.ChongQing*

BACKGROUND-AIM

This study investigates the potential of AI-driven automated blood analysis to enhance diagnostic precision and efficiency.

METHODS

We utilize deep learning algorithms in artificial intelligence technology, especially convolutional neural networks (CNN), to automatically recognize and classify blood cell images. We have trained and validated a large number of blood sample images, and established an AI-driven automated blood analysis system. The system is capable of automatically identifying components such as red blood cells, white blood cells, and platelets in the blood, and quantitatively analyzing their abnormal changes. In the study, we compared the analysis results of the AI system with the results of traditional manual microscopy to evaluate its diagnostic performance.

RESULTS

Artificial intelligence systems have high accuracy in identifying blood components and detecting abnormalities, and have strong consistency with the results of manual microscopic examination. The AI system can quickly process a large number of blood sample images, significantly reducing diagnostic time. The AI-assisted digital morphology analyzer improves the efficiency of manual white blood cell differentiation, reducing the classification time of each smear by an average of 204 seconds. In addition, compared with traditional methods, the diagnostic accuracy of AI automatic recognition systems exceeds 95%, showing significant differences.

CONCLUSIONS

AI systems help reduce the impact of human factors on diagnostic accuracy by reducing misclassifications caused by technology and improving the consistency of results. The AI-driven automatic blood analysis system has significantly improved the accuracy and efficiency of diagnosing blood-related diseases, bringing great hope for future clinical diagnosis. Its high sensitivity and specificity pave the way for the application of personalized medicine and precision therapy.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0046

COMPARATIVE STUDY OF PLASMA AND URINE OSMOLALITY MEASUREMENT WITH ARKRAY OM-6050 AND OM-6060 OSMOMETERS

M.d.V. Romero Real [1], M. Pascual Ramirez De Arellano [1], J. Cabanes Madrid [1], S. Peral García [1], J. Sanz Gómez [1], M.C. Burgos Ballester [1], R.V. Melgares De Aguilar Marco [1], M. Blanco Colomo [1], A. González Quintana [1], E.A. López Jiménez [1]
[1]*Hospital Universitario 12 de Octubre*

BACKGROUND-AIM

The measurement of plasma and urine osmolality determines the concentration of dissolved particles in body fluids, enabling the assessment of a patient's electrolyte balance. Its utility is particularly notable in the diagnosis of diabetes insipidus and polyuria through the water deprivation test.
After the replacement of the osmometer in our laboratory, a verification study was conducted to assess the intercomparability of results between both instruments.

METHODS

A total of 52 serum samples and 50 urine samples were collected, and plasma and urine osmolality were measured using the OSMO STATION OM-6050 and OM-6060 osmometers.
Both instruments determine osmolality based on a colligative property of the sample, measuring freezing point depression, which is directly correlated with osmolality through a previously established calibration curve.
Results were compared using MedCalc statistical software, employing Passing-Bablok regression and Bland-Altman difference analysis.

RESULTS

The Pearson correlation coefficient (r) was ≥0.975 for both plasma and urine osmolality ranges, indicating an adequate sample size and allowing for regression analysis.
In both analyses, the slope of the Passing-Bablok non-parametric regression was unity (b=1); however, the intercept did not include zero. This indicates a constant systematic error, with the OM-6060 consistently yielding lower results compared to the OM-6050.
Additionally, the Bland-Altman analysis of absolute differences showed that the confidence interval did not include zero, confirming statistically significant differences between the two devices. Thus, the results from the OM-6050 and OM-6060 are not interchangeable, highlighting a consistent systematic bias.

CONCLUSIONS

The results obtained from the two osmometers demonstrate poor concordance, rendering them non-interchangeable for clinical assessment of osmolality. However, the observed systematic error remains constant and may be clinically acceptable without impacting patient outcomes.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0047

QUALITY INDICATORS IN THE PREANALYTICAL PHASE IN A SPANISH THIRD LEVEL HOSPITAL IN 2024

M. Lozano De Diego [1], A. Aranda Tejada [1], A. Casado Prieto [1], M.d.S. López-Vélez [1]
[1]*Hospital Universitario Virgen de las Nieves, Granada, Spain*

BACKGROUND-AIM

As stated by ISO:15189-2022, laboratories must define and monitor quality indicators (QIs) throughout the overall analytical process. Pre-analytical phase has proven to be the main source of laboratory errors.
This study is aimed to review quality indicators in the preanalytical phase based on those established by Spanish Society of Laboratory Medicine (SEQCML) during 2024.

METHODS

During 2024, all incidents registered in the Automated Biochemistry Laboratory of the University Hospital Virgen de las Nieves was gathered monthly through the laboratory information system (Modulab) and classified by type of specimen. Errors were defined as: sample not received, hemolyzed sample, insufficient sample volume, clotted sampled and unidentified sample.

RESULTS

The total number of laboratory requests was 298561 and the total number of samples received was 1095717. Among these, 13625 samples contained an error which represents an average rejection rate of 4,56% per month below the minimum acceptance criteria stablished. The samples with the highest number of errors were urine samples (41,7%) due to “sample not received”. It was followed by serum samples (29,7%) and whole blood-EDTA samples (16,4%). The most common error in serum sample was hemolyzed samples (58,5%) while for whole blood-EDTA samples was clotted samples (58,24%). Moreover, insufficient sample volume was the most common error in plasma-citrate samples (40,32%).

CONCLUSIONS

Continuous monitoring of QIs is crucial for the improvement of the entire laboratory process and enhancing the quality in the preanalytical phase. The predominant errors were related to sample collection. The implementation of good practices in the extraction, labelling and identification is essential to provide a good quality service. Overall preanalytical performance of our laboratory met quality specifications stated, but this does not prevent us from exploring new forms of improvement.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0048

STUDY OF THE PRECISION OF A MEASUREMENT PROCESURE IN A CLINICAL LABORATORY

E. Martínez Rua [1], S. Esteve Poblador [1], F. De La Fuente García [1], J. Liron Hernandez [1], M. Ortuño Alonso [1]
[1]*Hospital Universitario de la Ribera*

BACKGROUND-AIM

ISO 15189 emphasises the importance of assessing precision when verifying a measurement method in the laboratory. The objective of the study is to verify the total calcium accuracy established by the manufacturer taking into account both repeatability and reproducibility.

METHODS

This study is carried out in the Biological Diagnosis Area of the Hospital Universitario La Ribera (Alzira). The biochemistry analyser used is the Atellica CH Analyzer from Siemens Healthineers. The magnitude studied is total calcium in both serum and urine in the different modules of the emergency and routine Atellica. The measurement method in use is arsenazo III, detected spectrophotometrically. Commercial control material from BioRad is used, considering two control levels, one with a value within the physiological and one within the pathological range.
To estimate imprecision, the document of the Spanish Society of Clinical Chemistry based on the guidelines published by the Clinical and Laboratory Standards Institute is followed. Three replicates of each control are analysed in a single series each day for 5 days. Both intraserial imprecision and laboratory imprecision are calculated. Finally, the values obtained in the different modules are compared with the specifications provided by the manufacturer.

RESULTS

The results obtained in serum were: intraserial coefficient of variation (CV) in the 2 routine modules between 0.59-1.05% and in the emergency module between 0.53-1.45%; laboratory CV for the routine modules between 0.58-1.99% and for the emergency module between 0.55-1.29%.
The results obtained in urine were: intraserial CV in the 2 routine modules between 0.79-2.80% and in the emergency module between 1.68-2.92%; laboratory CV in the routine modules between 1.68-2.93% and in the emergency module between 1.62-2.55%.

CONCLUSIONS

The manufacturer's specifications to be met are an imprecision ≤3% in serum and in the case of urine an imprecision ≤5% for the physiological level and ≤5.5% for the pathological level. The results obtained demonstrate adequate accuracy in all modules in both serum and urine.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0049

FROM THEORY TO PRACTICE: IMPLEMENTING AND SUSTAINING QUALITY IMPROVEMENT PROJECTS IN KING ABDULAZIZ HOSPITAL MAKKAH ALMOKARRAMA MEDICAL LABORATORY

M.H. Morsy [2], M.S. Al-Dosari [1], M.M. Abulaban [1], A.M. Al-Maghrabi [1], Y.A. Shaikhbudan [1], M.F. Shabikni [1], A.M. Kabbil [1], B.O. Al-Qurashi [1], A.A. Al-Thobity [1], M.M. Al-Jahdali [1], M.A. Al-Saedi [1], A.S. Almalki [1]

[1]*Medical Laboratory and Blood Bank Dept., King Abdul Aziz hospital, Makkah Almokarrama, KSA*

[2]*Medical Laboratory and Blood Bank Dept., King Abdul Aziz hospital, Makkah Almokarrama, KSA; Clinical Pathology Dept., Alazhar School of Medicine, Cairo, Egypt*

BACKGROUND-AIM

Quality improvement in medical laboratories is central for enhancing patient care and operational efficiency. This study aims to examine the lifecycle of quality improvement projects from conception to implementation and sustainability, using six years data of Key Performance Indicators (KPIs) from King Abdulaziz Hospital Makkah Al-Mokarrama Medical Laboratory. The primary focus is on case studies of specific improvement projects, the challenges encountered, and strategies for ensuring long-term success.

METHODS

Over a six-year period (2018-2023), six key performance indicators were monitored: (1) Rate of identification errors, (2) Rate of corrected laboratory reports, (3) Rate of critical results immediate notification to the appropriate healthcare staff (4) Rate of sample rejection, (5) Rate of blood culture contamination, and (6) Rate of STAT samples released within the predefined Turnaround Time (TAT). KPI Data analyzed annually and half annually, accordingly multiple improvement projects were implemented, including dedicated teams, software solutions, educational sessions, policy updates, and motivational strategies to address each KPI.

RESULTS

The rate of notification of critical results showed a dramatic improvement, increasing from 51.8% in 2018 to 98% in 2023. Sample rejection rates improved from 2.4% in 2018 to 1.08% in 2023, while blood culture contamination rates decreased from 5.1% in 2018 to 1.37% in 2023. The rate of identification errors, corrected laboratory reports, and STAT samples released within the predefined TAT were consistently maintained within target ranges throughout the six years.

CONCLUSIONS

The study demonstrates that structured and multifaceted improvement projects can significantly enhance laboratory performance. Key factors contributing to success included continuous monitoring, staff education, policy updates, and motivation. The findings underscore the importance of a systematic approach to quality improvement in clinical laboratories, offering valuable insights and practical strategies for other laboratories aiming to achieve and sustain high-performance standards.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0050

VERIFICATION OF THE LACTATE DESHYDROGENASE DOSAGE METHOD USING ABBOTT ARCHITECT CI8200 EXPERIENCE OF THE BIOCHEMISTRY LABORATORY, CHU MOHAMMED VI OUJDA, MOROCCO

S. Moulay Rchid [1], K. Jamal [1], O. Kharkhach [1], D. El Moujtahide [1], E.H. Sebbar [1], M. Choukri [1]
[1]*Biochemistry laboratory of Mohammed VI University Hospital, Oujda*

BACKGROUND-AIM

The aim of our work is to evaluate the analytical performance of lactate dehydrogenase (LDH) assay, a key enzyme in glycolysis. It catalyzes the reversible conversion of pyruvate to lactate, with simultaneous production of NADH from NAD+. This evaluation forms part of a comprehensive process to validate the methods used in the central laboratory of the Mohammed VI University Hospital in Oujda, with the objective of assembling an accreditation file that meets the NF ISO 15189 standard requirements.

METHODS

The methodology adopted in our study is based on the recommendations outlined in the COFRAC accreditation technical guide SH GTA 04 protocol. The verification process included an evaluation of both repeatability and reproducibility.

RESULTS

The verification of the LDH assay criteria demonstrated satisfactory repeatability across all three levels, with CV1=1.34%, CV2=0.71% and CV3=0.60% respectively. Similarly, intra-laboratory reproducibility was deemed satisfactory for all levels, with CV1 = 3.06%, CV2 = 2.50%, and CV3 = 1.77% for the respective levels.
The verification of an analytical method is a critical step in ensuring that the obtained results closely align with the reference values of the sample. A comparison of our findings with the CV standards set by the SFBC (a quality control system) and RICOS (an international quality control network) indicates that our results comply with, and remain below, the acceptable limits.

CONCLUSIONS

By implementing rigorous analytical performance verification, laboratories guarantee reliable clinical outcomes. This study enhances the existing knowledge base regarding the accuracy and reliability of serum LDH measurements.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0051

VERIFICATION OF ANALYTICAL PERFORMANCE OF THE TRIGLYCERIDE ASSAY ON THE ARCHITECT CI-8200®: EXPERIENCE OF THE CENTRAL LABORATORY MOHAMMED VI OUJDA

M. Naciri [1], M. El Halas [1], D. Elmoujtahide [1], E.H. Sebbar [1], M. Choukri [1]
[1]*biochemistry laboratory, central laboratory, faculty of medicine and pharmacy of OUJDA / Mohammed 6 University Hospital Center, OUJDA, OUJDA*

BACKGROUND-AIM

Accurate triglyceride measurement is essential for the diagnosis and management of lipid disorders, particularly in the context of cardiovascular risk assessment. This study aimed to verify the analytical performance of the triglyceride assay on the Architect ci-8200® analyzer, ensuring compliance with international quality standards.

METHODS

The study was conducted in the clinical chemistry laboratory of Mohammed VI University Hospital, Oujda. Analytical performance was evaluated following SFBC and RICOS standards by assessing repeatability and reproducibility using patient samples and internal quality controls. Repeatability was measured by analyzing three concentration levels (low, medium, high) in 36 replicates under consistent conditions. Reproducibility was assessed over 30 days using daily control samples.

RESULTS

The repeatability assessment yielded low coefficients of variation (CV1: 0.57%, CV2: 0.69%, CV3: 0.46%), indicating excellent precision. Reproducibility results were equally favorable, with CV values of 1.77%, 1.82%, and 3.69% across the three levels, remaining within acceptable limits compared to SFBC and RICOS recommendations.

CONCLUSIONS

The triglyceride assay on the Architect ci-8200® demonstrated excellent analytical performance with minimal variability, ensuring precision and reliability for clinical diagnostics. These findings support the continued use of this method for routine triglyceride measurement in a clinical setting

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0052

SIX SIGMA IN MEDICAL BIOLOGY FOR IMPROVING LABORATORY EFFICIENCY AND DECREASING COSTS

M. Othmani [1], H. Zahra [1], S. Chelbi [1], A. Sneni [1], A. Bouachba [1], T. Ben Messaoud [1], R. Dabboubi [1]
[1]*Children's Hospital Bechir Hamza - Tunis*

BACKGROUND-AIM

The Six Sigma (6σ) methodology, originally developed in the industrial sector, has gradually been introduced into medical biology since the last years. Guaranteeing precision, and efficiency this method also offers the opportunity of a better resources management by decreasing error-associated costs.In this study we aimed to evaluate the impact of the implementation of the 6σ methodology on the number of control rejections and on cost.

METHODS

Our work was conducted in the biochemistry laboratory for a period of 31 days. We selected three parameters (CPK, Iron, and AST) for which we calculated the sigma value for one control level PCC1. The interpretation of the quality control (QC) was performed using both the classic Westgard rules (1-3S, R4S, 2-2S, 4-1S, and 10x) for Series 1 and the Westgard-Sigma rules for Series 2. We calculated the number of QC rejections for each series and estimated the additional cost generated by these rejections. Statistical analysis of these data was performed using Excel software.

RESULTS

We calculated the sigma values for the control level PCC1 for each parameter. For CPK, the sigma value was 6.19 ($\sigma > 6$). Applying the classic-Westgard rules, 6 rejections were noted (R4s n=2, 2-2s n=1, 4-1s n=3). In contrast, applying the Westgard-Sigma rules resulted in zero rejection. Concerning AST, the sigma value was less than 3 (σ=2.7). Both Series 1 and 2 had the same number of rejections (2-2s n=1, 3-2s n=1). The sigma value for the parameter Iron was 5.7. In Series 1, a total of 5 rejections were recorded (4-1s n=3, 1-3s n=2) compared to only 2 rejections in Series 2. The cost incurred by these rejections results in a 5.49% increase in the test cost.

CONCLUSIONS

The application of the sigma methodology in our laboratory is interesting for parameters with a good sigma level (5, 6 or above), where it is possible to interpret the QC with less stringent requirements. This allows: time, resource and above all costs savings. However, with parameters having poor performance (sigma <3), giving special attention and determining the origin of the problem is important in order to implement necessary corrective actions. Adopting this methodology will enable the consolidation of improvement strategies and ensure better results in the future.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0053

EVALUATION OF COBAS E 801 IMMUNOASSAYS USING SIX SIGMA METHODOLOGY

C. Papandreou [1], K. Piperaki [1], V. Karagianni [1], A. Theodorakopoulou [1], N. Courtis [1]
[1]*Biochemistry Laboratory, Athens Anticancer Hospital "Agios Savvas", Athens*

BACKGROUND-AIM

Six Sigma methodology is a highly effective tool for quality improvement as it provides a means of analytical method performance evaluation and allows the selection of appropriate quality control rules.
In the current study sigma values were calculated for 13 immunoassay tests performed on a Cobas e 801 (Roche) analyzer.

METHODS

For sigma value calculations, allowable Total Error (TEa) was obtained from the EFLM Biological Variation Database. The source of bias was the Bio Rad External Quality Assurance Program and the imprecision estimate (CV) was derived from the internal quality control process of our lab.

RESULTS

TSH and Total PSA showed excellent performance, with sigma values over 6. Ca 125, Ca 19-9, CEA, α-fetoprotein, Folate, NSE and Thyroglobulin gave sigma values between 3 and 6. For T4, free T4, T3 and free T3 the calculated values were below 3, which is considered as poor performance.

CONCLUSIONS

Application of six sigma methodology showed that most of the parameters measured on Cobas e 801 analyzer exhibited a reasonably good performance. The tests which are ranked below 3 need a more stringent plan in the internal quality process.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0054

CALCULATION OF RI FOR TSH IN ADOLESCENTS IN AN IODINE-DEFICIENT REGION USING INDIRECT METHODS

O. Plekhanova [2], O. Kalacheva [1], S. Tsvirenko [3], L. Saveliev [3]

[1]*Department of clinical laboratory diagnostics SmartLab, JSC Medsi Group, Moscow, Russia*

[2]*Department of clinical laboratory diagnostics SmartLab, JSC Medsi Group, Moscow, Russia; Ural State Medical University, Ekaterinburg, Russia*

[3]*Ural State Medical University, Ekaterinburg, Russia*

BACKGROUND-AIM

Over the past time, automatic methods and algorithms for indirect calculation of reference intervals (RI) have been proposed, each of which has certain properties, in particular, there is a problem of determining RI in skewed distributions. One of the key issues is also a quantity of pathological results in a database for correct indirect calculation.
The aim is to evaluate the capabilities of calculation methods for determining RI for an analyte with a skewed distribution of TSH for the adolescent contingent of the Sverdlovsk, iodine deficiency region, in the presence of direct calculation data.

METHODS

The indirect RI calculation was conducted in 1179 adolescents (542 males, 637 females) aged 13-16 y.o., increasing the sample using the Bootstrap method and conducting a simulation: adding %, 10% 15% 20% 25% 30% of the pathological distribution to the right, to the left and at both ends of the median of the simulated distribution. The methods used: TMC, RefineR, Kosmic, Bhattacharaya. The degree of quality of the calculation was carried out using an assessment relative to TE at three levels, and the pD criterion.

RESULTS

In comparison of direct and indirect methods, at the optimal level, the calculation of all RI boundaries by the TMC and RefineR methods can be considered successful, except for the upper RI boundary for females.
In evaluating both RI boundaries at once, TMC allows to calculate the RI from 15% of pathological values at the upper RI boundary with 5-30% of pathological values at the lower boundary. The RefineR method, on the contrary, allows to calculate from 5 to 30% of pathological values at the upper boundary, but in the presence of pathology at the lower boundary from 20% of pathological values (with a few exceptions). The Kosmic method, like the TMC, allows to calculate RI with pathological values from 15 to 30% at the upper boundary with any content (5-30%) at the lower (exception: 15% at the upper and 30% at the lower boundary simultaneously). The Bhattacharaya method, allows calculating the RI with up to 10% at the lower limit and up to 20% at the upper limit.

CONCLUSIONS

In general, when calculating using three of the four methods, there is a tendency to obtain acceptable results (desired TE) with an increase in the number of pathological values up to 60% in different location.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0055

EXTRA-ANALYTICAL PHASE: THE ROAD TO IMPROVEMENT. THE EXPERIENCE IN CENTRO MEDICINA LABORATORIAL GERMANO DE SOUSA

R. Ribeiro [1], M.J. Sousa [1], M. Albuquerque [1], C. Castaldo [1], J.G. Sousa [1], G. Sousa [1]
[1]*Centro de Medicina Laboratorial Dr. Germano de Sousa, Lisboa, Portugal*

BACKGROUND-AIM

The constant technological development and scientific advances in new equipment and tests, error types and frequency in the Clinical Laboratory have been changing. Nevertheless, most errors are due to pre-analytical factors (46-68.2% of total errors), while a higher error rate (18.5-47% of total errors) has been found in post-analytical phase. The main reason is the difficulty in controlling the pre-analytical and post-analytical variables, such as sample collection, handling, transporting and sample preparation. The use of key performance indicator (KPI) has been valued in the management of clinical laboratories to optimize the qualification and quantification of failures in the laboratory processes. Other advantages are the assistance in corrective and preventive measures implementation as well as in indications of effectiveness on the actions taken. In Centro Medicina Laboratorial Germano de Sousa we use several KPI in the pre-analytical and post-analytical phase. The aim of this study is to evaluate the path from KPI to error detection in our organization.

METHODS

Sigma analysis of sample collection repetition, wrong demographic data, requested and non-performed parameters and late results production. Use of appropriate statistical tools, namely the T-Test of proportions, using Minitab software.

RESULTS

In 2024 we obtained a mean Sigma of 3.904, 3.434 and 3.628 to KPI sample collection repetition, wrong demographic data and requested and non-performed parameters, respectively. In post-analytical phase we obtained a mean Sigma of 4.024 in KPI in late results production. After a critical analysis of the process under review, our organization understanded the different aspects of these issues and the justified need for additional time and resources. The description of KPI clarifies the meaning of collected data as well as the following actions to be taken, aiming the avoidance of future errors and nonconformities.

CONCLUSIONS

The most frequent errors and non-conformities occur in the pre- and post-analytical phases. The development of laboratory processes KPI, is a fundamental step in quality evidence providing and ensuring that continuous improvement activities are key for error risk reducing in the clinical practice.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0056

THE MOST COMMON PRE-ANALYTICAL ERRORS IN THE INSTITUT OF CLINICAL LABORATORY DIAGNOSTICS UKC RS

A. Stojnić [1]
[1]*Institut of Clinical Laboratory Diagnostics, University Clinical centre of the Repubic of Srpska*

BACKGROUND-AIM

It is necessary for each laboratory to define pre-analytical, analytical, and post-analytical errors and to monitor them continuously. The aim of this paper is to identify the most common pre-analytical errors of the Institute for Clinical Laboratory Diagnostics during six months from June to December 2024.

METHODS

Data were obtained from the laboratory information system for hemolyzed samples, incorrect sample type, and clotted hematological samples in relation to the total number of samples received at the laboratory over a period of six months.

RESULTS

In the period of six months, the total number of samples received in the laboratory is 375635 samples. The percentage of hemolyzed samples, (number of samples with free hemoglobin > 0,5 g/L, detected by automated hemolytic index), was 1,81% or 6762 samples of the total number. The percentage number of samples with insufficient sample volume / total number of samples is 0.023% or 86 samples, and the percentage of clotted hematological samples was 0.71% or 2667 samples of the total number.

CONCLUSIONS

The highest percentage of pre-analytical errors of the Institute for Clinical Laboratory Diagnostics represents the share of hemolyzed samples. However, their number is also acceptable with the recommendations of the EFLM working group (WG-LEPS) in that period.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0057

ANALYTICAL PERFORMANCE EVALUATION FOR FREE THYROXINE ASSAY

H. Bouhajja [3], B. Khalfa [1], Y. Ghanem [1], S. Hammami [3], O. Salah [1], L. Jmal [2], S. Chaabouni [2], K. Guesmi [1], A. Jmal [2], E. Talbi [1], R. Mahjoub [3]

[1]*Clinical Biology Laboratory, Zouhair Kallel Institute of Nutrition and food technology, Tunis, Tunisia*
[2]*Laboratory of Clinical Biology, Hospital of Mahmoud Matri, Ariana, Tunisia*
[3]*Research Unit UR17SP01 - "Zouhair Kallel" National Institute of Nutrition and Food Technology - Tunis, Tunisia*

BACKGROUND-AIM

The evaluation of assay methods is essential for every medical biology laboratory. It guarantees compliance with normative requirements. The study aim was to evaluate the analytical performance of the FT4 determination by electrochemiluminescence (ECL) on Cobas® e411 (Roche-Diagnostics).

METHODS

Two levels of internal control were used for the accuracy study. For the comparative study, patient samples were analysed using the Cobas® e601 (Roche-Diagnostics) as a comparison system, using the ECL technique installed in another laboratory. The statistical study was carried out using Medcalc statistical software® to analyze Passing-Bablok linear regression and Bland-Altman difference diagrams, and to calculate coefficients of variation (CVs) and correlation coefficients. CVs were interpreted in accordance with SFBC recommendations.

RESULTS

The CVs obtained were within the limits of acceptability for the accuracy study. The results show satisfactory repeatability for both levels (1:low/2:high), with CV1=0.99% and CV2=1.13% respectively. Intra-laboratory reproducibility was satisfactory for both levels (CV1=1.61% and CV2=3.11% respectively). The comparison shows good agreement between the two techniques. The Bland Altman difference plot showed a statistically non-significant mean difference of +0.10 mIU/L. The Passing-Bablok regression line revealed the absence of proportional or systematic bias, with perfect correlation.

CONCLUSIONS

The results obtained for the various verification criteria studied for FT4 determination on the newly installed Cobas® e411 system (Roche-Diagnostics) were clinically acceptable. This study argues for our choice of method in daily practice, based on a standardized ISO15189:2022 protocol as part of an accreditation process.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0058

HBA1C MEASUREMENT ON TOSOH G11 ANALYZER VERSUS SEBIA CAPILLARYS 3 : A COMPARATIVE ANALYTICAL STUDY

F. Khamassi [1], N. Mseddi [1], O. Salah [1], K. Ghniya [1], S. Ben Yahyia [1], S. Hammami [2], M. Khmiri [2], W. Grouze [2], S. Oueslati [2], E. Talbi [1], R. Mahjoub [2]

[1]*Clinical Biology Laboratory, Zouhair Kallel Institute of Nutrition and food technology, Tunis, Tunisia*
[2]*Research Unit UR17SP01 - "Zouhair Kallel" National Institute of Nutrition and Food Technology - Tunis, Tunisia*

BACKGROUND-AIM

HbA1c is a key parameter in the diagnosis and monitoring of diabetes mellitus. There are numerous methods for measuring it, and new generations of HbA1c analyzers are constantly being introduced and marketed. This study aims to compare two analytical system: the Tosoh Glycohemoglobin Analyzer G11 and the Sebia Capillarys 3 for HbA1c measurement, in the presence and absence of hemoglobin variants.

METHODS

A total of 226 patient samples were analyzed on the two automated systems. Of these, 59 were carriers of hemoglobin variants and 167 were not. Analysis was carried out in parallel on Tosoh G11 (HPLC method) and Sebia Capillarys 3 Tera (capillary electrophoresis method). The statistical tools used for correlation were the Bland Altman difference diagram and the Passing bablok regression line. The statistical study was carried out using Medcalc version 20.104 software.

RESULTS

The comparative study demonstrated a strong correlation both in the presence and absence of hemoglobin variants, with Spearman's correlation coefficients of $r = 0.986$ ($p < 0.0001$) and $r = 0.995$ ($p < 0.0001$), respectively. Although the Passing and Bablok regression line showed a good correlation, it revealed a double systematic and proportional bias in the absence of hemoglobin variants, and a proportional bias in their presence. The Bland-Altman plots indicated a mean bias (limits of agreement) of 0.25% (-0.45 to 0.96) and 0.18% (-0.25 to 0.60), respectively.

CONCLUSIONS

The comparison between the two methods studied is satisfactory overall. In fact, the biases revealed by the statistical tools used do not appear to be clinically significant. A strong correlation was observed between the two analyzers, both in the absence and presence of hemoglobin variants, demonstrating the interchangeability of results between the two systems for the diagnosis and monitoring of diabetes mellitus.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0059

EFFECTS OF MESENCHYMAL STEM CELL-DERIVED EXOSOMES ON ENDOTHELIAL CELLS ON ANGIOGENESIS

P. Thummarati [1], N. Thuengain [1], P. Udomchoksakul [1], K. Mongkolkajornsin [1], T. Cherdkiatgumchai [1], C. Koaykul [1]
[1]*Chulalongkorn University*

BACKGROUND-AIM

Mesenchymal stem cells (MSCs) have recently shown promise in regenerative medicine due to their immunomodulatory properties and ability to promote tissue repair. Among their diverse functions, the secretion of extracellular vesicles (EVs), particularly exosomes, has emerged as a key mechanism for intercellular communication. MSC-derived exosomes (MSC-exosomes) are enriched with bioactive molecules such as proteins, lipids, and nucleic acids, which play a pivotal role in mediating various biological processes. Recent research highlights the potential of MSC-exosomes in angiogenesis, forming new blood vessels from existing ones, which are critical for tissue regeneration and repair. Angiogenesis depends on the coordinated activity of endothelial cells, including their proliferation, migration, and survival, which are essential to form functional vascular networks. However, the mechanisms by which MSC-exosomes influence these processes are incompletely understood. In this study, our objective is to investigate the effects of MSC-exosomes on endothelial functions, including proliferation, viability, migration, and vascular formation.

METHODS

Using the human umbilical vein cell line, EA.hy926, we treated cells with MSC-exosomes isolated under standard culture conditions. The proliferation and viability were evaluated using the Resazurin assay, while migration was evaluated using the Boyden chamber assay. We also propose a three-dimensional culture system using cell sheet technology to evaluate angiogenesis.

RESULTS

As a result, MSC-exosomes significantly enhanced the proliferation, migration and promote angiogenesis.

CONCLUSIONS

This study seeks to deepen the understanding of MSC-exosomes and their potential to develop innovative treatments for ischemic diseases.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0060

COMPARISON OF GLYCOSILATED HEMOGLOBIN (HB1AC) ON H8180V OF MENARINI DIAGNOSTICS ANS H8190V OF ARKRAY.

R. Sanchez Parrilla [1], B.M. Verdú Martí [1], I. Fort Gallifa [1], Á. Garcia Meseguer [1], F. Gómez Bertomeu [1], V.P. Lucia Del Carmen [1], C. Requena Triguero [1], N. Serrat Orús [1]
[1]*Joan XXIII University Hospital*

BACKGROUND-AIM

Determination of glycosilated hemoglobin (Hb1AC) is one of the more common requirements in daily clinical practice to control blood glucose levels.
The goal of the research is verification and validation of methods for determining Hb1AC and comparability of results obtained on ADAMS A1C HA-8180V of Menarini Diagnostics and ADAMS A1C HA-8190V of Arkray.

METHODS

Method verification (according to CLSI guidelines) was performed for the determination of Hb1AC on commercial control samples (two levels of control) ExtendSure Hb1AC lyophilised control (Catenbury Scientific, New Zeland) on both analysers.
Accuracy, imprecision in series and day-to-day imprecision were tested over 5 days in triplicate. Results are shown as coefficient of variation (CV), interserial, intraserial and total and compared with CV provided by the manufacturer.
On the veracity method (according to European Federation on Clinical Chemistry and Laboratory Medicine, EFML) the estimate of the systematic error was made by analyzing two series of two replicates of each control series each day, for 20 days. We take the value of the control as the true value to make the comparison with the maximum allowed error of the EFML database.
Methods comparison was conducted using 20. Statistical analysis was performed using a statistical program provided by the Spanish Society of Laboratory Medicine (SEQC). A Passing-Bablok regression analysis was also performed.

RESULTS

The measured values of the commercial controls were within the manufacturer's recommended values for both analysers.
Series imprecision and day-to-day imprecision results were within the manufacturer's criteria. Hb1AC imprecision values calculated in all controls were lower than the reference values (2.11% in both analyzers, compared to the maximum 3.1% allowed).
Passing-Bablok regression showed that there is no constant or proportinal measurement error between analylsers (y=1.0345x -0.1828) (IC: 95%).

CONCLUSIONS

The data analysis showed that the results obtained on the two analysers are comparable and interchangeable.
The tools applied were useful in confirming the veracity of the method and increased the level of patient safety in clinical pathology.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0061

RISK-BENEFIT ANALYSIS IN DECISION MAKING FOR THE SURVEILLANCE OF MEDICAL DEVICES

R. Yañez Vega [1]
[1]*CECMED Regulatory Authority for Medicines and Medical Devices.*

BACKGROUND-AIM

To protect public health, it is necessary to establish mechanisms that regulate and control the activity of post-marketing surveillance in a context in which Regulatory Authorities increasingly use Regulatory Science throughout the world, as it is promoted by regulatory bodies and forums. Regulatory Science is a multidisciplinary and interdisciplinary discipline, oriented to the development of new instruments, standards and processes to more effectively evaluate the safety, quality and efficacy of medical products. Objectives. To carry out a statistical, retrospective analysis from the surveillance of medical devices, at CECMED to demonstrate how Regulatory Science has been used in regulatory decision making applied to the surveillance of medical devices including in vitro diagnostics.

METHODS

Descriptive, retrospective, cross-sectional study from January to December 2022-2024 of statistics at CECMED and Regulatory Science tools such as ASF (Ashby and Smith framework) and Quality Decision Making Practice for medical decision-making.

RESULTS

The benefit-risk analysis applied for decision-making in 128 investigations in 2022, 140 in 2023, and 81 in 2024 is described through the use of an ASF tool algorithm that addresses five levels and the 10 levels of Quality Decision Making practices (which include the decision maker, possible actions, uncertain consequences, sources of evidence, and utility assessments) adapted to our practice through development of a procedure approved by the Center's Quality Management System, which integrates these methodologies with the evaluation of indicators of the WHO Global Bengmarking Tool for the evaluation of regulatory authorities (risk-benefit analysis, reliance, transparency and communication, access to information, and impact assessment).

CONCLUSIONS

It was demonstrated how the CECMED medical devices surveillance function applies Regulatory Science tools in decision-making to respond to the WHO Global Bengmarking Tool.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0062

THE IMPACT OF AMBIENT AIR EXPOSURE ON PARTIAL OXYGEN PRESSURE MEASUREMENT IN BLOOD GAS EXTERNAL CONTROLS: A CASE REPORT

A. Bachali [1], I. Yousfi [1], C. Rhimi [1], L. Sghaier [1], I. Ghachem [1], M.Y. Kaabar [1]
[1]*Clinical Biology Laboratory,Mohamed Taher Maamouri Hospital, Nabeul,Tunisia*

BACKGROUND-AIM

External quality control is essential for evaluating measurement accuracy and ensuring continuous improvement in the reliability of results. In this context, it plays a crucial role in validating blood gas measurements.However, a question remains underexplored: the effect of ambient air exposure on the measurement of partial oxygen pressure (PO2) in blood gas external controls.

METHODS

A case study investigating the impact of ambient air exposure on PO2 measurement in blood gas external controls. An EQAS (BIO-RAD) external control vial was analyzed in September 2023 on GEM® Premier 3000 blood gas analyzers installed in three different departments (pulmonology, intensive care, and the shock room of the emergency department) at Mohamed Taher Maamouri University Hospital, Nabeul, Tunisia.

RESULTS

The same EQAS external control vial was analyzed using identical blood gas analyzers in three different departments. The vial was first opened in the first department and immediately analyzed.It was then resealed to minimize contact with ambient air,which could interfere with the PO2 measurement. This procedure was repeated in the subsequent departments.The blood gas reports revealed a progressive increase in PO2,despite efforts to limit ambient air exposure.To investigate this interference,the results from the third department were sent for external evaluation.The external control report confirmed the impact of ambient air exposure: all parameters were validated except PO2, which had a Z-score of 3.24 compared to peer group data.Measurements from the other two departments were also analyzed. In the first department, PO2 was close to the peer group mean, with a Z-score between 1 and 2. In the second department, PO2 was less accurate, with a Z-score between 2 and 3. All other tested parameters were validated for all three departments.

CONCLUSIONS

This case study highlights a potentially overlooked factor in blood gas external controls: the impact of ambient air exposure on PO2 results. Even short-term exposure can positively interfere with the measurement of the PO2.These findings emphasize the importance of maintaining strict anaerobic conditions when analyzing external controls, as well as for arterial blood sampling in patients.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0063

HEMOLYSIS INTERFERENCE ON TWENTY-THREE BIOCHEMICAL PARAMETERS MEASUREMENT

L. Jmal [1], K. Zaouche [2], A. Hezami [1], Y. Gaies [1], R. Guidara [1], A. Dhieb [1], A. Jmal [1]
[1]*1- Laboratory department. Mahmoud El MATRI hospital. Faculty of medecine of tunis. Tunisia*
[2]*2- Emergency department. Mahmoud El MATRI hospital. Faculty of medecine of tunis. Tunisia*

BACKGROUND-AIM

Hemolysis of biological samples has long been considered to have an impact on the results of biochemical parameters. The aim of this study was to investigate the interference of hemolysis on the determination of 23 biochemical parameters.

METHODS

Using blood samples taken from 30 apparently healthy subjects in heparinised tubes, the interference of hemolysis was studied on the following 23 biochemical parameters: 6 electrolytes (sodium(Na+), potassium (K+), chlorides (Cl-), calcium (Ca2+), phosphorus(P), magnesium (Mg2+)),9 substrates (total cholesterol (TC), triglycerides (TG), total bilirubin (TBIL), direct bilirubin (DLB), glucose (GLU), uric acid (UA), total protein (TP), creatinine (CREAT), urea (UR)),8 enzymes (aspartate amino transferase (ASAT), alanine amino transferase (ALAT), alkaline phosphatases(PAL), lactate dehydrogenase (LDH), creatine kinase(CK), gamma glutamyl transferase (GGT), amylase (AMYL), lipase (LIP)). These parameters were assayed on a Roche Diagnostic Cobas 6000 before and after haemolysis. Hemolysis was carried out mechanically by shaking and centrifugation at 2500g for 10 minutes until a red-coloured plasma was obtained. Percentage changes in the parameters studied were then calculated using SPSS statistics software. The variation was considered significant if the percentage variation was >10%.

RESULTS

The parameters studied were classified as follows: parameters with a positive impact leading to a significant overestimation of the result: LDH, ASAT, TG, CK, K+, GGT and UA and parameters with a negative impact leading to a significant underestimation of the result: BILD and GLU. The other biochemical parameters (Ca2+, Na+, Cl-, Mg2+, P, CT, BILT, UR, PT, CREAT, ALAT, PAL, AMYL, LIP) showed no significant variation.

CONCLUSIONS

Hemolysis can significantly affect the accuracy of certain biochemical analyses. Understanding the extent of this interference allows biologists to take appropriate measures when handling hemolyzed samples, ensuring the reliability of the results.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0064

THE COMMUNICATION BETWEEN MEDICAL LABORATORY TECHNICIANS AND THE MEDICAL STAFF AND ITS CONTRIBUTION TO THE RELIABILITY OF TEST RESULTS AND THE QUALITY OF TREATMENT

R. Abu-Ata Mahamid [1]
[1]*medical laboratories at Ha'emeq hospital by Clalit, Afula*

BACKGROUND-AIM

Modern medicine relay on lab tests and to ensure accurate results, strict protocols are given for sampling process which include pre-analysis, analysis and post-analysis. Errors occur at any stage and affect test reliability and patient care. Labs often focus on improving analysis phase while greater improvements can be achieved in pre and post analysis phases. Plebani (2006) pointed that most errors in the process are result of poor communication and this study focused on investigating communication and the impact on lab test reliability.

METHODS

156 questionnaires collected about lab testing and communication. 884 lab tests were analysed and data of rejects collected. 5 tests were selected by senior doctors and lab director to assess following protocols and how incompliance affect test reliability.

RESULTS

~90% of errors occurred in pre-analysis phase. Better communication led to less rejects (-0.3), while poor knowledge sharing increased errors (0.81). Both staffs stated the need for clearer guidelines, improve sample preparation and more information about test limitations to ensure accurate interpretations. The study revealed gaps in communication as only 42% of doctors received instructions from labs in the year before. 51% had issues with lab tests but only 35% reached out to labs, while 84% of lab staff who faces issues contact the department. 58% lab staff shared problems with managers and 42% with colleagues in contrast of medical staff. Hierarchy played a role in handling errors as senior doctors address disqualification more than trainees($p=0.0008$). Intervention temporarily reduced test rejects but, staff turnover during the study disrupted progress. Results show the need for better guidance and communication, ongoing training and better practices to maintain improvements.

CONCLUSIONS

Poor communication and information sharing are major contributors to errors in lab testing. To address these challenges, hospitals need to adopt communication strategies, continuous training programs, and regular updates for staff together with new staff training. Establishing shared forums should be considered from both staffs. Long-term communication strategies and continuous collaboration between labs and medical teams, are important to ensure accurate and reliable laboratory testing process.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0065

EXTERNAL QUALITY ASSESSMENT: INTERLABORATORY COMPARISON INITIATIVE IN ALGERIA ACCORDING TO ISO IEC 17043

S. Aguini [2], A. Aguini [1], B. Djemai [2], A. Khaldi [1]
[1]*INNOLAB - Laboratoire d'analyses médicales, Mohammadia, Alger, Algérie*
[2]*LAMA (Laboratoire d'Analyses Médicales Dr AGUINI S.), Bab-Ezzouar, Alger, Algérie*

BACKGROUND-AIM

Proficiency testing (PT) and inter-laboratory comparisons (ILC) are widely recognized as an essential tool to demonstrate the competence of laboratories and the reliability of their results. Currently in Algeria and Africa, no proficiency testing provider exists in the field of medical laboratory. In this context, the aim of this study is to set up a ILC/PT campaign among medical laboratories.

METHODS

The proficiency testing round was designed and executed according to the recommendations of the ISO IEC 17043 standard and the data collected and processed according to the ISO 13528 and ISO 5725 standards. The round was open to laboratories carrying out blood tests of the 21 targeted biochemical parameters at their level. Invitations were sent to national and Senegalese laboratories engaged in an accreditation process.

RESULTS

The processing of the results obtained before and after distribution of the entities indicates that the samples produced are homogeneous and stables when stored at +4°C.
The distribution of the participants' results and their individual performances differ according to the parameter considered, the method adopted and the equipment used. The main criterion for evaluation and comparison of the laboratories selected is the Z-Score, the number of laboratories having obtained compliant Z-Scores is: glucose (n=21), urea (n=22), creatinine (n=27), uric acid (n=25), total cholesterol (n=25), triglycerides (n=28), HDL-c (n=21), total proteins (n=20), albumin (n=23), calcium (n=26), phosphorus (n=23), iron (n=18), magnesium (n=20), ASAT/TGO (n=25), ALAT/TGP (n=25), PAL (n=23), gGT (n=25), total bilirubin (n=26), direct bilirubin (n=26), CRP (n=17), LDH (n=18).
The performances change if we consider each reference individually but clearly shows that there are parameters commonly mastered by a large number of participants due to their stability and the robustness of the techniques used and others that require harmonization and better comparability of results.

CONCLUSIONS

This work remains an initial draft that should be consolidated by the efforts of local learned societies, authorities and laboratories as well as the encouragement of real PT providers accredited according to the ISO IEC 17043 standard.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0066

COMPARISON OF POINT-OF-CARE GLYCOSYLATED HEMOGLOBIN AND LABORATORY HBA1C AND ITS RELATIONSHIP TO TIME-IN-RANGE AND GLUCOSE VARIABILITY

A. Al Hayek [1], A. Al Hayek [1]
[1]*Department of Endocrinology and Diabetes, Prince Sultan Military Medical City Riyadh*

BACKGROUND-AIM

The main objective of the current study was to perform a comparison of point-of-care testing for hemoglobin A1c (POCT-HbA1c) versus standard laboratory method (Lab HbA1c) and their relationship to time-in-range (TIR) and glucose variability (GV) among patients with diabetes mellitus (DM) presented to the outpatient diabetes clinics.

METHODS

This single-center cross-sectional study was carried out on diabetic patients (aged ≥14 years of both genders) who undergo routine follow-up at our institution and whose physicians ordered HbA1c analysis for routine care. The included patients were using the Continuous Glucose Monitoring (CGM) system for at least three months and regular CGM users with at least 70% use.

RESULTS

We included 97 diabetic patients (41 female and 56 male), with a mean age of 29.75±13.55 years and a mean DM duration of 10.33±5.48 years. The mean values of Lab-HbA1c and POCT HbA1c were 8.82%±0.85% and 8.53%±0.89%. The TIR, time below range, and time above range were 33.47±14.38 minutes (47.78%±14.32%), 5.44±2.58 minutes (8.41%±4.42%), and 28.8±8.27 minutes (43.81%±13.22%). According to the Bland-Altman plot analysis, the POCT-HbA1c values are consistent with the standard Lab-HbA1c values (SD of bias= 0.55, and 95% CI= -0.78 to 1.4). Using the univariate linear regression analysis showed a statistically significant relationship between laboratory HbA1c and POCT HbA1c (R2= 0.637, p <0.001), TIR (R2= 0.406, p <0.001), and GV (R2= 0.048, p= 0.032). After adjusting for age, gender, disease duration, diabetes type, and percentage of sensor data in a multivariable linear regression model, the linear associations remained significant (all $p < 0.05$).

CONCLUSIONS

TIR and GV have promise as preferred measures for identifying clinical trial endpoints, estimating the likelihood of DM-related complications, and gauging a patient's glycemic condition.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0067

EVALUATION OF THE ANALYTICAL PERFORMANCE OF BETA-2 MICROGLOBULIN IMMUNOASSAY USING SIX SIGMA METHODOLOGY AND DETERMINATION OF MEASUREMENT UNCERTAINTY

R. Ayhan [1], A. Sener [1], R. Seker [1], C. Topcuoglu [1]
[1]*Ankara Etlik City Hospital*

BACKGROUND-AIM

Beta-2 Microglobulin (B2M) is encoded by the B2M gene, a component of the MHC Class I molecule. B2M is an important biomarker for prognosis and monitoring in diseases such as multiple myeloma, lymphoma, and chronic lymphocytic leukemia. Evaluating and improving B2M's analytical performance is essential for patient safety. This study aimed to assess the analytical performance of the B2M protein test using the Six Sigma methodology and to determine the measurement uncertainty.

METHODS

B2M analysis was performed using the immunoturbidimetric measurement method on the cobas c702 (Roche, Germany) analyzer, and retrospective analysis was conducted using internal and external quality controls data between February 2024 and July 2024. For each control level (2 levels), the 6-month average coefficient of variation (CV%), within-laboratory reproducibility (Rw), relative within-laboratory reproducibility (u(Rw)), bias%, the uncertainty of nominal values (u(Cref)), the external quality control uncertainty component (u(bias)), and Root Mean Squares of Bias (RMS bias) were calculated. The Complex standard uncertainty (uc) and expanded uncertainty (U) were calculated in six steps according to the Nordtest guidelines. For Six Sigma calculations, the internal quality data from each month and control level were used for the CV%, while external quality data provided the bias. The Six Sigma formula used was: Sigma = (TEa% - bias%) / CV%, where total error (TE) represents TE= bias% + (1.65 x CV%). The total allowable error (TEa%) was used as the value the American Association for Bioanalysis (AAB) recommended.

RESULTS

The CV% for Level 1 was 3.13%, and for Level 2 was 2.56%. The Rw value was 2.86%, uRw was 1.43%, the RMS bias was 2.13%, u(bias) was 5.15%, and u(Cref) was 0.78%. The combined measurement uncertainty (uc) was 5.35%, and the expanded uncertainty (U) was 10.7% (k=2). The sigma level for Level 1 was 7.88, with a TE of 10.48%, and the sigma level for Level 2 was 9.75, with a TE of 9.49%.

CONCLUSIONS

Both control levels of the B2M test demonstrated world-class performance. Each laboratory should continuously evaluate its analytical performance and make improvements where necessary.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0068

INFLUENCE OF HEMOLYSIS ON ROUTINE HEMOSTASIS TESTS (APTT, PT, AND FIBRINOGEN)

M. Belhedi [1], W. Lazzem [1], H. Bergaoui [1], a. Abidi [1], i. Chaabene [1], n. Mahdaoui [1], s. Chouaieb [1]
[1]*Department of Laboratory, Habib Thameur Hospital Tunis, Tunisia*

BACKGROUND-AIM

The pre-analytical phase in hemostasis is a fundamental step in conducting biological examinations and determines the reliability and validity of results. Hemolysis constitutes the most frequent error in the pre-analytical phase. The aim of this work was to study the influence of hemolysis on the determination of activated partial thromboplastin time (aPTT and APTT-K), prothrombin time (PT), and fibrinogen (Fg).

METHODS

This experimental study was conducted at the Habib Thameur Hospital laboratory. Twelve samples were prepared (6 from a pool of normal plasmas and 6 from a pool of pathological plasmas). Hemolysis was induced by freezing-thawing the red blood cell pellet at -80°C for 20 minutes. The samples were spiked with hemolysate at seven increasing hemoglobin concentrations. Hemostasis parameters were measured on a 3.2% citrated tube using an ACL TOP 550 analyzer. The hemolysis index (HI) was determined using the AU DXC 700 analyzer. Coefficients of variation related to hemolysis (CVH%) were calculated for each Hb concentration.

RESULTS

Normal PT values were significantly influenced by hemolysis starting from HI=5 (400 mg/L). aPTT was significantly increased by hemolysis starting from HI=4 (250 mg/dL). Regarding fibrinogen, an overestimation was observed starting from a hemoglobin concentration of 400 mg/dL (HI=5).
For pathological values, the effect of hemolysis was more pronounced. PT was significantly influenced starting from a hemoglobin concentration of 150 mg/dL (HI=3). Fibrinogen was overestimated starting from HI=2 (150 mg/dL). However, no influence of hemolysis was observed on APTT-K and aPTT up to a hemoglobin concentration of 1g/dL (HI=7).

CONCLUSIONS

Understanding the impact of hemolysis on hemostasis parameters helps avoid inappropriate rejection of hemolyzed samples or unnecessary test repetition due to this error.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0069

SIX SIGMA EVALUATION OF HBA1C MEASUREMENT ON CAPILLARYS 3 OCTA: COMPARISON OF QUALITY SPECIFICATIONS

m. Belhedi [2], W. Lazzem [2], A. Ba [1], H. Bargaoui [2], o. Soltani [2], N.e.h. Gnounou [2], E. Dakhil [2], S. Chouaieb [2]
[1]*biochemistry laboratory, main military hospital of Tunis Tunisia*
[2]*laboratory department, Habib Thameur hospital in Tunis, Tunisia*

BACKGROUND-AIM

The Six Sigma approach, a quality improvement methodology, makes it possible to evaluate and optimize analytical processes. However, specifications for total acceptable error (TEa) vary considerably depending on the recommendations of different scientific societies and international organizations. This study aims to apply the Six Sigma methodology and compare the different specifications of learned societies to evaluate the analytical performance of the HbA1c assay.

METHODS

The study analyzed quality control data from the HbA1c assay by the CAPILLARYS 3 OCTA analyzer using different quality specifications: Cruise Lines International Association (CLIA), Westgard, Spanish Society of Laboratory Medicine (SEQC) and European Federation of Clinical Chemistry and Laboratory Medicine EFLM. The sigma index was calculated, based on the external quality control bias and the internal quality control variant coefficient, for each capillary.

RESULTS

The overall analysis revealed sigma indices greater than 3 regardless of the specifications and the level of control. The index was respectively for levels 1 and 2 of 5.55 and 5.45 according to CLIA and Westgard; 4.78 and 4.47 according to the SEQC; 3.24 and 3.27 according to minimum TEa recommended by EFLM. Capillary analysis demonstrated excellent performance with sigma indices varying from 4.28 to 7.53 according to CLIA. Only one capillary had a sigma index <3 according to EFLM.

CONCLUSIONS

The application of the Six Sigma methodology to the determination of HbA1c by CAPILLARYS 3 OCTA demonstrated satisfactory analytical performance of each capillary despite the lack of consistency between the different scientific societies.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0070

POPULATION BASED AND TRIMESTER SPECIFIC REFERENCE INTERVAL OF TSH DURING PREGNANCY

A. Besbes [2], b. Chafi [5], K.M. Arabi [3], I. Benmahdi [4], A.S. Benaissa [1], m. Nachi [1]
[1]*Clinical Biochemistry Laboratory of University Hospital Establishment of Oran Premier Novembre*
[2]*Clinical Biochemistry Laboratory of University Hospital Establishment of Oran Premier Novembre*
[3]*clinical laboratory of Regional Military University Hospital of Oran*
[4]*clinical laboratory of Regional Military University Hospital of Oran*
[5]*obstetrics and gynecology department of university hospital of oran Premier Novembre*

BACKGROUND-AIM

Pregnancy affect profoundly thyroid function, variations in thyroid stimulating hormone (TSH) reference interval are seen in several studies and are population and assay dependent. Therefore 2017 American association of thyroid (ATA) guideline has recommended to each laboratory establishing its own trimester specific RI.
The aim of our study was to establish TSH reference interval during pregnancy in population who lives in Oran (northwestern Algeria).

METHODS

Robust method was used to calculate RI according to EP28A3c standard published by clinical laboratory standard institute (CLSI). Apparently healthy women were selected using NACB (national academy of clinical biochemistry) exclusion criteria: personal or familial thyroid history, visible or palpable goiter, positive antithyroperoxydase antibody (ATPO). The study included 228 women, 81 in first trimester from 5th to 13th gestational week (GW) , 75 in second trimester from 13GW+ 1day to 28th GW, and 72 in third trimester from 28GW+ 1day to 40th GW. Serum TSH test was performed on Cobas e411. Outliers were removed by tukey method.

RESULTS

At first, second and third trimester, age median were respectively 29y (years), 30y, 30y and gestational age median were 8.1 GW, 19GW, 36.5GW. After outliers removing, first, second and third trimester TSH reference intervals were respectively: 0.34-3.49 U/L, 0.11- 3.44 U/L, 0.15 – 3.99 U/L.

CONCLUSIONS

In this study TSH reference interval was calculated using Robust method, however, to be more accurate we need to increase the number of reference subject in order to follow CLSI recommendation that preconize determination of RI by non-parametric method which need a minimum of 120 reference values.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0071

DETERMINATION OF TOTAL PSA AND SERUM FREE PSA STABILITY.

A. Cumplido Portillo [1], A. Alonso Llorente [1], A. Blanquero Porras [1], L. Fraile García [1], M. Jiménez Domínguez [1], A. Ramos Gorostiaga [1], M. Bernal Morillo [1], A.C. Sopena Murillo [1], M. Ibarz Escuer [1]
[1]*Hospital Universitari Arnau de Vilanova (Lleida)*

BACKGROUND-AIM

Prostate-specific antigen (PSA) is a protein synthesized in the prostate that participates in the dissolution of the seminal clot and it can be found in free form (fPSA) or bound to proteins. High total PSA (tPSA) levels and low serum tPSA/fPSA ratios may suggest the presence of prostate cancer, although they may be altered in benign pathology too. In Spain, prostate cancer is the third most common tumour in men and the third leading cause of cancer death. For all these reasons, serial PSA measurement facilitates the diagnosis, prognosis and follow-up of patients with this tumour. The following study focused on determining whether the stability of serum tPSA and fPSA in samples stored at 2-8ºC is greater than 24 hours, as marked by the commercial company. The serum reference values for tPSA are below 4 ng/mL, with the tPSA/fPSA index being between 0.25-1.

METHODS

tPSA and fPSA were determined prospectively in 20 samples upon arrival at the laboratory, at 24 hours and 48 hours, in the UniCel DxI analyzer (Beckman Coulter). Following the indications of the document Definition of the limit of stability of the magnitudes in the biological samples of the SEQC-ML and the minimum specifications of the EFLM, the stability of these parameters was calculate. The coefficient of variation (CV) was 5.1% for the tPSA with the maximum variation allowed (CV*1.65) being 8.42. For the fPSA, the CV was 5.3% and the maximum variation allowed was 8.76. The study was carried out by a mean difference comparison (MD).

RESULTS

The means of the tPSA measurements were 4.12 ng/mL at 0 hours, 3.96 ng/mL (MD 3.94) at 24 hours and 3.91 ng/mL (MD 5.35) at 48 hours; the maximum variation allowed was 8.42.
The means of the fPSA measurements were 1.2 ng/mL at 0 hours, 1.15 ng/mL (MD 3.88) at 24 hours and 1.08 ng/mL (MD 10.61) at 48 hours; the maximum variation allowed was 8.76.

CONCLUSIONS

According to the results, the stability of serum tPSA and fPSA in samples stored at 2-8ºC was greater than 24 hours. However, although the stability of the tPSA was greater than 48 hours, the stability of the fPSA was lower than that time. For it, the samples will continue to be analyzed in the first 24 hours, since the stability of the fPSA was lower than 48 hours, which would produce altered results of the tPSA/fPSA ratio.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0072

IMPLEMENTATION OF AN INTERNAL CONTROL SYSTEM FOR CYTO-MORPHOLOGICAL ANALYSIS IN HEMATOLOGY AND CYTOLOGY.

A. Chakroun [1], s. Sfaxi [1], S. Sabbagh [1], N. Gharbi [1], H. Baccouche [1], J. Eddhib [1], S. Mahjoub [1]
[1]*Hematology laboratory, Rabta Hospital, Tunis, Tunisia*

BACKGROUND-AIM

The adoption of an internal quality control (IQC)in Manual white blood cell count (WBCc) and morphological analysis of blood smears is important in the ISO 15189. However, in our laboratory the periodic evaluation via the scanned blood smear slides is not yet available. The aim of our study was to establish an ''in-house'' IQC system to assess the staff competencies.

METHODS

Records, instructions and procedures related to blood smear test have been developed regarding the recommandation of ISO15189.
Two 'in-house' QIC were designed based on two sets of 03 blood smears and delivered to the staff for evaluation.
Target values, acceptability limits (CV reproducibility limit, acceptability margin), comments and expected advice have been defined by the biologist.
Staff included in the study has participated to the two evaluations. A cytology training was provided via two video-capsules after evaluation by the first 03- blood smears 'in-house'IQC. A survey assessing previous skills and training, satisfaction with training and expectations for future training was distributed to participants via google Forms.
Assessement of the staff performance for each 'in-house' QIC was conducted by calculating the means, coefficients of variation (CV) and biases and the impact of the training was estimated.

RESULTS

Sixteen participants were included: 11 biology residents, 03 biology technicians and 02 biology technician trainees.
At the first 'in-house' IQC, eight non-conformities at level of the WBCc (of the CVs > CV limit reproducibility) (2 on slide 1, 2 on slide 2 and 4 on slide 3) and several deficiencies in the qualitative study were noted. Overall scores (WBCc and qualitative study including advisory service) varied from 6/81 to 42/81.
At the 2nd 'in-house' QIC a rise in the scores of comments and an improvement in advice provided have been observed. A progress in the overall scores between the two cyto-morphological ''in-house'' IQC was noted in (11/16) participants with an individual overall score ranging between 7/81 and 78/81. 2/3 of the participants reported that they had updated their previous knowledge/skills through the training.

CONCLUSIONS

Ongoing-training and maintenance of blood cytology skills are required. Practical workshops should be regularly planned.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0073

ASSESSMENT OF BLOOD ORDERING PRACTICES IN A TERTIARY HOSPITAL

A. Chavez [1], S. Watanabe [1]
[1]*Batangas Medical Center*

BACKGROUND-AIM

Blood banks are the exclusive providers of blood products that are used by many clinicians every day. The blood bank manager and clinicians are encouraged to communicate actively and work together to guarantee the rational use of blood products. The aim of this descriptive, non-randomized study is to evaluate the blood ordering practices of packed red blood cells by the clinicians at Batangas Medical Center (BMC) as per the Philippine Clinical Practice Guidelines (CPG) for the Rational Use of Blood and Blood Products and Strategies for Implementation and in accordance with the institution's Blood Bank Laboratory Manual, particularly the accepted crossmatch to transfusion ratio stated (2.5 or below).

METHODS

All blood requests received from January 2020 to March 2020 for in-patients aged 18 years and above were analyzed. The study only included the crossmatched blood units. Data reviewed contained the demographic profile of the patient, the baseline hemoglobin prior to transfusion, and the clinical indication for blood transfusion. The requests were categorized as either appropriate or inappropriate based on the existing Philippine CPG for rational blood use.

RESULTS

The data showed 56.71 % of the blood requests for adult patients were medical cases and 43.29% were surgical cases. The crossmatched to transfusion ratio of the medical and surgical cases are both 1.11. Of all 1,497 requests, 88.44% were categorized as appropriate and 11.56% were considered inappropriate.

CONCLUSIONS

The blood ordering practices for packed red blood cells for adult patients at BMC is highly acceptable with a crossmatched to transfusion ratio of 1.11 and an 88.44% appropriate blood requests in accordance with the Philippine CPG for the Rational Use of Blood and Blood Products and Strategies for Implementation (2017).
The overall result showed an optimistic blood ordering practices in terms of application of the clinical practice guidelines and the computed CT ratio. Contributory to this is due to the proactive screening of blood request in part of the laboratory and the conscious implementation of the CPG in the part of the clinician. This emphasizes the significance of inter-cooperative effort on the part of both blood bank and clinician to promote rationale blood use alongside qualitative patient care.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0074

RETROSPECTIVE COMPARISON OF MOVING AVERAGE VALUES BETWEEN TWO LABORATORIES.

J. Culej [1], H. Tonković [2], D. Kralj [1], A. Paškvan [1], S. Janečić [1], H. Breyer Priselac [1]
[1]*Breyer Polyclinic, Zagreb, Croatia*
[2]*Ekonerg Konzalting, Zagreb, Croatia*

BACKGROUND-AIM

The moving average is a concept designed as an assistant for daily quality control using patient test results. The most challenging step is setting criteria that will ensure optimal QC performance. Our clinic operates at multiple locations, and the hypothesis of this study is that the daily moving average will not differ between the two locations, allowing application of the same rules in laboratory information system (LIS) regardless of location. The aim of this study was to test differences between moving average values between two locations.

METHODS

Tests selected for comparison were ALP, ALT, AST, bilirubin, GGT and total cholesterol. These tests were analyzed on Beckman Coulter DxC700 on central location and AU480 on second location. Statistical software that was used: MedCalc® version 23.0.9. Preparation of data for analysis, excluding out-of-reference-range outliers and moving average calculation was performed in Oracle Database Express edition.

RESULTS

The moving average was calculated over a one-month period for each location separately based on 20 measurements. Total number of measured tests (ALP, ALT, AST, bilirubin, GGT and total cholesterol) on both locations was 4850, where central location has higher patient flow. Distribution of results was not normal (D'Agostino Pearson test, P< 0.005), so the Mann-Whitney test for independent samples was used. Statistically significant difference between locations was present with every test (P<0,05) except AST (P=0,586). However, median value difference between locations, were lower than between-subject biologic variation (CVg). ALP: 3,80% (CVg 26,10%), ALT: -3,36% (CVg 41,60%), AST: 34,69% (CVg 23,1%), bilirubin: -6,62% (CVg 28,4%), GGT: -6,62% (CVg 42,15%), and total cholesterol: 4,92% (CVg 15,3%).

CONCLUSIONS

Differences in measurements between locations should not be an obstacle to establishing unified criteria for both locations based only on CVg. However, since moving average criteria often require specific considerations for each test separately, statistically significant differences should be considered.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0075

UTILITY OF GFAP AND UCH-L1 BIOMARKERS IN EVALUATION OF BRAIN DAMAGE DUE TO MILD TBI

M. Cifuentes Flores [1], J.C. Alcalá Escamilla [1], C. Campos Moreno [1], A. Gonzalez Raya [1], T. De Haro Muñoz [1]
[1]*Clinical laboratory, Clinical Analysis, San Cecilio University Hospital, Granada*

BACKGROUND-AIM

Glial fibrillary acidic protein (GFAP) and Ubiquitin carboxyterminal hydrolase L1 (UCH-L1) are two biomarkers used in the initial evaluation of patients with suspected mild traumatic brain injury (TBI).
In June 2024, a new protocol was established in our center to quantify GFAP and UCH-L1 in all patients with mild TBI in less than 12 hours, and a value of 13-14 on the Glasgow scale or 15 with symptoms and/or risk factors.
The aim of this study is to evaluate the usefulness of these determinations in the initial evaluation of the patient with suspected mild TBI to rule out brain damage.

METHODS

A retrospective study is carried out selecting all patients with these requested biomarkers from June to December 2024. The determination of GFAP and UCH-L1 is performed on the Alinity analyzer (Abbott), using chemiluminescence immunoassay.
A review of medical records is performed, checking imaging tests and/or readmissions for relapses/worsening within a period of one month from the first episode.

RESULTS

A total of 103 patients were included on the study, 70 of them had one of the two biomarkers above the cut-off point. 32 had both biomarkers elevated, 28 only with elevated GFAP and 10 with UCH-L1.
Of the 70 patients with positive results, the presence of intracranial hemorrhage was confirmed in 10 of them. In these patients, the GFAP value was pathological in all of them, while UCH-L1 presented values higher than the normal range in 8 of the 10 cases.
With these results, it was estimated a positive predictive value (PPV) of 0.14 and a NPV of 1.
None of the patients with normal biomarker results were diagnosed with a brain damaged pathological imaging test or had a readmission in the month after the episode.

CONCLUSIONS

The high NPV of these biomarkers is confirmed to rule out the presence of brain damage. Although a more extensive study would be necessary, the data obtained seem to indicate that in the event of a negative result, performing imaging tests on these patients could be avoided with great safety, with the consequent savings in economically, human resources and patient safety.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0076

EVALUATION OF QUALITY MONITORING PRACTICES AMONG CLINICAL LABORATORIES IN THE PHILIPPINES: A PCQACL PASSION STUDY FOR QUALITY BENCHMARKING

G.E. De La Cruz [2], S.J. Datay-Lim [1], R. Lim [1], M. Orillaza [1]
[1]*Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL)*
[2]*The Medical City*

BACKGROUND-AIM

This study aims to describe the current state of quality monitoring and practices among Philippine clinical laboratories by describing how many laboratories use quality indicators, differentiating the quality indicators monitored by laboratories, and describing how they monitor these quality indicators.

METHODS

Clinical laboratories accredited by the Philippine government's Department of Health (DOH) were conveniently sampled through the Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL)'s network. A questionnaire was made to evaluate quality indicators based on the literature and authors' experience, and were answered by laboratory heads, which were pathologists or medical technologists. Key informant interviews provided additional information on quality monitoring practices.

RESULTS

268 laboratories participated in the study, with more secondary (36%) and tertiary (49%) than primary (15%) laboratories, more private (65%) than government (35%) laboratories, more institution-based (77%) than non-institution-based (23%) laboratories, and more small (71%) than medium (24%) and large (5%) laboratories. Less than half (37%) of laboratories had external standards accreditation. Patient satisfaction (95%), turnaround time (TAT) (93%), specimen acceptability (86%), critical results reporting (85%), quality control (76%), corrected/amended reports (71%), and sample recollection rates (65%) were monitored by most laboratories. A wide TAT range was reported across types for both routine and stat samples. Competency and safety, test stability (including quality control, participation in external quality assurance programs), turnaround time (including critical results reporting), and feedback were themes that emerged from the interviews.

CONCLUSIONS

TAT (including critical results reporting), patient satisfaction, and test stability (including quality control and participation in external quality assessments) emerged as the indicators prioritized by most Philippine laboratories. This study also presents opportunities for further exploration of selected quality indicators, such as improvement of participation in external standards, factors affecting TAT, nuances of patient satisfaction, and incorporating staff competency as quality indicators.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0077

EVALUATION OF THE HEMATOLOGY ANALYZER TEST PERFORMANCE USING SIX SIGMA METRICS: A CROSS SECTIONAL STUDY

P.M. Dy [1], K. Damian [2], E.I. Villanueva [2]
[1]*Department of Laboratories, Philippine General Hospital, Manila*
[2]*Department of Pathology, University of the Philippines College of Medicine, Manila*

BACKGROUND-AIM

The six sigma metric is used to assess the performance of a measurement procedure in comparison to the medical requirement. This study aims to evaluate the performance of hematology analyzers using the six sigma scale.

METHODS

This is a descriptive cross-sectional study wherein quality control data from hematology analyzers were obtained. The mean, standard deviation, coefficient of variation, bias and sigma value of the RBC, WBC, hemoglobin, hematocrit, and platelet parameters were determined and the performance of Beckman Coulter DxH 900 was assessed by plotting a normalized OPSpecs chart.

RESULTS

The WBC and platelet parameters had sigma values of more than 6. Less stringent quality control measures could be applied these parameters which include fewer Westgard rules and fewer control runs. The RBC and hemoglobin parameters had sigma values of at least 3. The hematocrit parameter had a sigma value of less than 3. Improving this parameter could be done by performing optical channel evaluation, using multiple Westgard control rules, increasing the number of control materials and the number of runs.

CONCLUSIONS

This study has demonstrated the analytical performance of hematology analyzers on the six sigma scale, which in turn allows for the selection of the appropriate statistical quality control rule. Ultimately, statistical quality control is only one part of a laboratory's quality management system. The sigma quality of the testing process, as well as choosing the appropriate control rules and number of controls, may provide the basis for the total quality control strategy of the laboratory.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0078

QUALITY CONTROL IN THE PRE-ANALYTICAL PHASE OF BIOCHEMISTRY: INSIGHTS FROM MOHAMMED VI UNIVERSITY HOSPITAL, OUJDA

D. El Moujtahide [1], E.H. Sebbar [1], M. Choukri [1]
[1]*Centre hospitalier universitaire MOHAMMED VI d'Oujda*

BACKGROUND-AIM

The pre-analytical phase in clinical biology encompasses steps preceding sample analysis, including collection, transportation, storage, and preparation. Errors here significantly impact result reliability.

METHODS

A 6-month prospective, descriptive study assessed pre-analytical phases, especially sampling, at Mohammed VI University Hospital's central laboratory. It involved 8 weeks of observations and 4 months of data analysis.

RESULTS

Common non-conformities (NC) included prescription form and patient preparation (29% each), sampling procedure (17%), equipment preparation (14%), and waste management (10%), with no NC in sample transfer. Prescribers consistently recorded patient details with no identification errors. Patient preparation NCs mainly involved inadequate patient resting time and medication verification, each at 31%, followed by fasting duration verification (29%) and patient information (10%).

CONCLUSIONS

Rigorous quality control procedures throughout the pre-analytical phase are crucial to minimize errors and ensure reliable clinical biology analysis results. Employing tools like the Ishikawa diagram could help identify and address potential problems effectively.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0079

COMPARATIVE ANALYSIS OF TECHNICAL MODIFICATIONS IN CLINICAL LABORATORY REAGENTS

A. Lopez-Martos [1], S. Elena-Perez [1], G. Rodriguez-Perez [1], M. Calzada-Gonzalez [1], M. Lopez-Guio [1], A. Perez-Arribas [1], F. Hernandez-Pacho [1], I. Jimenez-San Segundo [1], C. Hierro-Delgado [1], S. Muñoz-Hernaz [1]
[1]*Nuestra Señora de Sonsoles Hospital, Ávila*

BACKGROUND-AIM

The clinical laboratory contributes significantly to patients' health. Therefore, it is crucial to ensure the accuracy of analytical procedures, as it is a requirement of the ISO 15189 standard by the International Organization for Standardization.
This study presents the results of the verification protocol for Iron, AST, ALT, LDH and ALK measurement.

METHODS

140 samples were selected and 40 determinations were performed for each assay using both reagents on the Alinity c autoanalyzer (Abbott®).
MethodValidator® intercomparison software was used and outliers were excluded (five data points). The Bland and Altman method (relative) were conducted, along with Passing-Bablok regression, considering both the intercept (a) and the slope (b).

RESULTS

Bland and Altman method
- IRON: -12.7 (-14.1 a -11.2)
- AST: 7.99 (-1.8 a 17.8)
- ALT: -1.06 (-1.52 a -0.588)
- LDH: -0.335 (-3.62 a 2.95)
- ALK: 18.6 (13 a 24.1)

Passing-Bablok regression
IRON
- b: 0.922 (0.913-0.934)
- a: -4.8 (-6.0 a -3.8)
- r: 0.999

AST
- b: 1.067 (1.038-1.082)
- a: 0.4 (0 a 1.3)
- r: 1.000

ALT
- b: 0.990 (0.979-1.009)
- a: -0.4 (-1.1 a -0.1)
- r: 1.000

LDH
- b: 0.948 (0.924-0.976)
- a: 13.3 (5.3 a 18.7)
- r: 0.999

ALK
- b: 1.101 (1.09 a 1.11)
- a: -0.8 (-1.7 a 0.6)
- r: 0.999

CONCLUSIONS

Bland and Altman method:
IRON
- BBV(#): no.
- BSC: no.
- ToB: constant and proportional.

AST
- BBV(#): yes, minimum.
- BSC: NA*.
- ToB: no.

ALT
- BBV(#): yes, desirable.
- BSC: NA*.
- ToB: no.

LDH
- BBV(#): yes, desirable.
- BSC: NA*.
- ToB: no.
ALK
- BBV(#): no.
- BSC: no.
- ToB: proportional.
BBV - Based on biological variation
BSC - Based on statistical criteria
ToB - Type of systematic bias
*NA- Not applicable, as it conforms to biological variation data.
(#)For the biological variation, the EFLM Biological Variation Database was consulted.
Passing-Bablok regression:
IRON
- b: yes.
- a: no.
- ToB: constant.
AST
- b: yes.
- a: yes.
- ToB: no.
ALT
- b: yes.
- a: yes.
- ToB: no.
LDH
- b: yes.
- a: no.
- ToB: constant.
ALK
- b: no.
- a: yes.
- ToB: proportional.
b - Slope analysis
a - Intercept analysis
ToB - Type of systematic bias
It is crucial to assess analytical interchangeability when a technical modification is implemented, as these variations could affect clinical practice.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0080

ASSESSMENT OF PROCALCITONIN ON THE DXI9000 ANALYZER BY BECKMAN COULTER

M.L. Navas Gómez [1], S. Martín Gabriel [1], P. Ramos Mayordomo [1], M. Baladron Segura [1], M. Capilla Díez [1], N. Fernández García [1], B. Calvo Antón [1], M. Fernández García [1], Á. Sánchez Sánchez [1], J.A. Garrote Adrados [1], P. Duarte García [1]
[1]*Análisis Clínicos, Hospital Universitario Río Hortega, Valladolid*

BACKGROUND-AIM

The use of the biomarker procalcitonin(PCT) can be very useful in pacients with systemic inflammation or bacterial infections. It measures the risk of critically ill patients developing severe sepsis. Beckman Coulter has marketed its DxI9000 analyzer, which includes the Access PCT assay, allowing for reduced response times.
Verify the interserial imprecision provided by the manufacturer.
Analyze the result interchangeability of PCT between DxI9000 and DxI800, analyzer currently used in our laboratory.

METHODS

The estimation of imprecision in verifying the manufacturer's specifications was carried out following the 2014 recommendations of Spanish Society of Laboratory Medicine. Three levels of BioRad Multichem IA Speciality Control were analyzed in triplicate, in a single series, over 5 consecutive days.
For the result interchangeability study, 68 lithium heparin plasma samples from patients covering the full linearity range of the technique were selected. Samples were processed in DxI800 immediately after collection, while in DxI9000, they were processed after thawing and adequate homogenization.
Both assays use chemiluminescent paramagnetic microparticle immunoassay (CMIA) methodology, but DxI9000 uses an enhanced substrate and disposable pipettes.
Statistical analysis of the data, using Passing-Bablok regression and Pearson correlation, was performed using the MedCalc program(v20.2).

RESULTS

The coefficients of variation(CV%) obtained for the evaluated control levels were: 5,38; 8,71, and 0,92, respectively.The interserial imprecision obtained for control levels 1 and 3 is below the manufacturer's specification (CV≤8%), while for level 2, it exceeds the reported value.
After comparing both analyzers, the following results were obtained with a 95% confidence interval:
Intercept: -0,007(-0,016--0,001); Slope: 1,016(0,099-1,04); Pearson correlation: 0,992(0,987-0,995).
There is a statistically significant correlation between the two instruments studied (p<0,0001).A constant systematic error, but not a proportional one, was observed.

CONCLUSIONS

The compliance with the manufacturer's imprecision specifications(CV≤8%) is verified for levels 1 and 3.The results obtained from both instruments are interchangeable, with no significant differences observed after studying the present systematic error.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0081

OPTIMIZATION OF WORKFLOWS BY STUDYING THE STABILITY OF SUGAR INTOLERANCE AND MALABSORPTION TESTS IN EXHALED AIR

L. Garcia Medina [2], G. Queipo De Llano Orellana [2], M.I. Vázquez Tavero [2], A.I. Aguiló Cuenca [2], M.J. Menéndez García [2], I. Llompart Alabern [2], D. Morell-Garcia [1]

[1]*Laboratory Medicine Department, Son Espases University Hospital and Institute for Health Research Balearic Islands, Palma, Spain*

[2]*Laboratory Medicine Department, Son Espases University Hospital, Palma, Spain*

BACKGROUND-AIM

Measurement of hydrogen (H2) and methane (CH4) in exhaled air is an important tool in the diagnosis of carbohydrate malabsorption, intolerance and bacterial overgrowth (SIBO).
When carbohydrates are not well digested, their fermentation by the intestinal flora releases gases that diffuse, reaching the lungs for elimination by exhalation.
Aim: to test the stability of H2 and CH4 samples, belonging to three substrates used in the exhaled air test (fructose, lactose and lactulose), 24 hours after their first analysis.

METHODS

Fifty-four consecutive samples from six exhaled air tests were measured by infrared determination on the BreathTracker (Quintron,US), on the day of reception and 24 hours later.
Permitted coefficients of analytical variation (CVp) were calculated for each gas using a monthly interseries of the internal control.
To assess whether stability existed, the permitted variability (PV) was calculated according to the formula:
PV = CVp * 1.65.
For each sample of the curves, the percentage difference between both measurements was calculated, considering unstable those higher than PV.
An adjusted Cohen's Kappa test was performed to obtain the concordance between diagnoses at time 0 and 24 hours.
Positivity criteria for fructose and lactose is an elevation of H2 concentration >20ppm and/or an elevation of CH4 >12ppm from baseline. For lactulose, it is the same proportion but in the first 90 minutes.

RESULTS

The final diagnosis for each test did not vary over time, with 2 positive curves reported for H2 values and 4 negative curves for both gases.
The result of the analytical report is qualitative and considers that concentration increases proportionally, and the test results can be assumed to be concordant in all cases, yielding an adjusted Cohen's Kappa index of 1.
The limitations of the present study lie in the technical impossibility of eliminating the bias produced by the opening of bags for repeated measurements over time, which is associated with an inherent exchange of gases with the medium that affects the measurements taken after the initial one.

CONCLUSIONS

The 24-hour stability of H2 and CH4 in exhaled air samples allows modification of current workflows and optimisation of the analytical process to reduce waiting lists associated with these home tests.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0082

GENDER DIFFERENCES IN LIPID STATUS PARAMETERS AND ATHEROGENIC RISK FACTORS IN TYPE 2 DIABETES MELLITUS PATIENTS

V. Gluvic-Celic [1], T. Marjanovic [1]
[1]*Department of laboratory diagnostics, Public Health Institution,Gradiska, Bosnia and Herzegovina*

BACKGROUND-AIM

This study aimed to assess differences in lipid profile parameters and atherogenic risk factors between male and female T2DM patients to determine gender-specific risks for CDV development.

METHODS

A total of 337 T2DM patients (157 men, 180 women; mean age: 66,2+- 9,16 years) participated in the study. Lipid parameters, including fasting blood sugar (FBS), HbA1c, TC, TGs, HDL-C, and LDL-C, were analyzed using standard laboratory procedures between January and July 2022 at the Department of Laboratory Diagnostics, Public Health Institution "Dom zdravlja" Gradiska (RS/BiH). Statistical analysis was performed using SPSS versin 24.0.

RESULTS

Women exhibited higher values of TC, TGs and HDL-C compared to men, while LDL-C was higher in men. Atherogenic indices-including CR1, CR2, atherogenic coefficient (AC), and atherogenic index of plasma (AIP)-were significantly elevated in both genders (CR1, r=0,004; CR2, r=0,03; AC, r=0,04; AIP, r=0,323; p<0,05). Significant positive correlation were observed between lipid parameters: TC (r=0,119), LDL-C (r=0,620), TGs (r=0,430), and HDL-C (r=0,01), all with p<0,05.

CONCLUSIONS

The findings indicate that female T2DM patients have a higher risk of dyslipidemia and subsequent CDV compared to males. Gender-specific approaches in managing lipid profiles may be necessary to reduce cardiovascular risks in this population.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0083

ANALYSIS OF NON-CONFORMITIES AT THE PRE-ANALYTICAL STAGE IN THE BIOCHEMISTRY LABORATORY

m. Boudaya [1], E. Guermazi [1], r. Marrakchi [1], n. Gati [1], d. Jmal [1], i. Kharrat [1], k. Jamoussi [1], m. Turki [1]
[1]*biochemistry department ,faculty of medicine of sfax/CHU Hédi Chaker. Sfax-Tunisie*

BACKGROUND-AIM

The objective of this study was to identify, classify and quantify non-conformitiesobserved during the pre-analytical phase in the biochemistry laboratorybiochemistry laboratory of the Hédi Chaker hospital in Sfax, in order to suggest improvements to guarantee the quality of analyses.

METHODS

This is a descriptive retrospective study carried out over a period of 15 months, from January 2022 to March 2023. A total of 893 samples showing non-conformities among the 124564 samples received.
The pre-analyzed non-conformities were classified according to their nature : identification errors, insufficient sample or errors in the choice of tubes, routing conditions not respected, destination errors and patients who had already paid the discharge before the assessment was processed.

RESULTS

Of all the samples analyzed, 0.71% presented non-conformities. The most frequent error was the destination error (38.75%), followed by the sample identification error (28.67%). These non-conformities came mainly from the endocrinology (12.38%) and pulmonology (11.87%) departments. Other errors, such as insufficient samples or tube errors (16.12%), the problem of discharged Patients (15.9%) and the non respect of transport condition were (0.56%). The analysis of the causes highlighted a lack of training and information for the staff, as well as an overload of work in the clinical departments.

CONCLUSIONS

Rigorous management of non-conformities in the pre-analytical phase is a crucial factor in guaranteeing the quality of analyses and patient safety.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0084

COMPARATIVE EVALUATION OF ELECSYS® AFP BY ROCHE AND ARCHITECT AFP BY ABBOTT METHODS

A. Izquierdo Martínez [1], J. Montenegro Martínez [1], D. Núñez Jurado [2], J.M. Guerrero Montavez [1]
[1]*Hospital Universitario Virgen del Rocio*
[2]*Hospital Universitario Virgen Macarena*

BACKGROUND-AIM

The alpha-fetoprotein (AFP) analysis technique is widely used in the diagnosis and monitoring of liver diseases and primary liver cancers. This measurement is crucial for early detection and monitoring of disease progression, making it essential to have accurate and validated measurement methods.

METHODS

A total of 139 serum samples were analyzed, obtained from both patients diagnosed with liver diseases (n=98) and healthy individuals (n=41). AFP measurements were performed using the Elecsys® AFP assay by Roche and compared with results obtained via ARCHITECT AFP by Abbott.
Data analysis was conducted using the Passing-Bablok method to evaluate the relationship between the two measurement methods. Statistical analysis was performed using MedCalc and SPSS v.26.0 software.

RESULTS

The results of the Passing-Bablok analysis show that the relationship between Abbott's Y method and Roche's X method is described by the following regression equation: Y=0.2623+1.0427X. Upon evaluating the regression equation, the slope is close to 1 (95% CI: 1.000 to 1.0838), indicating that both methods are proportionally similar. However, the intercept (95% CI: 0.092 to 0.4100) does not pass through zero, suggesting a systematic bias between the two methods.

CONCLUSIONS

The results indicate that while the two evaluated methods exhibit a significant linear relationship, they are not fully interchangeable due to the bias in the intercept. This finding is relevant because, although both methods provide proportionally similar results, the measurements are not equivalent across all ranges. The discrepancy in the intercept suggests that adjustments or calibrations may be necessary in future studies to ensure greater accuracy.
Further studies with different samples and conditions are recommended to confirm these findings and assess the impact on the clinical application of the measurement methods.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0085

THE CHALLENGES ENCOUNTERED DURING THE IMPLEMENTATION OF THE EQA PROGRAM IN CAMBODIA FROM 2018-2023

K. Hem [1], D. Chau [1], K. Sar [1]
[1]*National Institute of Public Health,Cambodia*

BACKGROUND-AIM

The External Quality Assessment (EQA) program is designed to objectively evaluate a laboratory's performance. It plays a critical role in ensuring the reliability of laboratory tests for informed decision-making. This study aimed to assess the EQA results from laboratories participating in the EQA program for biochemistry, hematology, and serology with the National Institute of Public Health and identify key challenges encountered in implementing the EQA program.

METHODS

This study utilized existing data from the biochemistry, hematology, and serology EQA programs enrolled between 2018 and 2023, along with responses from an EQA survey conducted between April 17 and May 19, 2024. Forty-three laboratory heads and quality officers voluntarily completed a self-administered questionnaire via Google Forms. The questionnaire covered staff qualifications, the condition of analyzers, the availability of reagents, frequently unavailable serology reagents, and quality assurance performance. Descriptive statistical analysis was used to determine the frequency, proportion, and mean of the variables of interest.

RESULTS

The average percentage of EQA scores for biochemistry and serology gradually improved, while the average hematology EQA score remained stable from round 1 in 2018 to round 2 in 2023. However, the average EQA scores for hematology were still below the target threshold of 80%. Additionally, three out of thirteen laboratories consistently ran out of hematology supplies, and four laboratories reported serology analyzers were out of service. Among the 11 laboratories that responded, 9.1% indicated that they always faced stock shortages. 74.4% of laboratories reported assessing staff competency, 76.7% performed internal quality control before testing, and 83.7% took corrective actions when EQA results were discordant.

CONCLUSIONS

This study revealed that the EQA results for biochemistry and hematology remained low, with hematology results particularly underperforming. A variety of biochemistry and hematology analyzers were in use. The challenges faced during EQA implementation included equipment malfunctions, outdated instruments, reagent shortages, staff competency issues, irregular internal quality control procedures, and the failure to take corrective actions when results were inconsistent.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0086

PRACTICAL SKILLS VS ERROR SOURCES FROM THE PRE-PRE-ANALYTICAL PHASE

C. Delianu [2], L.L. Hurjui [2], I.A. Hurjui [1], M. Entuc [3], I. Hurjui [3], L. Foia [2]
[1]*University of Medicine and Pharmacy "Grigore T. Popa" Iasi, Romania*
[2]*University of Medicine and Pharmacy "Grigore T. Popa" and Emergency County Clinical Hospital "St. Spiridon#, Iasi, Romania*
[3]*University of Medicine and Pharmacy "Grigore T. Popa" Iasi, Romania*

BACKGROUND-AIM

More than fifty years ago, the specialists from the College of American Pathologists advanced the concept of laboratory medicine as the core of the patient safety solution, due to its reliability in medical decisions making, and therefore because of the accurate diagnosis and therapies that could be established upon the released results. Through a trinomial collaboration: laboratory-clinician-patient, the disclosure of pre-analytical and post-analytical rejected samples, as well as the reporting of critical values, support promoting appropriate results, in relation to the real biological state of the patient.

METHODS

Our main goal was to determine the bulk of sample rejection and report of critical values, in the period 2020 – 2023, in the Hematology Department of the "St. Spiridon" Emergency County Clinical Hospital in Iasi. The study was carried out on the basis of the identification of pre- and post-analytical non-conformities (using the transvasation procedure).

RESULTS

In the mentioned interval, a number of 12842 samples were rejected pre-analytically, 2924 samples were rejected post-analytically and 9041 critical values were reported. In 2020, a number of 2254 samples were rejected pre-analytically, 493 post-analytically and 2000 critical values were reported; in 2021, 3112 pre-analytical samples were rejected, with 639 post-analytically while 2603 critical values were reported; in 2022 pre-analytically 3925 samples were rejected, post-analytically 974, and the reported critical values recorded a number of 2253. In 2023, 3551 samples were rejected pre-analytically, 818 post-analytically and 2185 critical values were reported.

CONCLUSIONS

Our study confirms that the quality control system needs to be improved in order to boost sample management and quickly identify any shortcomings. Provision of training on blood sample collection and transport could significantly reduce the rate of sample rejection. Moreover, the identification of the clot post-analytically by transvasation reduces the risk of bicytopenia, pancytopenia, false thrombocytopenia and ensures the avoidance of false hyper-, hypocoagulability or dysfibrinogenemia reporting.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0087

VERIFICATION OF THE LAMBDA LIGHT CHAIN ASSAY METHOD ON THE ABBOTT® ALINITY ANALYZER: BIOCHEMISTRY LABORATORY EXPERIENCE AT MOHAMMED IV UNIVERSITY HOSPITAL IN OUJDA

K. Jamal [1], H. Lekfif [1], D. El Moujtahide [1], E. Sebbar [1], M. Choukri [1]
[1]*Biochemistry Laboratory, Central Laboratory Department, CHU Mohammed VI - Oujda, Faculty of Medicine and Pharmacy of Oujda.*

BACKGROUND-AIM

The verification of analytical methods is a requirement of ISO 15189. It involves evaluating the performance of an analytical method according to a well-defined protocol and comparing it to pre-established analytical objectives. Mastery of this process should be a concern for every biologist. Through this work, we present the results of the verification protocol for the Lambda light chain assay method by comparing two analyzers: Abbott® ALINITY. This work serves as a fundamental basis for establishing an accreditation procedure as part of the quality process in which our laboratory is engaged.

METHODS

The verification of the Lambda light chain assay method on ALINITY is carried out using a specific quantitative immunoturbidimetric method between the polyclonal anti-lambda antiserum and the corresponding antigen, under optimal pH conditions and in the presence of polyethylene glycol (PEG).The adopted working methodology is based on the Verification/Validation protocol. The evaluation of analytical performance in terms of repeatability and intermediate precision was performed using two levels of quality control. A method comparison was conducted between two ALINITY analyzers. The statistical data analysis was performed using the method validation module of the BYG Informatics software.

RESULTS

The obtained results show satisfactory repeatability for the two levels (1: low / 2: high) with CV1 = 0.47% and CV2 = 0.49%, respectively. The intra-laboratory reproducibility was satisfactory for the two levels with CV1 = 0.85% and CV2 = 0.22%, respectively. Comparing these with the CV set by SFBC, the results are consistent. The mean bias between the two analyzers is approximately 0.03%, with a linear regression equation of Y = 0.01 X - 1.30. The mean difference is 0.07 g/L, and the standard deviation of the differences is 0.209 g/L.

CONCLUSIONS

The obtained results allowed us to verify the performance of the Lambda light chain assay method and compare them to the analytical objectives set within the accreditation process in which our laboratory is engaged.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0088

METHOD VERIFICATION OF ANTI-THYROPEROXIDASE ANTIBODY ASSAY ON ABBOTT® ALINITY ANALYZER: BIOCHEMISTRY LABORATORY EXPERIENCE AT MOHAMMED IV UNIVERSITY HOSPITAL IN OUJDA

K. Jamal [1], D. El Moujtahide [1], E. Sebbar [1], M. Choukri [1]
[1]*Biochemistry Laboratory, Central Laboratory Department, CHU Mohammed VI - Oujda, Faculty of Medicine and Pharmacy of Oujda.*

BACKGROUND-AIM

Anti-thyroperoxidase (anti-TPO) antibodies target the enzyme thyroperoxidase, which is essential for thyroid hormone synthesis. Their presence is associated with autoimmune thyroid diseases such as Hashimoto's thyroiditis and Graves' disease. They disrupt hormone production, leading to hypo- or hyperthyroidism. The anti-TPO test is used to diagnose and monitor these conditions. Elevated levels can also complicate pregnancy, increasing risks for both the mother and the fetus. The objective of this work is to conduct an evaluation of anti-TPO dosing on the Alinity c Abbott analyzer. This evaluation forms a crucial basis for developing an accreditation procedure, aligning with the quality assurance approach our laboratory has undertaken.

METHODS

The method verification focused on the anti-TPO assay on the Alinity c analyzer to evaluate the analytical performance in terms of repeatability and intra-laboratory reproducibility, carried out using samples from patients hospitalized in our hospital and internal quality controls. Statistical data processing was performed using the intermediate EVM module from BYG Informatics. To ensure the reliability of the obtained results, we compared these measurements to the standards established by the French Society of Clinical Biology (SFBC), and scientific societies (RICOS).

RESULTS

The results obtained for the different verification criteria of the anti-TPO assay show satisfactory repeatability for the three levels (1: low / 2: medium / 3: high) with CV1=1.67%, CV2=1.97%, and CV3=1.17%, respectively. Intra-laboratory reproducibility was also satisfactory for the three levels, with CV1=1.90%, CV2=1.96%, and CV3=1.38%, respectively.

CONCLUSIONS

The results obtained for the various verification criteria of the anti-TPO assay on our Abbott® ALINITY system are accurate and below the tolerated limits when compared with data from the supplier, SFBC, and scientific societies (RICOS). Our study allows us to conclude that our verified system provides the required analytical performance for a reliable anti-TPO assay. We believe that our study constitutes a solid foundation for implementing an accreditation procedure for the tests used in our laboratory.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0089

A NOVEL INTEGRATED APPROACH USING STANDARD DEVIATION AND VARIANCE INDEX SCORING SYSTEMS FOR DETECTION OF PROFICIENCY TESTING INCONSISTENCIES IN MEASURAND PERFORMANCE

P. Jana [1], E. Debnath [1], P. Chauhan [1], R. Singh [1]
[1]*Dept of Biochemistry, Lady Hardinge Medical College & Associated Hospitals, University of Delhi, New Delhi*

BACKGROUND-AIM

Proficiency testing (PT) is integral to a laboratory's quality improvement process. PT programs utilize different scoring methods for assessing measurand performance of participating laboratories like Standard Deviation Index (SDI), and Target Score (TS). Variance Index Score (VIS) is an alternative method that uses a chosen Coefficient of Variation (CV%) in the index system, allowing laboratories to define individualized imprecision acceptance limits. Our study has evaluated each score's empirical performance and developed a novel approach for improved detection of inconsistencies in PT performance.

METHODS

Performance of 27 measurands routinely assayed by the laboratory, enrolled with a UK-based PT provider, was recorded throughout 2024. SDI and TS were obtained from monthly PT reports. VIS was calculated individually for each measurand based on CV% from PT monthly reports (VIS1), CV% which fulfills Clinical Laboratory Improvement Amendments criteria for acceptable PT performance (VIS2), and median CV% for within-subject biological variation obtained from the European Federation of Clinical Chemistry & Laboratory Medicine database (VIS3). A PT report was defined as inconsistent if SDI≥2, TS≤50, or VIS1/2/3 ≥200.

RESULTS

Receiver Operator Characteristics curve analysis showed that VIS3 had a higher Area Under Curve (AUC) than VIS1/2 (0.97>0.94>0.936, p<0.001). VIS3 also had a higher AUC than TS and SDI (0.97>0.957>0.956, p<0.001). Cohen's κ analysis showed significant agreement between VIS1/2/3 and between VIS3 and TS/SDI (p<0.001). Scatter analysis between SDI & VIS3 showed significant heteroscedasticity, corrected by log transformation of VIS3. The harmonic mean (HM) of SDI and LogVIS3 was calculated and found to have higher AUC than TS (0.963>0.957, p<0.001). Univariate logistic regression model showed that HM predicted PT inconsistencies with 99.3% accuracy (R^2=0.965, p<0.001).

CONCLUSIONS

Our novel harmonic mean-based approach improves detection of PT inconsistencies compared to conventional scores, integrates laboratory-optimized allowable imprecision accounting for biological variation, and overcomes the limitations of TS. However, it needs multiple interlaboratory validations for practical applications.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0090

EVALUATING THE EFFECT OF MEDICAL GLOVES ON HAND TACTILITY OF THE PHLEBOTOMISTS

C. Kao [2], P. Su [2], J. Huang [1]
[1]*Department of Education and research, St. Martin De Porres Hospital, Taiwan*
[2]*Department of Laboratory Medicine, St. Martin De Porres Hospital, Taiwan*

BACKGROUND-AIM

The World Health Organization mandates gloves during blood collection to minimize the risk of infections from sharps injuries and exposure to bodily fluids. While many healthcare professionals acknowledge the importance of wearing gloves, some fear that gloves may reduce tactile sensitivity and hinder patient vein identification. This study explores the impact of various medical glove materials and thicknesses on tactile sensitivity and patient vein identification skills, considering the experience level of phlebotomists.

METHODS

Objective tactile sensitivity was evaluated using the Semmes-Weinstein Monofilament (SWM) test across seven glove conditions: ungloved (bare hands) and six types of gloves (single and double layers of latex, vinyl, and nitrile). Data was analyzed with two-way ANOVA and Kruskal-Wallis tests to compare glove conditions and phlebotomists' experience levels. Thirty-two participants with varying experience levels rated their subjective experiences with vein identification on a five-point Likert scale. Logistic regression assessed the risk of impaired vein identification by glove type.

RESULTS

The two-way ANOVA showed no interaction between glove conditions and experience levels, but significant differences in tactile sensitivity were noted among glove types. Post hoc tests indicated that ungloved conditions yielded higher sensitivity than all gloves. Logistic regression analysis revealed that double-layer gloves were associated with a higher risk of impaired vein identification, with double-layer latex gloves presenting a nine-fold risk compared to single-layer latex gloves. No significant correlations were found between objective tactile sensitivity and subjective experiences with vein identification.

CONCLUSIONS

The study emphasizes the importance of selecting appropriate gloves for blood collection, as both single and double-layer gloves can diminish tactile sensitivity, affecting patient vein identification. Experience level did not significantly impact tactile sensitivity, indicating that even seasoned practitioners might struggle with certain glove materials and wearing glove layers. It stresses the necessity of carefully considering glove materials and wearing glove layers to ensure optimal safety and effectiveness.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0091

PROBLEMS AND CHALLENGES FOR THE WORK OF LABORATORY DIAGNOSTICS DEPARTMENTS IN FRONTLINE REGION DURING WARTIME

M. Kuznetsova [1], V. Bibichenko [1], I. Kuznetsova [1], K. Kuznetsov [1]
[1]*Kharkiv national medical university*

BACKGROUND-AIM

The war in Ukraine has changed the views on doctors' professional activities in many medical occupations and laboratory doctors in particular. Well-coordinated work of laboratory departments in hospitals directly provides a positive treatment result in 95% of cases. So it is of interest to understand how exactly the war may change the work organization of laboratory directors and their subordinates.
The aim of current work was the determination of the war impact on the activity of laboratory departments in hospitals of Kharkiv city.

METHODS

Materials and methods. 79 participants were involved into the investigation (67 women and 12 men). Everyone among them had either secondary or higher medical education and were employed in Kharkiv city hospitals. Sociological research was conducted through surveys and interviewing.

RESULTS

Results. 97% of respondents reported about changes in mode of their duty performance; together with that 89% mentioned an increased concentration on express diagnostics while the rest (11%) have focused on routine examination.
Main problems which the medical laboratory employees face the most were the intensification of the workload because of staff reduction in hospital laboratory departments due to migration from frontline regions. Many of laboratory directors had to deal with staff deficiency mostly by retraining of workers remained (86%) and by invitation of graduates from medical universities and colleges (14%). Furthermore, the were 47% of cases when the head of laboratory complained about an discrepancy between present medical regulatory standards and actual problems and challenges which the laboratory workers have to cope with being on duty.

CONCLUSIONS

The essentials of the results obtained from conducted research allow to state that one of the most serious challenges for the development of laboratory medicine is acute deficiency of qualified personnel and regulatory standards that are inconsistent to actual work cases in this branch of healthcare system.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0092

SETTING UP A QUALITY-MANAGED LABORATORY FOR CLINICAL VACCINE TRIALS DURING PUBLIC HEALTH EMERGENCIES IN A RESOURCE-CONSTRAINED SETTING: THE SIERRA LEONE EXPERIENCE

B.J. Lawal [2], F. Faye [2], G.T. Otieno [2], M.T. Kroma [1], A. Drammeh [2], A.S. Turay [1], B. Lowe [2], B. Leigh [1], M. Samai [1], B. Greenwood [2], D. Watson-Jones [2]

[1]*College of Medicine and Allied Health Sciences, University of Sierra Leone*
[2]*Faculty of Infectious Tropical Disease, Department of Clinical Research, London School of Hygiene and Tropical Medicine*

BACKGROUND-AIM

Quality laboratory results are crucial to detecting and responding to emerging and re-emerging infectious diseases. We share our experiential learnings in creating a quality-managed laboratory in a resource-constrained setting during an emergency disease outbreak.

METHODS

The laboratory was established in September 2015 in Kambia, northern Sierra Leone. Starting with two prefabricated containers, one international laboratory scientist and two local laboratory technicians with basic experience, the laboratory supported the assessment of eligibility, safety, and storage of blood samples to evaluate a prophylactic Ebola vaccine regimen. Within the first two years, quality-oriented activities were implemented such as temperature and humidity monitoring, developing Standard Operating Procedures (SOPs), training, regulatory inspections, and internal audits. Quality Management System (QMS) was introduced to control all the phases of laboratory work. In 2019, the QMS was strengthened following an external assessment and laboratory processes were aligned with the Good Clinical Laboratory Practice (GCLP) standard.

RESULTS

In nine years, facilities expanded to 12 rooms - a combination of prefabricated containers and a mortal building, equipped with modern analysers and equipment, and the staff strength rose to 20 at the peak. The technical and quality competences of local and international staff heightened to perform complex sample analysis instead of shipping them to foreign laboratories. Queries and lab errors dropped by 80%, External Quality Assurance (EQA) performance rose from an average of 70% to 90% and above, errors were detected proactively and prevented from recurrence, and compliance with health and safety rules improved. The testing capacity advanced from basic tests to include molecular techniques, multiplex bead-based ELISA, Immunology, and biobanking. To date, the laboratory has successfully supported seven clinical trials of phases II and III of Ebola vaccines, COVID-19 vaccine, and many observational studies. In August 2024, the laboratory attained the GCLP accreditation.

CONCLUSIONS

With a resilient and competent team willing to adapt, setting up laboratories in resource-constrained settings with quality-oriented work outputs is doable.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0093

COMPARISON OF SERUM SPECIFIC IGE ANTIBODIES MEASUREMENT ON W1, D1 ALERGEN AND GX1 ALERGEN MIXTURE ON TWO THERMO FISHER PHADIA PLATFORMS

I. Lokner [2], S. Marević [1], I. Imširović [1]
[1]*Clinical Department for Laboratory Diagnostics, University Hospital Dubrava, Zagreb, Croatia*
[2]*Department of Laboratory Diagnostics, Special Hospital for Pulmonary Diseases, Zagreb, Croatia*

BACKGROUND-AIM

Specific IgE antibodies are produced by our immune system in response to allergens, and their presence in blood can indicate sensitization to a specific allergen. We compared the results of measurement of specific IgE on w1 (Ambrosia artemisiifolia (ragweed)), d1 (Dermatophagoides pteronyssinus (house dust mite)) and alergen mix gx1 (Dactylis glomerata (cocksfoot); Festuca elatior (meadow fescue; Lolium perenne (Reye grass); Phleum pratense (Timoty grass); Poa pratensis (meadow grass)) on two Thermo Fisher Phadia platforms. Phadia 250 is high throughoutput instrument (250 tests/hour), while Phadia 200 is intended for medium throughoutput laboratories.

METHODS

In Special hospital for pulmonary diseases we analysed 40 fresh patient samples on Phadia 250 by ImmunoCAP method for the presence of specific IgE antibodies on w1, d1 and, gx1 alergens. Frozen samples were transported to University Hospital Dubrava and analyzed on Phadia 200 by the same method. Statistical analysis was done in MedCalc Statistical Software (version 14.8.1, Ostend, Belgium) with Bland-Altman analysis (BA), Passing-Bablock regression (PB), and κ-coefficient ($P<0.05$).

RESULTS

Results of BA analysis (mean difference and 95% CI) and PB regression Phadia 200 vs. Phadia 250 were as follows: for d1 (46.3 (-33.7-126.2 %); (y=0.009 (-0.001 to 0.012) + 0.52 (0.461 to 0.600) x), for w1 (52.4 (-62.9-167.6) %); (y=-0.004 (-0.006 to 0.001) + 0.691 (0.648 to 0.727) x). For gx1 we tested 25 negative samples and 15 positive samples. There is a slight disproportion in results around the cut-off value, nevertheless, kappa coefficient of 0,833 was obtained, which represents a strong agreement.

CONCLUSIONS

No significant differences were found between Phadia 250 and Phadia 200 measurements, hence the results between these two instruments are interchangeable.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0094

IS HEMOLYSIS REFLECTED IN THE POTASSIUM OF A BLOOD GAS?

J. Cabanes Madrid [1], R. Mateos Pablos [1], M.d.V. Romero Real [1], S. Peral García [1], J. Sanz Gómez [1], F. Calvo Boyero [1], D. Párraga García [1], E.A. López Jiménez [1]
[1]*Hospital Universitario 12 de Octubre, Madrid*

BACKGROUND-AIM

In many cases, mainly from the Emergency Department, our laboratory receives both a lithium heparin tube (LHT) for plasma biochemistry analysis and a heparinized syringe (HS) for venous blood gas analysis from the same patient.
For LHT samples, according to the method insert, our laboratory has established that when the hemolysis index (HI) is between 90 and 299, the potassium ion value in serum/plasma is reported with a comment indicating “Result affected by hemolysis” and, if the HI is 300 or higher, the potassium value is cancelled. In contrast, in our setting, blood gas analysis lacks a measurement for the HI.
Therefore, the aim of the study is to determine whether there are differences between plasma potassium values at different levels of hemolysis and the corresponding blood gas analysis obtained from the same patient in a single laboratory request.

METHODS

Using the OMNIUM program from Roche Diagnostics®, all requests from 2023 in which hemolysis index (HI) and plasma potassium were measured in LHT (by indirect potentiometry on the Cobas 8000 ISE module) and in HS (by direct potentiometry on the GEM PREMIER 5000 system) were collected (n=1580). The values are categorized based on the HI of the plasma samples into 9 groups.
Finally, an analysis of the mean difference between the potassium values of the plasma samples and their corresponding blood gas analysis in the different hemolysis groups is performed using the Bland-Altman method.

RESULTS

Although it is true that potassium levels increase in both types of samples as the hemolysis index (HI) rises, a growing systematic bias is observed between them as the ion value increases (the mean difference becomes progressively larger), with the LHT showing the largest increase in magnitude.

CONCLUSIONS

This difference may be due to the centrifugation process to which the LHT is subjected, unlike the HS. Another possibility is the processing time, which is longer for the LHT. However, the correlation between the HI and the potassium value in the HS suggests that, although it undergoes less hemolysis than plasma, its values may still be interfered with.
For all these reasons, a new laboratory test should be requested from the referring service in order to provide the patient with a reliable result and avoid any diagnostic error.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0095

COMPARATIVE STUDY OF TWO DIFFERENT METHODS FOR FECAL CALPROTECTIN MEASUREMENT

M.d.V. Romero Real [1], R. Mateos Pablos [1], J. Sánchez Munárriz [1], S. Peral García [1], J. Cabanes Madrid [1], J. Sanz Gómez [1], A. Delmiro Magdalena [1], E.A. López Jiménez [1]
[1]*Hospital Universitario 12 de Octubre*

BACKGROUND-AIM

Calprotectin is a calcium- and zinc-binding protein released during gastrointestinal inflammation processes due to the degranulation of neutrophil granulocytes in the intestinal mucosa. Due to its stability in stool samples, calprotectin provides a non-invasive option for assessing localized inflammation, being highly sensitive for detecting intestinal inflammation and useful in the differential diagnosis of Inflammatory Bowel Disease, which includes Crohn's disease and ulcerative colitis, and Irritable Bowel Syndrome.
The aim of this study was to compare the performance of two methods for fecal calprotectin analysis to evaluate their interchangeability and clinical applicability

METHODS

A total of 114 stool samples were collected for calprotectin determination using turbidimetric immunoassays from Bühlmann and Sentinel Diagnostics. Fecal extracts were prepared using the CALEX® sample container for Bühlmann assay and the CALiaGold ® container for Sentinel assay. In both cases, samples were vortexed to achieve complete homogenization. The obtained results were compared using MedCalc statistical software, applying Passing-Bablok regression and Bland-Altman difference analysis, as well as Cohen’s Kappa index.

RESULTS

The Passing-Bablok regression equation, y = 17.4199 (10.2286–18.4367) + 0.4486 (0.3760–0.5518)x, indicates both constant and proportional error between the two methods, as the slope does not include the value 1 and the intercept does not include zero within their confidence intervals. Regarding the Bland-Altman mean difference, the confidence interval for absolute differences does not include zero, demonstrating the presence of constant error too.
Both methods define the following ranges for clinical evaluation: <50 as a negative result, >200 as a positive result, and 50–200 as an indeterminate zone. Cohen’s Kappa index was calculated to assess the level of agreement across these categories. A Cohen's Kappa index of 0.507 was obtained indicating moderate agreement between methods.

CONCLUSIONS

Due to the quantitative and categorical discrepancies observed, the two methods cannot be considered interchangeable.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0096

DETERMINATION OF LOWER ANALYTICAL LIMITS FOR THYROID STIMULATING HORMONE 3RD INTERNATIONAL STANDARD ASSAY ON THE ANALYZER BECKMAN COULTER DXI 800

L. Mavrić [1], S. Semenski [1], B. Kranjčec [1], V. Šenjug [1], K. Klenkar [1], G. Tkalec [1], A. Lešković [1]
[1]*Zabok General Hospital and Hospital of Croatian Veterans*

BACKGROUND-AIM

For determination of thyroid stimulating hormone (TSH) levels, Medical Biochemistry Laboratory of the Zabok General Hospital and the Hospital of Croatian Veterans uses Beckman Coulter's Access TSH 3rd international standard (3rd IS) assay, which is claimed by the manufacturer to be capable of providing 3rd generation TSH results, and thus requires verification of the lower analytical limits. The aim of the research is to confirm the manufacturer's validated lower analytical limits of the assay.

METHODS

The verification procedure was performed according to the Clinical & Laboratory Standards Institute's guidelines CLSI: EP17-A2:2012 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures. It included verification of Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantification (LoQ).

RESULTS

For LoB, 20 measurements of a sample that does not contain TSH were made, and the values obtained for each TSH measurement were arranged in an ascending series of values. The 95th percentile of the data distribution was determined. Then 20 TSH measurements were determined for the LoD at the limit for which the condition is that 85% of the measurements have a value above the LoB. If the LoD meets the predefined acceptance criteria of the method, it is considered equal to the LoQ. For LoB TSH 3rd IS, the 95th percentile is the 19.5th value for TSH, which is 0.001 mIU/L and covers the interval up to 0.004 mIU/L. For this reason, a TSH value of 0.005 mIU/L was taken for the LoD, where CV=19.09% was determined, so it can be concluded that the criterion for analytical quality is met according to the defined biological criterion of desirable values for the total error of the method for Access TSH 3rd IS. Therefore LoD can be considered equal to LoQ.

CONCLUSIONS

After verification of the lower analytical limits, the LoD for TSH of 0.005 mIU/L is accepted according to the manufacturer's declaration for the Access TSH 3rd IS assay and thus the determination of extremely low TSH levels was confirmed to be reliable.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0097

STABILITY STUDY OF LACTATE DEHYDROGENASE

P. Orejas Rodríguez-Marqués [1], R. Nicolás De Blas [1], M. Menacho Román [1], S. Olivares Romero [1], I. Arribas Gómez [1]
[1]*Clinical Biochemistry Laboratory, Ramón y Cajal University Hospital, Madrid, Spain*

BACKGROUND-AIM

Lactate dehydrogenase (LDH), a key biomarker released during tissue damage, is crucial for cellular energy metabolism. In the laboratory, we questioned whether LDH activity could remain stable over the weekend for processing on Monday. The aim of this study was therefore to assess the stability of LDH in blood samples stored under refrigerated conditions.

METHODS

For such purpose, 10 samples of serum free of haemolysis were split into seven aliquots that corresponded to each time studied: baseline, 12, 24, 36, 48, 60 and 72h, which were stored at 4-8ºC. At each designated time point, the corresponding aliquots were frozen at -80°C. All aliquots were thawed, homogenized and analysed in a single run. Following IFCC guidelines, LDH activity was determined by the lactate:pyruvate method in Alinity analyser (Abbott). Determinations were performed in sextuplicate considering the ratio between maximum allowable difference (MAD) and the usual analytical imprecision in our laboratory (CV=2.18%).
Loss of stability was expressed as the percentage difference (%PD) between the replicate measurements in each sample calculated using the formula:
%PD = [(Concentration (Xh) – Concentration (0h)) / Concentration (0h)] * 100
The MAD was determined according to laboratory quality standards (4.7%, minimum systematic error calculated using the Biological Variation formula provided in the EFLM database). The PD that exceeding this threshold were considered indicative of clinically significant instability.

RESULTS

After analysing the samples, the following instability equation was obtained, PD%= -0.0616 x time (h). This equation has a Pearson correlation coefficient of 0.74. This equation shows a daily loss of stability of 1.5%. Using the MAD of 4.7%, the calculated stability limit for LDH under these conditions is 72 hours. These results are consistent with the observed results, which show a progressive decrease in LDH activity with increasing refrigerated storage time.

CONCLUSIONS

The study showed a loss of LDH activity over several hours in refrigerated samples, with a loss of stability after 72 hours. It's important to be cautious when monitoring LDH in refrigerated samples, as the progressive loss of stability could affect the reliability of diagnostic results.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0098

EVALUATING THE ROLE OF STRUCTURED TRAINING MODULES IN ENHANCING NABL ACCREDITATION PREPAREDNESS

V. Patel [1], D. Verma [1], A. Ahirwar [1], S. Datta [1]
[1]*Department of Laboratory Medicine, All India Institute of Medical Sciences, New Delhi*

BACKGROUND-AIM

In India, the National Accreditation Board for Testing and Calibration Laboratories (NABL) is the sole laboratory accreditation body, operating under ISO's International Standards via its membership in APLAC and ILAC, with global recognition through MRA. Achieving accreditation involves strict compliance with protocols across pre-analytical, analytical, and post-analytical processes. Structured staff training is a key component in ensuring laboratories meet these stringent requirements. This study investigates the impact of such training programs on staff competency, adherence to protocols, and overall laboratory preparedness for NABL accreditation.

METHODS

This observational study was conducted in a clinical laboratory attached to a tertiary care teaching hospital in India for a period of 8 months. Training modules were developed to address the gaps such as sample handling, quality control measures, analytical workflows, documentation practices, and result reporting, as per the internal audits. Staff competency was assessed both before and after training. Additionally, audit results, final NABL assessment reports, and NC logs were analyzed to evaluate changes in compliance. Improvements in staff competency, reductions in NCs, and audit performance were evaluated using appropriate statistics like paired t-test etc.

RESULTS

Staff competency improved significantly from Pre-training mean score of 4.5+1.5 to 8.5+1.0 Post-training ($p < 0.001$).Staff feedback indicated enhanced understanding of ISO 15189:2022 standards and greater confidence in implementing quality practices. Pre-analytical errors showed a substantial decline, while accuracy in reporting improved considerably.

CONCLUSIONS

Following the training, staff competency improved by 40%. Nonconformities decreased significantly, with reductions of 50%, 35%, and 40% observed in the pre-analytical, analytical, and post-analytical phases, respectively. This study demonstrates that targeted training interventions not only facilitate successful NABL accreditation but also establish a robust quality culture within the laboratory.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0099

PERFORMANCE ASSESSMENT OF BIOCHEMICAL ANALYTES USING RISK MANAGEMENT INDEX AND SIGMA METRICS

S. Perkov [1], M. Dorotić [1], N. Parašilovac [1], I. Friščić [1], M.M. Kardum Paro [1]
[1]*Department of Medical Biochemistry and Laboratory Medicine, Merkur University Hospital, Zagreb, Croatia*

BACKGROUND-AIM

The risk management index (RMI) is a new risk based quality management tool that relates the predicted probability of patient harm (PH) to the acceptable PH. The aim of this study was to evaluate and compare RMI with the sigma metric (SM) of biochemical analytes using Bio-Rad Mission Control (MC) software.

METHODS

The analytical performance of Beckman Coulter DxC700AU measurement system was evaluated using third-party QC materials from Bio-Rad across two levels for 23 biochemical analytes. RMIs were calculated as the ratio of predicted PH to the allowed PH according to input parameters (number QC results and patients per day, QC rules, source of Total Error allowable (TEa), mean time between failures, probability and severity of PH). MC software calculated the SM for each QC concentration as well as the average sigma over the concentration range.

RESULTS

Of the 23 biochemical analytes, 6 (gamma glutamyltransferase, cholinesterase, creatine kinase, total bilirubin, creatinine, iron) showed world-class performance (SM>6), 13 (alkaline phosphatase, alanine aminotransferase, lactate, direct bilirubin, total protein, UIBC, urea, inorganic phosphorus, albumin, triglycerides, glucose, potassium, magnesium) showed satisfactory performance for both QC levels (3>SM<6), while 5 showed poor performance on one or both QC levels (SM<3). All analytes showed managed RMI (RMI≤ 1). Biochemical analytes with poor performance included chlorides (SM 2,7 for QC level 1, RMI 0.021), sodium (SM 2,8; RMI 0,619), total calcium (SM 2,5; RMI 0,489), HDL cholesterol (SM 2,4 for QC level 1; RMI 0,067) and total cholesterol (SM 1.6; RMI 0.369).

CONCLUSIONS

MC software is an excellent risk management tool that quantitatively evaluates RMI. For all biochemical analytes, the RMI was ≤ 1, indicating that the capability and reliability of the measurement system, combined with the laboratory's internal QC strategy, keeps the risk of unintentional PH at an acceptable level. Furthermore, analytes with low SM, due to their low biological variation, present a challenge in meeting the strict requirements of TEa.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0100

FAECAL IMMUNOCHEMICAL TEST (FIT) EQAS SCHEMES: THE IFCC FIT WORKING GROUP SURVEY

C. Piggott [4], M. Thelen [2], S. Jones [5], P. Kocna [3], S. Benton [1]
[1]*Berkshire and Surrey Pathology Services, Royal Surrey NHS Foundation Trust, Guildford*
[2]*Foundation for Quality Assessment In Medical Laboratory Diagnostics (SKML), Nijmegen*
[3]*Gastroenterology Laboratory, Institute of Medical Biochemistry and Laboratory Diagnostics, Prague*
[4]*NHS Bowel Cancer Screening Programme, Southern Hub, Guildford*
[5]*Welsh External Quality Assessment Scheme (WEQAS), Cardiff*

BACKGROUND-AIM

Faecal immunochemical tests for fecal haemoglobin (FIT) are used to triage patients for lower gastrointestinal tract investigations in colorectal cancer (CRC) screening programmes, and increasingly in patients with symptoms of CRC. External quality assessment schemes (EQAS) enable clinical laboratories to monitor FIT performance compared with other users. EQAS for FIT exist worldwide, and though ISO standards exist, there is no guidance specifically for FIT.
A term of reference for the International Federation of Clinical Chemistry (IFCC) FIT Working Group (FIT WG) was to investigate the availability and detail of FIT EQAS.

METHODS

A survey was designed consisting of 21 questions about the schemes' purpose, testing environments, distribution frequencies, sample presentation, target value source, units, concentration ranges, result analyses and performance criteria. The survey was sent to European EQA Organizers in Laboratory Medicine (EQALM), the Japanese Association of Medical Technologists (JAMT) and to other EQAS that showed FIT on websites, identified by Google searches.

RESULTS

24 schemes were identified, though assay information was not easily available on all EQAS websites; there were 16 survey responses. The results showed that schemes exist for CRC screening programmes and symptomatic testing, for qualitative and quantitative testing, in laboratories and point of care testing. There were 1-12 sample distributions per year. Results were reported in a variety of units including ng/mL, µg/L, µg/g and ng/g. 11 concentration ranges were covered. 69% of schemes did not provide faecal-based samples and 88% did not provide samples in the bottles that patients use. For schemes providing faecal-based samples, 63% used a generic buffer. For source of target values, 63% of schemes used the method group consensus; for performance criteria 50% used state-of-the-art analytical goals. Performance was reported using 5 different methods.

CONCLUSIONS

As a result of the survey the group is considering 'What does an ideal FIT EQAS look like?' and aims to provide guidance to enable schemes to be fit for purpose. The outcome of this survey will also be used by the FIT WG to identify which aspects are required for guidance towards an ideal EQA, to check successful implementation of assay harmonisation.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0101

THE POTENTIAL OF PLATELET TGF-β AND SMAD2 MRNAS AS BIOMARKERS FOR COLON CANCER DIAGNOSIS AND GRADING

H. Shao [3], Y. Huang [3], Q. Wang [1], R. Liu [2], L. He [1], L. Qu [3]
[1]*Department of Gastrocolorectal Surgery, General Surgery Center, The First Hospital of Jilin University, Changchun*
[2]*Department of Genetics and Prenatal Diagnosis, Hainan Women and Children's Medical Center, Haikou*
[3]*Department of Laboratory Medicine,The First Hospital of Jilin University, Changchun*

BACKGROUND-AIM

Currently, liquid biopsy have been widely investigated for improving diagnosis and monitoring in colon cancer management. As a potential sample type, platelets are abundant in the circulation taking multiple information closely related to tumors. Previously we found potential relationship of TGF-β/Smad2 expression in circulating platelets and local tumor tissues. In this study, we reported our further work on platelet TGF-β/Smad2 expression with regard to carcinogenesis and metastasis in colon cancer. As well, we investigated the feasibility of platelet TGF-β/Smad2 as diagnostic and predictive biomarkers.

METHODS

We performed bioinformatics study on GSE68086 database to identify differentially expressed platelet mRNAs, followed by Kyoto Encyclopedia of Genes and Genomes (KEGG) pathway enrichment. For the 104 participants including colon cancer patients and healthy individuals, expressions of TGF-β and Smad2 mRNAs were quantified in platelets and tissues. We analyzed correlations of platelet mRNAs with local tumor and the pathological characteristics. We also established the cut-off values of platelet TGF-β and Smad2 mRNA level for colon cancer diagnosis.

RESULTS

KEGG displayed highly enrichment of platelets TGF-β and SMAD2 in colon cancer. TGF-β and Smad2 mRNAs were upregulated in patients' platelets and tumors ($P<0.05$). Platelets Smad2 expressed higher levels in high-grade tumors ($P<0.05$). Diagnostic performance of platelets TGF-β and Smad2 mRNA levels showed sensitivity and area under curve (AUC) of 86.36% and 0.8947, respectively ($P<0.05$).

CONCLUSIONS

Platelets TGF-β and Smad2 can synchronously reflect local tumor malignancy and differentiation, which may be potential biomarkers for colon cancer diagnosis.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0102

UTILIZATION PATIENT RESULT THROUGH PATIENT-BASED QUALITY CONTROL (PBQC) IN SMALL LABORATORY: SERUM SODIUM EXAMPLE

U.R. Hapsari [1], B.N. Rohima [1]
[1]*Department of Laboratory, Dr. Yap Eye Hospital, Yogyakarta, Indonesia*

BACKGROUND-AIM

Internal quality control (IQC) is a main strategy of laboratory quality control. Serum sodium patient results can be used for internal quality control (IQC) in medical laboratories through patient-based quality control (PBQC) as it needs a small biological variation and requires high analytical performance. PBQC is a tool that monitors the performance of testing processes. Patient-generated data is better at detecting errors when there is less biological variation. Using patient serum sodium data compared error detection effectiveness PBQC and IQC. Objective: To utilize patient serum sodium data for internal quality control in a medical laboratory through patient-based quality control (PBQC). Comparison of the effectiveness the quality control based on moving average value and traditional method.

METHODS

Serum sodium was measured by using an indirect ion-selective electrode method. Data collection with a small examination volume in a small laboratory takes longer to be used and utilized for patient-based results quality control. The number of serum sodium patient-generated data and 805 IQC from October 2022 to December 2024 (2 years) were used. For PBQC, average values, and standard deviations were calculated, and z-score charts were plotted for the selection of bias detection simulation methods.

RESULTS

Data collection with a small examination volume takes longer but utilization of patient-based results for internal quality control may be running. Data taken for 2 years from serum sodium examination preferred set moving average method with a block size 20 to detect 5% bias for 0% of Acceptable False Positive Rate. Using 805 IQC data, there were 3 systematic and 5 random errors detected on the 540th day. Meanwhile, using PBQC, 24 alarms were detected on the 531st day.

CONCLUSIONS

This study showed that utilization of sodium patients results in a small volume laboratory, previously optimized Moving Average procedures could be implemented and used for continuous quality control. PBQC timeliness alarm detected earlier the the IQC.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0103

ISSUE IN THE VERIFICATION OF AN ANALYTICAL TECHNIQUE: LIPOPROTEIN (A)

I. Aníbarro Miralles [1], S. Rubio Lanchas [1], L. Mayán Santos [1], S. Herrero Castellano [1], A. García Varela [1], W. Trapiello Fernández [1], A. Zapico Belloso [1], B. Aguirre Gervas [1], G. Velasco De Cos [1], A.B. Guerrero Peral [1], M.D. Calvo Nieves [1]
[1]*Hospital Clínico Universitario de Valladolid*

BACKGROUND-AIM

In this study, we present a practical case where initial verification did not yield satisfactory results but revealed an issue that was resolved through specific modifications.

METHODS

The study focused on the Lipoprotein(a) technique by Binding Site®. The verification used controls provided by the manufacturer: High Control(HQC) Low Control(LQC)
Study Design:
Intra-day:16 consecutive measurements of HQC and LQC were performed in a single day.
Inter-day:27 measurements of both controls were conducted over multiple days.
Standard deviation(S), standard score(Z), and analytical coefficient of variation(CVa) were calculated.

RESULTS

HQC:
Intra-day:
S:4.13
Z:0.35
CVa:3.41
Inter-day:
S:2.88
Z:0.25
CVa:2.96
LQC:
Intra-day:
S:-2.65
Z:-0.56
CVa:5.46
Inter-day:
S:-3.41
Z:-0.70
CV:5.17
To accept the technique, desirable CVa values of <5% were sought, according to the biological variability of Lp(a).
The initial results showed that the low controls did not meet this specification.Examination of the data revealed significant negative deviations in several measurements,.
This finding was concerning because the low control is critical for evaluating the threshold between normal and pathological Lp(a) levels.
Lp(a) measurement should only be performed once in a lifetime, except in specific cases (Lp(a)-reducing treatments or the onset of cardiac pathology).Therefore, this technique needed to meet high standards of precision and reproducibility.
All process steps were reviewed.
During inspection, it was observed that the reagents had bubbles generated during transport, which could have affected measurement accuracy.After carefully removing the bubbles, the technique verification process was repeated.
In the new verification, the results improved significantly, meeting the required criteria to approve the technique.

CONCLUSIONS

This case highlights the importance of reviewing all factors, especially in situations with unsatisfactory results, before discarding a technique.A meticulous inspection can reveal correctable issues and prevent the rejection of valid and useful methods for the laboratory. Additionally, analyzing such data could assist other laboratories when facing similar problems.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0104

INTERCHANGEABILITY STUDY OF FREE LIGHT CHAIN RESULTS BETWEEN OPTILITE® AND BNII®.

M. Ruiz Medina [2], A. Caro Pradillos [2], M.T. Carande Del Río [1], N. Rico Ríos [2], A. Sáez-Benito Godino [2]
[1]*Hospital Universitario de Badajoz, Badajoz (Spain)*
[2]*Hospital Universitario Puerta del Mar, Cádiz (Spain)*

BACKGROUND-AIM

Quantification of FLCκ and FLCλ in serum allows calculation of the κ/λ ratio, one of the diagnostic, prognostic and follow-up criteria for monoclonal gammopathies.The aim of the study is to evaluate the interchangeability between the Optilite(The Binding Site) analyzer for FLC quantification by immunoturbidimetry and the currently used BNII(Siemens-Healthineers) analyzer based on nephelometric methods, in order to implement such determination on the Optilite

METHODS

54 patient samples were selected for FLC quantification. They were processed in parallel and comparison was performed by Passing Bablok regression analysis and Bland-Altman difference analysis using Analyse-it for Microsoft Excel

RESULTS

The results of the statistical analysis obtained are as follows:
- FLCκ: regression analysis Y=3,22(95%CI:1,93-4,78)+0,86(95%CI: 0,83-0,93)X; correlation coefficient 0,98. The mean of the differences is -0,36%(95%CI: -4,49-3,78)
- FLCλ: regression analysis Y=-1,36(95%CI:-2,11 to -1,05)+1,06(95%CI:1,05-1,08)X; correlation coefficient 0,99. The mean of the differences is -3,52%(95%CI:-7,65-0,61)
- κ/λ ratio: regression analysis Y=0,12(95%CI:-0,004-0,28)+0,91(95%CI: 0,84-1,03)X; correlation coefficient 0,99. The mean of the differences is 3,13%(95%CI: -3,12-9,37)

CONCLUSIONS

From the Passing-Bablok regression analysis, a correlation coefficient greater than 0.975 is obtained in all cases, indicating that the correlation is good. In the case of the FLCκ and FLCλ measurement, it's deduced that there's a constant and proportional systematic error, due to the fact that in both cases the confidence interval for the ordinate and slope doesn't include the value 0 and 1, respectively. In both cases the slope is positive, which indicates that Optilite has a constant and higher systematic error than BNII. However, when calculating the κ/λ ratio, these errors are compensated and there's no bias, the technique being totally interchangeable for this purpose. From the Bland-Altman analysis we conclude that there's a homogeneous distribution and no bias, since the confidence interval of the mean of the differences passes through zero. Moreover, these means are lower than the optimal total error calculated by EFLM. Therefore, they're interchangeable and it wouldn't be necessary to obtain new reference ranges.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0105

APPLICATION OF THE SIX SIGMA APPROACH IN HEMOSTASIS AT THE HEMATOLOGY LABORATORY OF LA RABTA HOSPITAL

S. Sfaxi [1], S. Sarra [1], N. Gharbi [1], H. Baccouche [1], S. Mahjoub [1], A. Chakroun [1]
[1]*Hematology laboratory, Rabta Hospital, Tunis, Tunisia*

BACKGROUND-AIM

In medical biology, the pursuit of quality should be the constant concern of every laboratory director to ensure the reliability of results. In this regard, implementing a quality control management system is crucial.
Our objective is to apply the Six Sigma method to hemostasis in the hematology laboratory at La Rabta Hospital.

METHODS

This is a prospective descriptive study conducted in the hematology laboratory at La Rabta Hospital. It focused on six hemostasis parameters: prothrombin level (PL), activated partial thromboplastin time (aPTT), fibrinogen, factor VIII, antithrombin (AT), and D-dimers.
The analytical performance of these parameters was evaluated by calculating the Six Sigma level over one-month period (February 19 – March 19, 2024). To achieve this, the coefficient of variation (CV) and bias were calculated from the data of the external quality assessment (EQA) reports. The acceptable total error (ATE) was determined from various reference standards.

RESULTS

Our study revealed insufficient performance for factor VIII (Six Sigma level was 0.44 and 1.33), intermediate performance for PL, aPTT, INR (Six Sigma level for PL ranged from 0.02 to 3.07, for aPTT from 0.64 to 4.8, and for INR from 0.22 to 3.8), fibrinogen (Six Sigma level ranged from 1.88 to 3.84), AT (Six Sigma level ranged from 0.06 to 3.26), and D-dimers (Six Sigma level ranged from 2.61 to 5.3), as well as insufficient to excellent performance for aPTT (Six Sigma level ranged from -0.28 to 6.38). According to these results, the Westgard rule that should be applied is the 8x rule.

CONCLUSIONS

Six Sigma showed weak to moderate performance for hemostasis tests, requiring the strict application of Westgard rules. However, these parameters have limitations, as they depend on ATE values that vary according to reference standards and biases that vary depending on peer results.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0106

ASSESSMENT OF PERCEPTIONS OF PATIENT SAFETY CULTURE ACROSS PROFESSIONAL CATEGORIES IN CLINICAL LABORATORIES FROM BRAZIL

W. Shcolnik [3], D. Jerônimo [1], A. Duarte [2], A. Vieira [1], L. Bottino [1], R. Lopes [1], J. Poloni [1], V. Biasoli [1]

[1]*Controllab, Rio de Janeiro - Brazil.*

[2]*Faculdade de Medicina da Universidade de São Paulo (FMUSP); Clinical Pathology Area – Rede D'Or, São Paulo – Brazil.*

[3]*Grupo Fleury, São Paulo - Brazil; Sociedade Brasileira de Patologia Clínica/Medicina Laboratorial (SBPC/ML), Rio de Janeiro –Brazil.*

BACKGROUND-AIM

Patient safety culture (PSC) is the collective values and behaviors that healthcare organizations prioritize. It encourages open communication, error reporting, and teamwork to prevent harm. The present study aimed to assess the perceptions of PSC among clinical laboratory professionals and explore whether differences in perception exist across various professional categories.

METHODS

An adapted version of the 'Hospital Survey on Patient Safety Culture 1.0' from the Agency for Healthcare Research and Quality, retaining all 12 original dimensions, was administered to clinical laboratory professionals across various categories (managers, analysts, technicians, and administrative staff). Perceptions were classified as positive or negative, and Odds Ratios (OR) were calculated to explore the relationship between professional categories and PSC perceptions.

RESULTS

A total of 1,414 professionals participated in the study. Managers were significantly more likely to have positive perceptions in 10 out of the 12 dimensions, with ORs 1.5 to 2 times higher than the overall OR (OOR) in most dimensions ($p<0.05$). These dimensions included: "Communication Openness" (OR=3.03), "Management Support for Patient Safety" (OR=6.50), "Organizational Learning – Continuous Improvement" (OR=8.14), "Supervisor/Manager Expectations and Actions Promoting Patient Safety" (OR=5.34), "Frequency of Events Reported" (OR=4.49), "Overall Perception of Patient Safety" (OR=2.43), "Handoffs and Transitions" (OR=3.46), "Nonpunitive Response to Error" (OR=0.82), "Feedback and Communication About Error" (OR=4.17), and "Teamwork Within Units" (OR=6.18). Two exceptions were observed: "Teamwork Across Units" OR=2.08 vs. OOR=1.72 ($p=0.069$), where no significant association was found, and "Staffing" OR=1.04 vs. OOR=1.10 ($p=0.012$), where, despite the statistically significant difference, the OR values were very close, making it difficult to single out one category over others.

CONCLUSIONS

This study highlights significant differences in PSC perceptions, with managers being more likely to view it positively. Improving communication and aligning PSC perceptions across all staff levels is essential for consistent safety practices in clinical laboratories.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0107

EVALUATION OF ASSAY PRECISION OF VITAMIN B12 CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY ON ARCHITECT I1000SR

S. Stojanova-Kostadinoska [3], N. Grozdanovska [3], E. Abdiu Xhambazi [2], J. Bogdanska [1]

[1]*Institute of Medical and Experimental Biochemistry, Faculty of Medicine, Ss. Cyril and Methodius University, Skopje, Republic of North Macedonia*

[2]*PHI General Hospital - Kicevo, Republic of North Macedonia*

[3]*PHI University Institute for Clinical Biochemistry, Skopje, Republic of North Macedonia*

BACKGROUND-AIM

Vitamin B12 is essential for DNA replication and transcription and the most frequent conditions associated with its deficiency are those in connection to anemia. In order to establish Chemiluminescent Microparticle Immunoassay (CMIA) method for vitamin B12 determination in our laboratory and provide sufficient analytical quality for precise diagnosis and monitoring of therapy in patients, the aim of this study was to evaluate precision of the assay.

METHODS

Evaluation of the assay was done employing CMIA method on ARCHITECT i1000SR analyzer, following the CLSI EP 15-A2 Protocol. For the verification of the precision two levels (low and high) of a multi-constituent quality control samples were used. The measurements were done for 5 consecutive days with three replicates in triplicate per day for each level and repeatability and within-laboratory precision were calculated according to the Protocol.

RESULTS

The estimated repeatability of vitamin B12 for our laboratory was calculated to be 3.38 pg/ml with coefficient of variation (CV) of 1.4 % for low level control samples, and 8.69 pg/ml with CV of 0.98% for high level control samples respectively. Within-laboratory precision of vitamin B12 was calculated to be 3.8 pg/ml with CV of 1.57% for low level control samples, and 9.24 pg/ml with CV of 1.04 % for high level control samples respectively.

CONCLUSIONS

In conclusion, calculated repeatability and the within-laboratory precision for our laboratory were lower compared to the manufacturer claims, so the CMIA method for serum vitamin B12 quantification can be effectively introduced in our laboratory ensuring reliable and efficient testing for patients.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0108

OPTIMIZING TSH IMMUNOASSAY: ENSURING PRECISION AND RELIABILITY IN THYROID DIAGNOSTICS

H. Bouhajja [4], B. Khalfa [2], Y. Ghanem [2], S. Hammami [4], L. Jmal [1], S. Chaabouni [1], K. Guesmi [2], S. Oueslati [4], A. Enneifer [3], R. Mahjoub [2], E. Talbi [4]

[1]*Clinical Biology Laboratory, Mahmoud Matri Hospital, Ariana, Tunisia.*
[2]*Clinical Biology Laboratory, Zouhair Kallel Institute of Nutrition and food technology, Tunis, Tunisia*
[3]*Laboratory of Clinical Biology, Hospital of Mahmoud Matri, Ariana, Tunisia*
[4]*Research Unit UR17SP01 - "Zouhair Kallel" National Institute of Nutrition and Food Technology - Tunis, Tunisia*

BACKGROUND-AIM

Thyroid Stimulating Hormone (TSH) immunoassay is the primary biological test employed for diagnosing dysthyroidism and monitoring treatment efficacy. Adherence to ISO 15189 standards necessitates the verification of the performance of immunological techniques used in clinical settings. This study aimed to assess the analytical performance of TSH determination via electrochemiluminescence (ECL) on the Cobas® e411 platform from Roche Diagnostics.

METHODS

For the accuracy assessment, two levels of internal control were implemented. Patient samples were analyzed using the Cobas® e601 ECL system located in a different laboratory for comparative analysis. Statistical evaluations were performed using Medcalc statistical software®, which facilitated Passing-Bablok linear regression and Bland-Altman difference analysis, alongside the calculation of coefficients of variation (Cv) and correlation coefficients. The interpretation of CVs was based on recommendations from the SFBC.

RESULTS

The precision study yielded CVs within acceptable limits, demonstrating strong repeatability with a CV of 2.4% at the low level and 1.6% at the high level. Intra-laboratory reproducibility was also satisfactory, with CVs recorded at 3.2% for low levels and 4.8% for high levels. The Bland-Altman difference plot indicated a statistically insignificant mean difference of +0.10mIU/L. The Passing-Bablok regression analysis confirmed no proportional or systematic bias, exhibiting perfect correlation (Spearman coefficients > 0.98).

CONCLUSIONS

The findings from this study substantiate the reliability of the TSH assay technique under routine laboratory conditions. This research provides a robust foundation for fulfilling the accreditation requirements pertinent to our laboratory's commitment to quality standards.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0109

IMPROVING OF SPECIMEN REJECTION RATE IN CLINICAL CHEMISTRY LABORATORY THROUGH EDUCATIONAL INTERVENTION.

R. Alyaeesh [2], R. Alsaedi [2], A. Alhamad [2], M. Alshebani [2], A. Bahis [2], A. Alenazi [2], M. Kadory [2], F. Alkhuredly [2], N. Albagaei [2], M. Bukhary [2], D. Firaq [2], I. Alhassan [2], W. Tamimi [1]

[1]*Division of Clinical Chemistry, Department of Pathology and Laboratory Medicine, King Abdulaziz Medical City, College of Applied Medical Sciences, King Saud Bin Abdulaziz University for Health Sciences, King Abdullah International Medical Research Center,*

[2]*Division of Clinical Chemistry, Department of Pathology and Laboratory Medicine, King Abdulaziz Medical City, Riyadh, Saudi Arabia*

BACKGROUND-AIM

One of the important key performance indicators (KPI) in the pre-analytical zone of clinical laboratory is the rate of rejection of blood samples. The serum blood samples are normally collected form the different locations in the hospital by different health care providers. Unfortunately, some samples are not collected properly which will be subjected for rejection. This may impact on the health service by delaying analysis and increasing the turn-around-time (TAT). The aim of this study was to investigate causes of the blood sample rejection before and after implementing training and education.

METHODS

Data rejection of samples was collected and evaluated from different locations at King Abdullaziz Medical City in Riyadh form January 2023 to January 2024. Around 10 phlebotomy training sessions were offered and conducted yearly to all nurse staff. Types of inappropriateness were evaluated as follows: unlabeled specimen, mislabeled specimen, clotted specimen, quantity not sufficient (QNS), inadequately labelled, layered specimen, contaminated specimen, wrong collected tube, hemolyzed, age of specimen, and wrong storage condition.

RESULTS

A total of 178180 and 190133 samples were received and evaluated for month of January 2023 and January 2024 respectively. There was a tremendous reduction in the rejection rate at all sites in spite of 7% increase in the workload. The overall rejection rate has been dropped from 0.64% in Jan 2023 to 0.39% in Jan 2024 ($p<0.0001$). The most common reasons were found to be hemolyzed specimen (75.1%), quantity not sufficient (QNS) (9.5%) and contaminated specimen (10.5%) for Jan 2023 and 66.34%, 21.1% and 6.54% for Jan 2024 respectively.

CONCLUSIONS

The rejection rate was attributable to blood collection errors especially due to hemolyzed specimen, QNS and contaminated specimen. Based on this evaluation a collective effort of education, communications and frequent in-services were conducted to all over customers to adhere to the proper collection procedures of collection of the blood serum samples have resulted in significant improving and reduction of the rejection by January 2024.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0110

IMPLEMENTATION OF PATIENT-BASED REAL-TIME DATA MONITORING SYSTEM FOR TSH AND FREE T4 ASSAYS AT THE NATIONAL HOSPITAL, SRI LANKA

L. Thilakarathna [2], N. Amarasinghe [1], W. Abeywickrama [1], G. Katulanda [1]
[1]*Department of Pathology, National Hospital of Sri Lanka, Colombo 08*
[2]*Department of Pathology, National Hospital, Kandy, Sri Lanka*

BACKGROUND-AIM

Quality control is crucial in laboratory testing to ensure the precision and accuracy of patient sample results. Internal quality control (IQC) samples, typically run once daily, are inadequate for detecting systematic errors. Patient-based real-time quality control (PBRTQC) offers a promising solution to these limitations. This study aims to develop and implement a quality control protocol using patient-based real-time data to analyze failure and review analytical errors in thyroid-stimulating hormone (TSH) and free thyroxin (FT4) measurements. The study also seeks to verify appropriate block sizes, truncation limits, and the method's sensitivity, documenting the PBRTQC procedure's performance.

METHODS

TSH and FT4 results were extracted from the laboratory database over 14 months, accounting for variability in patient populations, reagent lots, and calibrator lots. Systematic errors were identified and excluded. Data normalization was achieved through monthly partitioning and Box-Plot and logarithmic transformations. Artificial biases of varying degrees were introduced randomly in 400 test results. Bias detection curves were generated against introduced bias, with minimum bias limits set at 12% for FT4 and 20% for TSH. The number of moving average (MA) results necessary for bias detection was counted post-bias introduction.

RESULTS

Due to the non-normal distribution of data, bias detection truncation limits were beneficial. The optimal block size for MA calculation was 40 for both biomarkers. Specific truncation limits were established: mean ± 1.5 IQR for FT4 and mean ± 1.0 IQR for TSH. The MA method showed high sensitivity, detecting biases >20% for FT4 and >30% for TSH. However, the lack of stratification of patient data, imprecision of the assay, and high biological variation of TSH limit this method's sensitivity.

CONCLUSIONS

This study demonstrates that the PBRTQC is effective in detecting systematic errors in real time, thereby enhancing the reliability of TSH and FT4 measurements. The implementation of optimized block sizes and specific truncation limits significantly improves the sensitivity of error detection, promoting better laboratory quality control. Implementing a more stringent data stratification method will substantially enhance the power of error detection.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0112

TOWARDS IMPLEMENTATION OF MEASURED UNBOUND FLUCLOXACILLIN CONCENTRATIONS IN ROUTINE PATIENT CARE.

C. Van Herteryck [1], N. Verougstraete [3], J. De Waele [2], V. Stove [3]
[1]*Department of Diagnostic Sciences, Ghent University, Ghent, Belgium*
[2]*Department of Intensive Care, Ghent University Hospital, Ghent, Belgium*
[3]*Department of Laboratory Medicine, Ghent University Hospital, Ghent, Belgium*

BACKGROUND-AIM

Flucloxacillin is a beta-lactam (BL) antibiotic, frequently used to treat Gram-positive bacterial infections. To improve dosing of BL, therapeutic drug monitoring is performed. Total drug concentrations are measured, with the assumption that the (biologically active) unbound concentration can be calculated, using a fixed free fraction (fu) value, i.e. 5% for flucloxacillin. However, conditions like hypoalbuminemia, common in the critically ill patient, alter the equilibrium between bound and unbound concentrations, making total flucloxacillin concentrations less reliable. The aim of our study was to validate and implement an in-house developed method to measure unbound flucloxacillin concentrations.

METHODS

Protocols for measuring bound and unbound flucloxacillin concentrations were developed and validated using an Ultimate 3000 (UHPLC) in combination with the Q-ExactiveTM hybrid quadrupole-OrbitrapTM (MS) (Thermo Fisher Scientific). Total and unbound concentrations were measured on remnant plasma samples (n=75 from 46 patients). Ultrafiltration was performed using Centrifree 30 kDa devices (incubation and centrifugation at 37°C, 1900g, 30 minutes). Target ranges for total and unbound concentrations were 50-125 mg/L and 2-20 mg/L respectively. The study adhered to the ethics declaration of Helsinki.

RESULTS

Processing temperature, incubation time and ultrafiltration devices were identified as variables affecting unbound concentrations. The median total concentration was 61.9 mg/L (range 3.76-154 mg/L), unbound concentration 8,86 mg/L (range 0.218-28.12 mg/L) and fu 14.0% (range 4.74% - 40.3%). Classification in subtherapeutic, therapeutic and toxic concentrations showed that for total concentration 25, 51 and 2 samples fell into these categories, respectively, compared to 12, 58 and 8 samples for unbound concentrations. In 21 cases, total concentration did not accurately reflect the unbound value.

CONCLUSIONS

We conclude that for highly protein bound drugs, like flucloxacillin, relying on total concentration measurements may lead to overestimation of dosing needs in critically ill patients. Unbound concentrations should be measured using a standardized protocol.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0113

ENHANCING PIPETTING QUALITY: MONITORING AND MAINTAINING USING EQA

K. Virtanen [2], R. Viertola [2], S. Mo [1], M. Sverresdotter Sylte [1], J. Pelanti [2], H. Berghäll [2]
[1]*Department of Medical Biochemistry and Pharmacology, Haukeland University Hospital, Bergen, Norway*
[2]*Labquality EQAS by Aurevia, Aurevia, Helsinki, Finland*

BACKGROUND-AIM

Labquality EQAS by Aurevia has developed a new EQA scheme, Pipette Control, to support laboratories in conducting intermediate performance checks between pipette calibration intervals. According to ISO 15189:2022, laboratories shall specify calibration and traceability requirements sufficient to maintain consistent reporting of analysis results. Pipette calibration can be performed by ISO 17025 accredited calibration facilities or internally by the clinical laboratories provided they follow standardized procedures. This study presents results from EQA program for pipettes during 2024.

METHODS

Two rounds were organized during 2024. For each round, two liquid samples were distributed. Three of the shipped samples contained sterile water, one sample contained glycerol. In both rounds, the pipetting volumes were 100 µL and 1000 µL. Participants reported the mean results from five parallel pipettings of the specified volumes. The participants could submit results from up to 5 pipettes. Reference values were determined by direct pipetting for water samples and by reverse pipetting for glycerol samples at a calibration facility equipped with air humidifier and weighed with a scale equipped with an evaporation trap.

RESULTS

135 individual pipettes from 43 laboratories across 13 countries were included. Results were reported from pipettes with maximum volumes ranging from 100µL - 1000µL. The CV% for purified water samples ranged from 0.3-1.3 and for the glycerol sample 1.7-8.5. With both sample materials, the highest CV% (8.5 for glycerol sample and 1.3 for purified water sample) was observed when a pipette with 1000µL max volume was used to pipette 100µL which is not an optimal volume for the pipette.

CONCLUSIONS

Many general variables influence the results of pipetting. This study highlights the importance of using an appropriate volume for the pipette and the correct pipetting technique when assessing pipette accuracy. This EQA program is suitable for monitoring pipette accuracy and the quality of pipetting practices.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0114

SIGNIFICANCE OF ANTIBODY SELECTION IN EARLY DEVELOPMENT OF A ROBUST PARTICLE ENHANCED IMMUNOTURBIDIMETRIC ASSAY (PETIA) FOR THE QUANTIFICATION OF FERRITIN

L. Wey [1], T. Engelmann [1], C. Kochem [1], I. Wieland [1], H. Müller [1], L. Kreckel [1], K. Prager [1], T. Masetto [1]
[1]*DiaSys Diagnostic Systems GmbH, Alte Straße 9, 65558 Holzheim*

BACKGROUND-AIM

Ensuring patient safety is the goal in laboratory diagnostics. As developers, it is our responsibility to prioritize patient safety, even during the early stages of development. In this work, we present the approach to develop a robust particle enhanced immunoturbidimetric assay (PETIA) for the quantification of ferritin. One of the main challenges in PETIA development is antibody selection, as the antibody, together with the particle, forms the core of the assay. We evaluated four different antibodies – two monoclonal and two polyclonal – through method comparison with human samples with a ferritin PETIA currently available on the market. Including human samples at this early stage ensures patient safety as commutability validates the data.

METHODS

18 human serum samples with ferritin concentrations ranging from 0-1000 µg/L were measured on a clinical chemistry analyzer with the four self-produced PETIA reagents (differing only in the antibody and its coupling pH). These results were compared against a commercially available PETIA reagent. Method comparison was performed using Passing-Bablok regression via Analyse-It software.

RESULTS

Correlation coefficients for the method comparisons were all $r \geq 0.993$, indicating strong agreement. Highest correlation was achieved with the polyclonal goat IgG reagent ($r = 0.997$), while the lowest correlation was observed with the polyclonal rabbit IgG reagent ($r = 0.993$).

CONCLUSIONS

The small variation between the correlation coefficients among the four reagents demonstrates a robust PETIA system, even at this early stage of development. The data indicates that development would be feasible using any of the four antibodies. Our work shows the importance of guaranteeing commutability in method comparison by measuring human samples, even in the early stages of development. This is crucial for gaining insights into antibody performance and for ensuring patient safety in the later stages.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0115

DIFFICULTY ENCOUNTERED IN INTERNAL QUALITY CONTROL OF SERUM IRON: A PRACTICAL CASE

A. Bachali [1], I. Yousfi [1], I. Ghachem [1], L. Sghaier [1], C. Rhimi [2], M.Y. Kaabar [1]
[1]*Clinical Biology Laboratory,Mohamed Taher Maamouri university Hospital, Nabeul,Tunisia*
[2]*microbiology Laboratory,Farhat Hached university Hospital,Sousse,Tunisia*

BACKGROUND-AIM

Internal quality control (IQC) is an essential activity in clinical biochemistry, ensuring the reliability of analytical results. At the same time, preventive and corrective maintenance measures play a key role in reducing analytical errors.The aim of this case report is to describe an investigative approach to an internal quality control issue.

METHODS

We report a case study from August 2024, highlighting an issue with the internal quality control of serum iron measured on a cobas® pure analyzer.

RESULTS

After a period of stability in the serum iron IQC, validated monthly by external quality control, a progressive deviation, characterized by increasing IQC values, was observed in early August 2024. This anomaly worsened, leading to alarming values that resulted in the rejection of results. To assess the inaccuracy of the measurements, the previous month's external control was analyzed as a patient sample. The results revealed a significantly elevated value (z-score = 3.9), confirming the consistency with the IQC results. A thorough investigation was conducted, including testing a new cassette from the same batch of serum iron reagent, which generated the same issue, as well as failed recalibrations. As a last resort, distilled water from the distiller was tested as a patient sample. The results revealed an
elevated serum iron concentration of 4.6 µmol/L, indicating contamination of the water. The maintenance technician was consulted to diagnose the cause of this contamination. Inspection revealed that the distiller filters were oxidized, explaining the contamination of the distilled water with iron.These filters had not been replaced within the recommended timeframe, despite repeated requests from the laboratory's quality manager to the maintenance department to replace them.

CONCLUSIONS

This case highlights the crucial importance of the integrity of water distillation systems, particularly for the measurement of electrolytes such as serum iron. Thus, this observation confirms that rigorous management of laboratory equipment is essential to avoid analytical errors and ensure the quality of biological analyses.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0116

UTILITY OF NOVEL SERUM BIOMARKERS IN MILD TRAUMATIC BRAIN INJURY: NEW CLUES FOR IMPROVEMENT."

J. Domínguez García [1], E. Melguizo Madrid [1], S. García Pinteño [1], S.E. Ochoa Guzmán [1], A.J. Reche Martínez [1], M. Mayor Reyes [1], C. Cañavate Solano [1], J.D. Santotoribio Camacho [1]
[1]*Servicio Andaluz de Salud*

BACKGROUND-AIM

Traumatic brain injury (TBI) is a leading cause of emergency department visits, with mild cases being the most prevalent. While non-contrast cranial computed tomography (CT) is the standard diagnostic tool, its increasing costs and wait times have driven interest in biomarkers like glial fibrillary acidic protein (GFAP) and ubiquitin C-terminal hydrolase L1 (UCH-L1). The objective of this study was to evaluate the ability of these biomarkers to rule-out intracranial injury and to assess the role of lactate dehydrogenase (LDH), Leukocytes, Polymorphonuclear cells, and C-reactive protein (CRP) in mild TBI.

METHODS

Adult patients with mild traumatic brain injury (TBI) of less than 12 hours since onset, meeting all criteria for the definition of mildness, were included in the study between May-October 2024. Heparinized plasma and serum samples were pre-analytically treated following Abbott's® instructions and analyzed using the Alinity c and i autoanalyzers. The TBI test was considered positive if one or both biomarkers exceeded their respective thresholds: GFAP (>35 pg/mL) and UCH-L1 (>400 pg/mL).

RESULTS

The sample comprised 61 patients (32 male and 29 female) aged 19 to 94 years (median: 67.47). The TBI test demonstrated a specificity of 36.84%, a sensitivity of 100%, a positive predictive value (PPV) of 10%, and a negative predictive value (NPV) of 100%. Using the TBI test as a screening tool could have avoided 21 CT scans for all 61 patients. However, given that in routine clinical practice not all patients with mild TBI undergo a CT scan, we estimate that in our case, the reduction in CT scans was 8.6%. Additionally, the leukocyte count and polymorphonuclear cell count showed moderate correlations with GFAP and UCH-L1 (Spearman's rho = 0.3–0.5), while a moderate correlation was observed between LDH and UCH-L1 (Spearman's rho = 0.399). However, no significant correlation was found between CRP and either GFAP or UCH-L1.

CONCLUSIONS

In conclusion, while the high efficacy of the TBI test in ruling out patients without intracranial damage has been demonstrated, further improvements to its PPV are needed. This could be achieved by incorporating additional markers, such as leukocytes or polymorphonuclear cells.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0117

STUDY OF INTERFERENCE DUE TO THE PRESENCE OF HEMOLYSIS IN THE NEW ATELLICA CI® ANALYZER (SIEMENS HEALTHINEERS)

S. LapeÑa Garcia [1], J. Sanchez Fuertes [1], M.J. Ruiz-Alvarez [1], Y. FernÁndez-Verduras [1], A.M. Moreno-Romero [1], A. AntÓn-Cornejo [1], T. Costales-Lucia [1], S. GarcÍa-Valdecasas Gayo [1], M. Barrionuevo-Gonzalez [1]
[1]*SERVICIO DE ANÁLISIS CLÍNICOS, HOSPITAL PRÍNCIPE DE ASTURIAS, ALCALÁ DE HENARES (MADRID)*

BACKGROUND-AIM

Hemolysis is the most common preanalytical error affecting biochemical determinations.
The objective of our study is to verify the hemolysis index in the Atellica CI analyzer to provide accurate results for patients' biochemical determinations.

METHODS

The study was conducted following the protocol "Procedure for the study of interference due to hemolysis, bilirubin, and turbidity and for the verification of hemolysis, jaundice, and lipemia index"(2013(SEQC-ML).
A hemolysate was prepared from whole blood samples and a base serum with a pool of patient sera.
Two sera were prepared: one without interferent and another with interferent. 8 serial dilutions were then made between both.
The concentration of biochemical determinations was measured, in the new Atellica CI analyzer, in each of the 8 dilutions in duplicate, aiming to evaluate how its concentration varies as hemolysis increases.
When the change in concentration (%change) due to the presence of hemolysate exceeds the established maximum limit, the interference is considered significant.
%Change=100(Ci(dilution)-C0(Without interferent))/C0(Without interferent)
Maximum allowable error = Z(CVAnalytical2+CVI Within-subject 2)1/2
Where Z=1,96 for 95% probability

RESULTS

According to these, in the Atellica CI analyzer, the analytes that show interference with hemolysis exceeding the established maximum limit are:
-LDH shows interference starting from the dilution with 0.05mL of hemolysate
-AST and potassium from the dilution with 0.2mL
-Alkaline phosphatase from the dilution with 0.4mL
-Total proteins, CK, and albumin from the dilution with 0.6mL
-Magnesium and cholesterol starting from the dilution with 0.8mL of hemolysate

CONCLUSIONS

After conducting this interference study, our laboratory does not report the results of biochemical determinations that have been shown to be affected by sample hemolysis above the established maximum limit. This ensures that patient results are accurate and reliable. Clinical laboratories must ensure the detection of hemolysis and have established actions to take with these samples, especially, after the incorporation of new analyzers in the laboratory.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0118

BIOLOGICAL VARIATION REFERENCE DATA; EFLM INITIATIVES AND DEVELOPMENTS TO ADDRESS DATA QUALITY ISSUES AND DELIVER DATA REQUIRED TO ENABLE ISO15189 2022 COMPLIANCE.

W.A. Bartlett [1], S. Sandberg [2], A.K. Aarsand [3]

[1]*Biomedical Engineering, School of Science and Engineering, University of Dundee, Scotland, UK. Expert Consultant, EFLM Committee Biological Variation and EFLM Technical Committee for the Biological Variation Data Base*

[2]*Norwegian Organization for Quality Improvement of Laboratory Examinations (Noklus), Haraldsplass Deaconess Hospital, Bergen, Norway; Chair of the EFLM Committee for Biological Variation.*

[3]*Norwegian Organization for Quality Improvement of Laboratory Examinations (Noklus), Haraldsplass Deaconess Hospital, Bergen, Norway; Chair of the EFLM Technical Committee for the Biological Variation Database.*

BACKGROUND-AIM

The ENO ISO 15189:2022 revision, titled "Medical laboratories – Requirements for quality and competence" recognises the need for laboratories to consider biological variation specifically in the context of measurement uncertainty. Biological variation data (BVD) are reference data used to define a range of analytical performance specifications (APS) with other applications to be embedded in ISO compliant quality management systems (e.g. assessment of validity of population-based reference values). Concerns about quality of BVD have been the focus of European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) groups.
Objectives:
To signpost EFLM developments and resources to aid compliance to the patient centred ISO15189 2022 that:
• enable access to BVD transportable as reference data.
• assess and drive-up quality of BVD by development of standards.
• promote user knowledge and understanding of biological variation and BVD applications.

METHODS

Reappraisal of BVD studies published in the last 35 years enabled groups of experts within the EFLM Biological Variation Working Group and Task Groups for The Biological Variation Database to address the objectives.

RESULTS

Delivery of:
• STARBIV Standard: A framework for reporting BVD studies, ensuring quality and transportability.
• Biological Variation Data Critical Appraisal Checklist (BIVAC): A tool to evaluate and assign quality grades (A-D) to studies.
• EFLM BV Database and website: A curated online resource containing over 3000 BVD estimates with detailed metadata, BIVAC scores, BVD metanalyses, APS and reference change value calculation.
• EuBIVAS Study: An exemplar BIVAC grade "A" European study providing new BVD.
• A knowledge base: More than 40 peer reviewed articles have been published; reporting new BVD; reviewing and critically appraising existing BVD; and addressing issues around old and new concepts (e.g. personalised reference interval, data mining).

CONCLUSIONS

High-quality BVD is an essential requirement for laboratory medicine service provision, to enable compliance with ISO 15189:2022, and safeguarding of patient care. The EFLM's efforts to develop tools, standards, and databases address quality issues with BVD and enable future innovations including data mining and personalised reference intervals.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0119

PERFORMANCE OF 'FLOURISHING HERDLESS' DIAGNOSTIC LABORATORIES: INSIGHTS FROM ENZYME ASSAY ANALYSES IN SELECTED PUBLIC AND PRIVATE HEALTH FACILITIES IN ADDIS ABABA, ETHIOPIA

S.K. Birru [1]
[1]*Addis Ababa University, college of Health Sciences*

BACKGROUND-AIM

In Ethiopia, diagnostic laboratory services have significantly expanded, driven by public subsidies for government facilities and minimal financial constraints for private facilities, despite growing concerns about inconsistencies in laboratory results.

METHODS

This cross-sectional study selected diagnostic laboratories using convenience sampling based on daily test volumes (≥100), automated analyzers, and adherence to IFCC assay methods. In-house control panels were prepared from pooled serum samples (clinically normal and pathological for AST and ALT), stored at +4°C, and dispatched anonymously to 12 laboratories (public: n=19, private: n=3). Percentage bias was calculated with thresholds of 10% and 20%, and results were summarized using Youden plots to identify systematic, random, and total errors.

RESULTS

Among the laboratories, 10/11 reported at least one result with a percentage bias >10%, and 4/11 exceeded the 20% threshold, highlighting result inconsistencies relative to peer-pooled averages. In the AST Youden plot, 4/11 results were outside the first square, with one 'normal panel' result falling beyond the second square, indicating positive constant bias (systematic error). Most results (10/11) were near the 45-degree line, suggesting acceptable random error levels. For ALT, larger errors were observed, with 7/11 results outside the first square, indicating higher systematic error. One 'pathological panel' result showed negative constant bias, and 5/11 results were far from the 45-degree line, reflecting significant random error.

CONCLUSIONS

This pilot study highlights significant systematic and random errors among participating laboratories, emphasizing the need for comprehensive performance evaluations across diverse sites. Despite providing relatively better service in terms of turnaround time and uninterrupted operations, these laboratories are metaphorically described as 'flourishing but herdless'—thriving yet isolated and uncoordinated, hindering the transferability of patient results. Persistent challenges, including inadequate training, insufficient vendor support, and fragmented systems, underscore the need for enhanced quality standards and coordinated improvements. A large-scale survey is warranted to address these gaps and strengthen laboratory performance.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0120

STABILITY OF INTERNAL QUALITY CONTROL MATERIALS OF ELECSYS BRAHMS PROCALCITONIN KIT

G. Lai [3], D. Szoke [1], C. Tamburnotti [1], S. Zampetti [1], F. Borrillo [1], A. Dolci [2]

[1]*Clinical Pathology Unit, ASST Fatebenefratelli-Sacco, Milan, Italy*

[2]*Clinical Pathology Unit, ASST Fatebenefratelli-Sacco, Milan, Italy; Department of Biomedical and Clinical Sciences, University of Milan, Milan, Italy*

[3]*Clinical Pathology Unit, ASST Fatebenefratelli-Sacco, Milan, Italy; Residency School in Clinical Pathology and Clinical Biochemistry, University of Milan, Milan, Italy*

BACKGROUND-AIM

In vitro diagnostic (IVD) manufacturers are requested to provide Internal Quality Control component I (IQC-I) materials with appropriate target values and acceptability range, designed for daily surveillance of the IVD measurement devices (IVD-MD) alignment when working according to the manufacturer's indications. However, the instructions for use (IFU) of the Elecsys BRAHMS procalcitonin (PCT) reagent kit (Roche Diagnostics) give indications for the use of IQC-I materials that limit their use to one month, but the reagents are stable for three months. Here, we evaluated the stability of IQC-I materials managed differently from the IFU as alternative procedure to control alignment over the entire reagent stability time frame.

METHODS

The PCT kit contains two levels of IQC-I material, PreciControl1 (PC1) and 2 (PC2). According to the IFU, frozen/thawed aliquots of IQC-I material should be used once, thus providing IQC-I material for 28 days. To extend the availability of IQC-I over time, each aliquot of IQC-I material (lot: 755971) was stored at 4°C after thawing and run daily over 5 consecutive days (total measurements = 69, number of aliquots = 14). Recovery of PCT over time was calculated as percentage of the initial value obtained on just thawed samples (T0) by dividing the concentrations at any 4 °C storage time by the concentration at T0.
During the experiment, the accuracy of the system alignment was checked by using a third party IQC-I materials provided by Roche (Lyphocheck Specialty Immunoassay Control – BIO RAD).

RESULTS

Target values of the IQC-I materials were 0.50 and 9.29 µg/L for PC1 and PC2. Recovery values ranged from 94% to 107% for PC1 and from 92% to 109% for PC2. Mean concentration (µg/L), bias (%) and imprecision (CV%) of 0.48, -4.00, 3.41 on PC1 and 9.02, -3.01, 4.00 on PC2 were estimated.

CONCLUSIONS

Our study shows that PCT on IQC-I materials is stable when stored at 4°C after thawing for 6 days. This procedure extends the usability of a 300-tests PCT reagent kit from 28 days to 16 weeks that is the on-board reagent stability. We suggest to the manufacturer to evaluate and validate on IFU that approach to overcome the issue of the restricted number of IQC-I materials provided.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0122

A CASE REPORT: COEXISTENCE OF MYELODYSPLASTIC SYNDROMES AND SYSTEMIC LUPUS ERYTHEMATOSUS

A. Coraj [2], E. Refatllari [2], T. Kurti Dedej [2], N. Heta [2], I. Korita [2], H. Lame [2], V. Tole [2], V. Semanaj [1], E. Cela [1], A. Kasneci Bulo [2]
[1]*University Hospital Center''Mother Theresa" Laboratory Department,Tirana,Albania*
[2]*University Hospital Center''Mother Theresa" Laboratory Department,Tirana,Albania/University of Medicine, Faculty of Medicine,Tirana ,Albania*

BACKGROUND-AIM

Myelodysplastic syndromes (MDS) are clonal hematologic disorders characterized by ineffective hematopoiesis, leading to cytopenias and a risk of progression to acute myeloid leukemia (AML). Systemic lupus erythematosus (SLE) is an autoimmune disorder that affects multiple organ systems. This case report presents a unique instance of a patient with SLE who developed MDS, shedding light on potential links between chronic inflammation and bone marrow failure.

METHODS

A 69-year-old female presented with fever (39°C), fatigue, cough with sputum, and arthralgia lasting for seven days. She appeared anemic with a palpable spleen. Her medical history included a two-year diagnosis of SLE, manifesting with hair loss, photosensitivity, oral ulcers, and headaches. Blood samples were analyzed using the Sysmex XN-1000, and biochemical tests were performed on the Alinity C modular system. Bone marrow smears were prepared using Giemsa stain for cytological evaluation.

RESULTS

On admission, laboratory findings revealed severe pancytopenia:WBC: 1.100/mm³,RBC: 2.19 x 10#/µL,Hemoglobin: 7.0 g/Dl,Platelets: 60 K/µL.Bone marrow cytology showed marked hypoplasia with:Myeloblasts 8%,Granulocytic series: 23%, without significant dysplasia.Erythroid series: 10%, with dyserythropoiesis, including macrocytes, megalocytes, internuclear bridges, and normoblasts with abnormal nuclei.Lymphocytic series: 55%, morphologically normal.Megakaryocytic elements were present, indicating ongoing platelet production.Flow cytometry revealed:Primitive myeloid cells: ~10%, expressing CD34+, CD117+, CD33+, and HLA-DR+.Chromosomal analysis detected deletion of chromosome 5q. Biochemical tests showed elevated lactate dehydrogenase (450 U/L), SGOT (45 U/L), SGPT (50 U/L), and total bilirubin (2.09 mg/dL). Ferritin :750 ng/mL. Autoimmune panel results:ANA IgG: Positive, homogeneous type, titer 1:1280,Anti-dsDNA antibodies: 230.6 IU/mL,Complement C3: 0.38 g/L ,Complement C4: 0.13 g/L .The erythrocyte sedimentation rate (ESR) was 88 mm/h. Tests for infectious diseases were negative.

CONCLUSIONS

This case highlights the possibility of SLE contributing to the development of MDS. Chronic autoimmune activity, persistent inflammation, and immune dysregulation may predispose patients to hematologic disorders.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0123

A DESIGNED DASHBOARD TO ADDRESS CLINICAL RISKS DUE DELAYED DIAGNOSTIC DATA IN A COMPLEX LABORATORY NETWORK

M. Donghi [1], M.T. Sandri [1], C. Lapucci [1], L. Milano [1], T. Trenti [1]
[1]*Bianalisi Healthcare Group, Carate Brianza, MB, Italy*

BACKGROUND-AIM

The aim of this project was to develop a real-time dashboard to track sample status, location, and condition, addressing the needs of Bianalisi, Italy's largest private diagnostic network, consisting of over 20 laboratories in a Hub-and-Spoke model. The dashboard was designed to enhance efficiency, ensure traceability, and reduce clinical risks, particularly those arising from sample misidentification and delayed diagnostics.

METHODS

A comprehensive blood sample tracking system, integrated with barcoding, was implemented to monitor samples from collection to reporting. The process incorporates key roles such as the CONTROLLER, CUSTOMER SERVICE, and PICK-UP POINT (PP), ensuring secure delivery through real-time alerts, cross-checks, audit logs, and a detailed dashboard. These features improve traceability and mitigate errors throughout the diagnostic workflow.
The system supports data exchange among laboratories, streamlining collaboration and reducing bottlenecks. It enables proactive monitoring of anomalies by type and volume, addressing errors on time. Key performance indicators (KPIs), derived from recommendations by the IFCC Working Group on Laboratory Error and Patient Safety and the EFLM Task Force, focus on all phases of the testing process. These include quality indicators tailored for clinical laboratories to evaluate performance and ensure reliability.

RESULTS

From January to November 2024, the dashboard monitored over 2,353,000 tubes and identified 12 main anomalies, totaling 12,753 non-conformities (0.54%). The most frequent issues, representing over 80% of cases, were missing samples (49.68%), unsuitable samples (18.65%), excess samples (8.99%), and insufficient samples (6.3%).

CONCLUSIONS

In conclusion, the dashboard enhances patient safety, optimizes workflows, and ensures reliable test results. This innovative solution has the potential to transform laboratory operations, seamlessly integrating safety and diagnostic accuracy within complex networks.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0124

ANALYSIS OF PRE-ANALYTICAL PHASE QUALITY INDICATORS BY SIX SIGMA IN A REFERENCE FLOW CYTOMETRY LABORATORY IN MEXICO

E. Fuentes Chavez [1], N. Mendez Ramirez [1], M.d.R. Herrera Estrada [1], M.d.R. Salazar Riojas [1], D. Gomez Almaguer [1]
[1]*Servicio de Hematologia Hospital Universitario Dr. Jose Eleuterio Gonzalez UANL*

BACKGROUND-AIM

Flow cytometry is a key methodology in the approach to hemato-oncology patients. Pre-analytic variables such as specimen collection, identification, transport, storage and the information provided that could negatively affect the approach to the sample or the reproducibility of the results. Tools such as quality indicators has been described to monitor critical processes and identify errors, failures and risks, in combination with six sigma, allows identifying and reducing the variability of the processes developed in this stage.

METHODS

Information was collected from July 2022 to November 2024 in a database, were included: Acute and Chronic Leukemia Panel, Measurable Residual Disease, CD34+ determination and Myelodysplastic Syndrome Panel. The Six Sigma harmonized indicators proposed by Sciacovelli et al.(2016) were used to classify the identified errors. The indicators that didn´t present any errors were discarded. The incidence of each defect and the total population were analyzed using Westgard's Six Sigma online calculator. The scale of the Six Sigma indicators was adopted from a study conducted by Grecu et. al.(2014) to evaluate laboratory performance during the pre-analytical stage.

RESULTS

8720 applications were analyzed for errors made during the pre-analytical phase in the flow cytometry area of the laboratory. Of the total population 18.2% correspond to ALP, 5.3% CLP, 42.4% MRD, 24.7% CD34+ and 9.4% MDS. Of the 26 quality indicators of the preanalytical phase evaluated, only 14 were identified. The indicators found with the highest incidence was requests without clinical data, with 663 cases, transcription errors with 174 cases and misidentified requests with 87 errors. The information obtained was used to calculate the value of DPMO and the sigma measure for each case. The ranges for frequency ranged from 0.11-7.39%, for DPMO from 1136-76032 and for sigma measure from 3-4.6.

CONCLUSIONS

In this study, 3 quality indicators were identified whose six sigma value has an opportunity for improvement. In each case, there was no negative impact on the proper approach to the specimen due to the laboratory's internal protocols. This type of evaluation enriches our risk management and encourages us to continue promoting continuing education and physician-laboratory interaction.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0125

PRE-ANALYTICAL PHASE: INTERFERENCE OF HEMOLYSIS ON NINE BIOCHEMICAL PARAMETERS

y. Ghedada [2], m.r. Bouzid [1], a. Chabane [1], w. Chaib [1]
[1]*faculty of pharmacy of algiers*
[2]*unit of niochemistry department of laboratory hmuscorfa algiers.*

BACKGROUND-AIM

Hemolysis is one of the most common interferences in laboratories during the preanalytical phase, compromising the reliability of test results.

METHODS

This study evaluates the influence of hemolysis on nine biochemical parameters: alanine aminotransferase (ALT), aspartate aminotransferase (ASAT), creatine kinase (CK), creatinine, blood sugar, lactate dehydrogenase (LDH) , calcium, phosphate and total proteins firstly then classify the biochemical parameters according to their variation after hemolysis by determining the hemoglobin threshold (cut-off).
The study was carried out on a healthy population using the COBAS Integra 400 plus automated system. The first method, according to the Valtec protocol, uses freezing/thawing to study the influence of hemolysis on biochemical parameters. The second method aims to determine a threshold (cut-off) by creating a calibration range involving an osmotic shock by the addition of hemolysate

RESULTS

The results indicate that, according to the first method, LDH, AST, ALT, CK, creatinine, total proteins and phosphate are positively influenced by hemolysis, while calcium is the only parameter of which the values decrease. Blood sugar levels showed no significant changes.
With the second method, ALT increases to 10.3 g/L of hemoglobin then decreases to 30 g/L, with a cut-off at 5.1 g/L. AST, LDH, CK, total protein and phosphate increase with a cut-off at 20.6 g/L of hemoglobin, while creatinine shows an increase with a cut-off at 10.3 g /L of hemoglobin. Calcium decreases with a cut-off at 20.6 g/L of hemoglobin

CONCLUSIONS

hemolysis leads to increased levels of ALT, AST, LDH, CK, creatinine, total protein and phosphate, while reducing calcium levels. On the other hand, blood sugar is not significantly affected.
The cut-off points vary for ALT and creatinine, but are the same for AST, LDH, CK, calcium, phosphate and total protein. The freeze/thaw and osmotic shock methods showed no significant differences when compared, demonstrating their concordance. Clinical biology laboratories must continue to strengthen quality control and assurance programs, and develop effective guidelines to reduce the frequency of hemolysis as well as any interference in the analytical phase.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0126

EXTERNAL QUALITY ASSESSMENT OF IMMUNOHEMATOLOGICAL TESTING IN MEDICAL LABORATORIES OF REPUBLIC OF BELARUS – SECOND ROUND.

N. Kaliadka [1], V. Velichko [1], L. Novak [2], F. Karpenko [2], Y. Pakhadnia [1]
[1]*National Antidoping Laboratory, Republic of Belarus*
[2]*Republican Scientific and Practical Center of Transfusiology and Medical Biotechnologies, Republic of Belarus*

BACKGROUND-AIM

External quality assessment (EQA) of laboratory tests is an integral part of the quality system of medical laboratories and a criterion for compliance with the requirements of the ISO 15189 standard. This is especially important for immunohematological tests, since the patient's life directly depends on them. In 2024 the Round 2 of EQA for immunohematological testing in the Republic of Belarus was conducted, in which 282 more laboratories took part (798) than in Round 1 (516) in 2022.

METHODS

The following samples were used as control samples (CS) for EQA: 6 ml blood in plastic tubes. CS were prepared by Republican Scientific and Practical Center of Transfusiology and Medical Biotechnologies (RSPC TMB). Longer stability of the CS was confirmed compared to Round 1 in 2022 due to the use of tubes with CPDA preservative. Four versions of CS were prepared. The values obtained in these CS in the reference laboratory of the RSPC TMB were accepted as assigned. The evaluated parameters were the following: determination of blood group according to the ABO and Rh systems; detection (screening) of alloimmune anti-erythrocyte antibodies (Ab); determination of Ab titer with a positive screening result. CS were blinded, marked and labeled by National Antidoping Laboratory. The tests were carried out by the participants by any means and methods available in the laboratory.

RESULTS

The results of EQA for determining blood groups according to the ABO system (228 participants) are satisfactory in 98.2% of cases, doubtful - in 1.8% of cases. The results of EQA for determining the blood group according to the Rh system (228 participants) are satisfactory in 96.1% of cases, doubtful - in 3.9% of cases. The results of EQA for detection (screening) of alloimmune anti-erythrocyte Ab (220 participants) are satisfactory in 80.5% of cases, doubtful - in 19.1% of cases, unsatisfactory - in 0.4% of cases. The results of EQA determining the titer of alloimmune anti-erythrocyte Ab (122 laboratories) are satisfactory in 86.1% of cases, unsatisfactory in 13.9% of cases.

CONCLUSIONS

Higher stability of non-commercial control samples, maximum coverage of external control of laboratories in the country allows you to effectively evaluate and compare the quality of tests performed in different laboratories.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0127

CURRENT PRACTICES IN CRITICAL VALUES MANAGEMENT IN SPANISH CLINICAL LABORATORIES: A NATIONAL SURVEY

M.E. López Guío [4], A. Fernández Alonso [1], M.H. Redín Sarasola [6], D. Pineda Tenor [3], A. Cosmen Sánchez [5], L. Sanmartin Fenollera [2], C. Lorenzo Lozano [11], E. Prada De Medio [10], S. Prieto Menchero [7], F. Gascón Luna [9], L. Criado Gomez [8]

[1]*Analiza Sociedad de Diagnóstico S.L. Madrid. Spain; Comité de Calidad, gestión, seguridad y evidencia. AEBM-ML*
[2]*Complejo Hospitalario Universitario de Santiago. Santiago de Compostela. Spain; Comité de Calidad, gestión, seguridad y evidencia. AEBM-ML*
[3]*Hospital de Antequera. Málaga. Spain; Comité de Calidad, gestión, seguridad y evidencia. AEBM-ML*
[4]*Hospital Nuestra Señora de Sonsoles. Avila. Spain; Comité de Calidad, gestión, seguridad y evidencia. AEBM-ML*
[5]*Hospital Santa Bárbara de Puertollano. Ciudad Real. Spain; Comité de Calidad, gestión, seguridad y evidencia. AEBM-ML*
[6]*Hospital Universitario de Donostia. San Sebastián. Spain; Comité de Calidad, gestión, seguridad y evidencia. AEBM-ML*
[7]*Hospital Universitario de Fuenlabrada. Madrid. Spain; Comité de Calidad, gestión, seguridad y evidencia. AEBM-ML*
[8]*Hospital Universitario de Móstoles. Madrid. Spain; Comité de Calidad, gestión, seguridad y evidencia. AEBM-ML*
[9]*Hospital Valle de los Pedroches. Córdoba. Spain; Comité de Calidad, gestión, seguridad y evidencia. AEBM-ML*
[10]*Hospital Virgen de la Luz. Cuenca. Spain; Comité de Calidad, gestión, seguridad y evidencia. AEBM-ML*
[11]*Hospital Virgen de la Salud. Toledo. Spain; Comité de Calidad, gestión, seguridad y evidencia. AEBM-ML*

BACKGROUND-AIM

Critical values (CVs) are laboratory results that indicate immediate risk for adverse events, requiring urgent communication to clinicians. Despite guidelines such as those from the Clinical and Laboratory Standards Institute (CLSI), no consensus exists regarding the definition, management, and notification protocols for CVs in Spain. This study aimed to evaluate current practices in CV documentation, differentiation, and communication across Spanish clinical laboratories.

METHODS

A 23-question survey was designed and distributed by the Quality, Management, Safety, and Evidence Committee (CCGSE) via the AEBM-ML website from May to June 2023. The survey targeted laboratory professionals nationwide. Responses were collected anonymously or with identification.

RESULTS

A total of 118 laboratories participated, predominantly from Madrid and Andalucía. Key findings included:
CV Documentation and Differentiation: 89.8% reported having a documented CV protocol. However, only 55% differentiate between CVs and significant risk values (SRVs), with 44.1% distinguishing by patient type (e.g., age or origin).
Notification Practices: 72% of CVs are communicated via telephone, while only 14.4% are reported through email, and 44.1% for SRVs. Documentation of the recipient's details occurs in 86.9% for CVs but only 58.5% for SRVs.
Among laboratories, 50% document CVs in the laboratory information system (LIS). Regarding the responsible party for communication, 45.8% of CV notifications are made by laboratory physicians, while 43.2% involve other staff. For SRVs, 41.2% are communicated to the prescribing clinician, and 11.9% are also shared with nursing staff.
Parameters Most Frequently Reported as CVs: Potassium, glucose, and hemoglobin ranked highest, followed by sodium and INR.

CONCLUSIONS

The survey revealed significant variability in CV practices, including a lack of differentiation between CVs and SRVs, inconsistent documentation protocols, and disparate communication strategies.
Standardization efforts, such as harmonizing definitions, implementing LIS integration, and using indicators for monitoring, are critical for improving patient safety and reducing variability.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0128

USING VERIFICATION DATA FOR ESTIMATING MEASUREMENT UNCERTAINTY IN A ROUTINE MEDICAL LABORATORY

S. Michaelis [1], L. Binder [1], C. Schneider [1], D. Enko [1]
[1]*Institute of Clinical Chemistry and Laboratory Diagnostics, General Hospital Hochsteiermark, Leoben, Austria*

BACKGROUND-AIM

The estimation of the measurement uncertainty for quantitative parameters is imperative for laboratories accredited according to ISO 15189. However, no universally accepted procedure for its calculation is available. Published guidelines differ in their general approach and extent of required measurements or data. The aim of this study was to evaluate a simplified procedure for the calculation of measurement uncertainty in a routine medical laboratory, based on already existing verification data and results from external quality assessment (EQA) schemes.

METHODS

Expanded measurement uncertainty (U, confidence interval 95%) was calculated for 23 clinical chemistry parameters using two different data sets applying the Nordtest calculation procedure. One U was determined utilizing routine internal quality control data from one year (60 measurements/level; two levels) and six EQA-samples (U(IQC)), the second U with routinely obtained verification data according to the CLSI EP15-A3 guideline (25 measurements/level, 5x5-scheme; 2 levels) and only 4 EQA samples (U(Verification)). The difference between U(IQC) and U(Verification) (∆U) was calculated. Where available, UIQC and UVerification were compared to published allowable performance goals (Rili-BAEK and Westgard).

RESULTS

In a majority of parameters, U was higher for U(IQC) (median 13.43 %, range 6.37 % - 22.83 %) compared to U(verification) (median 11.6 %, range 5.82 % - 18.98 %). The median ∆U was 1.55 % (range -3.95 % - 7.75 %). Six parameters showed a ∆U of > 3 %. Five parameters were observed with a higher U(Verification), only one parameter with a ∆U < -3 % (interleukin-6, U = -3.95 %). For most parameters U(IQC) and U(Verification) were within the Rili-BAEK and Westgard performance goals. Only for the creatinine kinase isoenzyme MB U(verification) (U = 15.23 %)was within the Westgard performance limit (16.5 %), while U(IQC) (U = 20.0 %)was above it.

CONCLUSIONS

A simplified procedure for the estimation of measurement uncertainty utilizing verification data may be suitable for use in routine medical laboratories.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0129

FAILURE MODE AND EFFECTS ANALYSIS OF FALSELY ELEVATED SERUM TOTAL CALCIUM RESULTS ON BECKMAN COULTER CHEMISTRY ANALYZER

N. Parašilovac [1], I. Friščić [1], S. Perkov [1], M.M. Kardum Paro [1]
[1]*Department of Medical Biochemistry and Laboratory Medicine, Merkur University Hospital, Zagreb, Croatia*

BACKGROUND-AIM

Falsely elevated serum total calcium concentrations can be the result of analytical errors, leading to unnecessary investigations, erroneous diagnosis and potentially inappropriate treatment. The aim of the study is to perform a failure mode and effects analysis (FMEA) after obtaining falsely elevated results for serum total calcium on the Beckman Coulter DxC 700 AU chemistry analyzer.

METHODS

Serum total calcium concentration was measured using arsenazo III method, accredited according to ISO 15189, on two Beckman Coulter chemistry analyzers: DxC 700 AU and AU 680 (Beckman Coulter, Brea, USA). FMEA was applied to analyze all possible causes of analytical error and score laboratory failures for the failure demerit value (FDV), probability of failure (PF) and probability of failure remedy (PFR). Based on obtained scores (on a 10-point scale) risk priority numbers (RPNs) were calculated.

RESULTS

A total of three failure modes were identified in the analytic process: technical, methodological and equipment problems. The baseline FMEA showed a moderate probability of falsely elevated total calcium concentration (PF 4) and a high probability of detecting an outlier (PFR 3), as samples with suspiciously high results were reanalyzed. The significance of the deviation was high (FDV 8) due to the possibility of incorrect clinical decisions. The overall risk size was significant (RPN 96), requiring corrective (detailed inspection of the analyzer, service support consultation) and preventive actions (automatic reanalysis of samples with total calcium $\geq$ 2.70 mmol/L). The new FMEA indicated a minimal probability of deviation (PF 1) with a very high probability of detecting falsely elevated results (PFR 1). The significance of the outlier remained unchanged (FDV 8) and the risk indicated by the new FMEA was insignificant (RPN 8).

CONCLUSIONS

Analytical errors are rare, take longer to be detected, and potentially cause significant harm to the patient. After implementing corrective and preventive actions, the risk of falsely elevated measurement results was greatly reduced.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0130

INCREASING INCLUSION: A NOVEL APPROACH TO BLOOD COLLECTION FOR PEDIATRIC PATIENTS WITH BEHAVIORAL AND LEARNING CHALLENGES

S. Greenberg [1], J. Crumbacher [1], A. Pyle-Eilola [1], H. Lawrence [1]
[1]*Department of Pathology and Laboratory Medicine, Nationwide Children's Hospital, Columbus, OH, USA*

BACKGROUND-AIM

Phlebotomy, either by intravenous or capillary stick, can be frightening for children. For children with learning and behavioral challenges, the process may be so difficult as to preclude routine blood collection, resulting in health inequity and disparities. Additionally, phlebotomists at our institution have experienced injuries by attempting phlebotomy on patients with learning and behavioral challenges when the patients have become violent in an attempt to avoid the procedure. Therefore, to increase inclusion of care for this patient population and decrease risk to phlebotomists, we implemented the S.A.F.E. (Safe Area For Everyone) Program.

METHODS

The S.A.F.E. Program entails the following interventions: 1) scheduling and registering patients in advance for specific time-slots instead of walk-in appointments, 2) individual patient assessment to determine patient's likes, dislikes, comfort items and triggers, 3) lab preparation to ensure all equipment is ready prior to patient arrival to the procedure room, 4) a "Social Story Book" illustrating the steps of the collection process is sent in advance so patients will know what to expect 5) post-collection surveys so the family can provide feedback on their experience. Staff are also provided training specific to these collections.
Data on enrollment and safety incidents are collected and reviewed annually, with data analysis in Microsoft Excel.

RESULTS

In 2023, 171 patients had blood collected through the S.A.F.E. Program, just 0.2% of our total outpatient collections. Of those 171, 71% were repeat patients from previous years and 7% went on to have successful collections without use of the S.A.F.E. Program. The age of patients utilizing the program in 2023 ranged from 1-30 years, with a median of 11 years. 69% of patients were male.
While employee serious safety events have increased in the general patient population collected at our outpatient labs, there have been zero such events associated with S.A.F.E. Program collections.
Post-collection surveys showed 100% of respondents were satisfied with the experience.

CONCLUSIONS

The S.A.F.E. Program is a novel approach to phlebotomy that both enhances phlebotomy safety and extends the opportunity for blood collection to those with behavioral and learning challenges.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0131

INTERNAL QUALITY CONTROL AUDIT: APPLICATION TO TUMOR MARKER ASSAYS

N. Rouibah [2], A. Nafir [1], D. Bouaichi [2], N. Habak [3], N. Raaf [1]
[1]*Biochemistry laboratory, CPMC Hospital, Faculty of Medecine,university of health sciences,algeria*
[2]*Biochemistry laboratory, CPMC Hospital, Faculty of Pharmay,university of health sciences,algeria*
[3]*Central laboratory, Ain Taya Hospital, Faculty of Pharmay,university of health sciences,algeria*

BACKGROUND-AIM

Internal quality control is the set of procedures that define the means used on a daily and permanent basis to detect and correct errors that could affect the results of biological tests.This is a key technical requirement for the accreditation of medical biology laboratories according to the NR EN ISO 15189 standard. The aim of our work is to verify the reliability of our laboratory results.

METHODS

Our work consists of an internal quality control audit applied to 3 parameters: ACE, CA19.9 et CA 15.3 .the control used are: PreciControl Tumor Marker 1 and 2; Roche,The machine used is the Cobas E 411 Roche diagnosis .the interpretation was made retrospectively by establishing LEVEY JENNINGS diagrams and following WESTGARD rules taking into account the means and standard deviations (1SD, 2SD, 3SD)

RESULTS

For ACE:Level 1: 79.41% of values did not exceed 1SD, 20.59% of values were between 1SD and 2SD and no value was between 2SD and 3SD .
Level 2: 69.7% of the values did not exceed 1SD, 27.27% of the values were between 1SD and 2SD and 6.06% of the values were between 2SD and 3SD, noted that rule 2 2S was violated on June 23 and 24 on the same control level indicating a systematic error requiring calibration.
For CA 19.9:Level 1: 91.42% of values did not exceed 1SD, 8.51% of values were between 1SD and 2SD and no value was between 2SD and 3SD .
Level 2: 74.29% of the values did not exceed 1SD, 25.71% of the values were between 1SD and 2SD and no value was between 2SD and 3SD.
For CA 15.3:Level 1: 54.55% of values did not exceed 1SD, 42.42% of values were between 1SD and 2SD and 3.03% of values were between 2SD and 3SD, noted that rule 1 2S was violated on June 3rd indicating acceptable random error.
Level 2: 48.48% of the values did not exceed 1SD, 39.39% of the values were between 1SD and 2SD and 12.12% of the values were between 2SD and 3SD, noted that rule 12S was violated 2 times on June 10 and July 2 indicating an acceptable random error and rule 2 2S was violated on June 25 on the same level indicating a systematic error requiring the regeneration of a new control with calibration.

CONCLUSIONS

Internal quality audit is an integral part of the quality system; it allows quality assurance by detecting random or systematic errors in order to guarantee a reliable and accurate result

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0132

TWO APPROACHES FOR RISK ASSESSMENT OF THE POST-ANALYTICAL PHASE. WHICH ONE IS BETTER?

S. Semenski [1], B. Kranjčec [1], K. Klenkar [1], V. Šenjug [1], G. Tkalec [1], L. Mavrić [1], A. Lešković [1]
[1]*Zabok General Hospital and Hospital of Croatian Veterans*

BACKGROUND-AIM

In the Medical and Biochemical Laboratory of the Zabok General Hospital and the Hospital of Croatian Veterans, a risk assessment is made for all three key phases of work. The goal of the research was to determine a suitable method to assess the risk for the patient in the case of errors in the post-analytical phase of the work of assessment, i.e. whether the patient is deprived of the quality of the obtained findings. A risk analysis was made for the samples where an error was identified in relation to all the findings made in the laboratory and compared with the data from the previous year.

METHODS

321,806 samples received between 01.01.2023 and 31.12.2023 from 144,966 patients, of which 23 had an error that led to recall of the findings (0.007%), were processed using Six Sigma and Failure mode and effects analysis (FMEA) methods. Then, 249,653 samples received between 01.01.2024 and 01.09.2024 from 111,944 patients were processed. Of these, 47 samples had an error that led to the recall of the findings (0.020%). The appearance and the sending of the findings were standardized by the system and verified, and the analysis of the risk assessment was based on the recalled findings.

RESULTS

Six sigma values for 17 types of errors that led to recalled findings ranged from 5.7 to 6.0 in 2023, and from 5.4 to 6.0 in 2024. In contrast, with the FMEA method of risk assessment by combining the significance of the error and its occurrence, 14 errors were classified in the Permitted risk without harm to the patient category, and 3 errors in the Minimal and acceptable risk category.

CONCLUSIONS

The Six Sigma method is not suitable for risk assessment of the post-analytical phase because the Six Sigma values above 5 could be misinterpreted that all errors are acceptable. Recalled findings are critical errors that directly affect the findings received by the patient and represent errors that should not occur. However, the FMEA method is suitable for risk assessment of the post-analytical phase, and errors that require the Laboratory's action are identified, which leads to a reduction in recalled findings and thus increases the quality of the Laboratory's service, as well as other hospital departments.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0133

ESTABLISHING AND IMPLEMENTING QUALITY INDICATORS FOR POINT-OF-CARE TESTING

J. Shaw [9], S. Arnoldo [10], I. Bouhtiany [11], D. Brinc [14], M. Brun [1], C. Collier [18], A. Fuezery [2], A. Fung [8], Y. Huang [13], S. Kaur [15], M. Knauer [16], E. Kostantin [4], L. Labrecque [5], F. Leung [7], V. Thakur [6], A. Venner [3], P. Yip [17], V. De Guire [12]

[1]*Alberta Precision Laboratories and Department of Laboratory Medicine and Pathology, University of Alberta*

[2]*Alberta Precision Laboratories and Department of Laboratory Medicine and Pathology, University of Alberta, Edmonton, Alberta, Canada*

[3]*Alberta Precision Laboratories and Department of Pathology and Laboratory Medicine, University of Calgary, Calgary, Alberta, Canada*

[4]*Clinical Department of Laboratory Medicine, Cite-de-la-Sante Hospital, Optilab LLL and University of Montreal, Montreal, Quebec, Canada*

[5]*Clinical Department of Laboratory Medicine, University of Montreal Hospital Center (CHUM), Montreal, Quebec, Canada.*

[6]*Department of Laboratory Medicine, Eastern Health Authority and Memorial University, St. John's, St. John's, Newfoundland and Labrador, Canada*

[7]*Department of Pathology and Laboratory Medicine, Sinai Health System, Department Laboratory Medicine and Pathobiology, University of Toronto, Toronto, Ontario, Canada.*

[8]*Department of Pathology and Laboratory Medicine, St. Paul's Hospital and University of British Columbia, Vancouver, British Columbia, Canada*

[9]*Division of Biochemistry, The Ottawa Hospital and Eastern Ontario Regional Laboratories Association. Department of Pathology and Laboratory Medicine, University of Ottawa, Ottawa, Ontario, Canada*

[10]*Division of Biochemistry, Unity Health and Department of Laboratory Medicine and Pathobiology, University of Toronto*

[11]*Division of Biochemistry, Vitalite Health Network, Edmundston, New Brunswick, Canada*

[12]*Hospital Maisonneuve-Rosemont, Grappe OPTILAB, Montreal CHUM, Montreal, Quebec, Canada.*

[13]*Kingston Health Sciences, Department of Pathology and Molecular Medicine, Queen's University, Kingston, Ontario, Canada*

[14]*Laboratory Medicine Program, University Health Network and Department of Laboratory Medicine and Pathobiology, University of Toronto, Toronto, Canada*

[15]*Lifelabs, Burnaby British Columbia, Canada*

[16]*Pathology and Laboratory Medicine, London Health Sciences and University of Western Ontario, London, Ontario, Canada*

[17]*Precision Diagnostics and Therapeutics Program, Sunnybrook Health Sciences Centre, Department of Laboratory Medicine and Pathobiology, University of Toronto, Toronto, Ontario, Canada.*

[18]*Royal Columbian Hospital and Department of Pathology and Laboratory Medicine, University of British Columbia, Canada*

BACKGROUND-AIM

Quality indicator (QI) monitoring is key to quality assurance for laboratory testing to allow for identification of processes at risk for patients and areas that needs improvement. Quality improvement through comparison is an essential aspect in Quality Management. As specific QIs are needed for Monitoring of the quality assurance of point of care testing (POCT), the aim of this study was to identify potential QI for POC glucose testing that are suitable for monitoring of processes but also compatible for comparison through national and international programs.

METHODS

This study builds upon previous work by our group in developing a process to establish QI for POC glucose testing, based on process mapping and risk assessment. Members of our working group used identified, by consensus, the potentially error-prone steps in the POC glucose testing process. A risk assessment was performed for each step, based on probability and consequence of occurrence. The ability to obtain data for each step was also assessed. Quality indicators were chosen based on their risk and the ability to obtain data.

RESULTS

Here, we present five recommended QI for POC glucose testing. These include positive patient identification (PPID), internal quality control (QC) monitoring, external quality assessment, critical results follow-up and operator training. Four of the five QI recommended have equivalent or similar QI recommended by the IFCC WG-LEPS for central laboratory testing. PPID has been successfully added to the QI comparison program of the Quebec Society of Clinical Biology, in collaboration with the Canadian Society of Clinical Chemists. Authors were invited to submit internal QC data for their site for preliminary validation of the internal QC QI. Results were obtained from twenty-two sites across Canada, representing the two most common hospital glucose meters.

CONCLUSIONS

Here, we present five recommended QI for POC glucose testing based on process mapping, risk assessment and availability of data. These QI are also applicable to POCT, other than glucose. Preliminary QI data are presented for each recommended QI as well as implementation strategies and challenges associated with each recommended QI.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0134

TREND ANALYSIS OF LABORATORY GLYCATED HAEMOGLOBIN REQUESTS FOR PAEDIATRIC AND ADOLESCENT PATIENTS FROM A TERTIARY HOSPITAL BETWEEN 2014- 2019

T. Simela- Tshabalala [1]
[1]*Sefako Makgatho Health Sciences University*

BACKGROUND-AIM

In the past three decades, studies that map trends of diabetes mellitus type 1(DM 1) and diabetes mellitus type 2 (DM 2) in the paediatric and adolescent population in developed countries have demonstrated that an increased number of individuals are affected by DM. These countries have the advantage of established data registries that are used in tracking newly diagnosed DM patients and monitoring those on treatment. In contrast, Sub-Saharan Africa has a paucity of data on the DM trends in this population. This study aims to assess the trend of laboratory based glycated haemoglobin (HbA1C) requests for paediatric and adolescent patients at Dr George Mukhari Academic Hospital (DGMAH) between December 2014 and December 2019 and to assess if the trend is in keeping with the increased global incidence and prevalence of DM in this population.

METHODS

In this retrospective trend analysis of HbA1C tests requested between December 2014- December 2019, study data was obtained from the National Health Laboratory Services Central Data Warehouse (NHLS CDW). SPSS version 25 was used to analyse data for annual rates of requests of HbA1C, month- to month variation of HbA1C requests over the study period and to assess for compliance with International Society for Paediatric and Adolescent Diabetes (ISPAD) quarterly HbA1C testing recommendations for patients with DM.

RESULTS

Overall, 11 536 entries were received from CDW but only 1 842 results were analysed after applying exclusion criteria. The mean age of the participants was 11.06 ± 5.57 years with females almost double the number of males, 1.8 more females. There was a 9.6% and 2.1% increase in HbA1C test requests between 2015- 2017 and 2018- 2019 respectively. The year-on-year differences in HbA1C test requests over the study period were statistically significant, $p<0.001$. The mean HbA1C concentration for the period January 2015- December 2019 was 9.3%. HbA1C concentration ≥6.5% was observed in more than half of the participants in each year.

CONCLUSIONS

Trend analysis of HbA1C test requests in the paediatric and adolescent population between December 2014- December 2019 demonstrates a steady rise in testing indicating an increase in DM screening, diagnosis and monitoring in this population. This increase in trend pattern is in keeping with global statistics.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0135

EVALUATING STABILITY OF HEMOLYTIC, LIPEMIC, AND ICTERIC INDICES IN BLOOD SAMPLES TRANSPORTED BY DRONES: IMPLICATIONS FOR MEDICAL LOGISTICS

N. Stierlin [1], F. Loertscher [2], S. Hanselmann [1], M. Risch [1], L. Risch [1]
[1](UFL) Private University of the Pricipality of Liechtenstein, 9495 Triesen, Liechtenstein
[2]Labormedizinisches Zentrum Dr Risch, 9470 Buchs Switzerland

BACKGROUND-AIM

Ensuring blood sample integrity during transport is critical for accurate diagnostics. Hemolytic, lipemic, and icteric (HIL) indices are vital preanalytical markers for detecting hemolysis, lipemia, and icterus, which can affect diagnostic accuracy. Drones are an emerging solution for medical transport, particularly in remote areas. This study evaluates drone transport's effect on HIL index stability in serum, EDTA whole blood, lithium-heparin plasma, and citrate plasma.

METHODS

Twenty-five samples from each blood type were transported via a custom medical drone over a 25-km route in 30 minutes at 100 km/h and 100 meters altitude. Samples were secured in containers designed to minimize vibration and temperature changes. Environmental conditions were monitored using data loggers and accelerometers. Pre- and post-transport HIL indices were measured spectrophotometrically, and paired t-tests assessed statistical differences ($p < 0.05$).

RESULTS

No significant differences in HIL indices were observed across all sample types. In serum, the hemolytic index changed by -0.15 ($p = 0.19$), and the lipemic index decreased by -0.20 ($p = 0.38$). EDTA whole blood showed similar stability, with the hemolytic index changing by -0.15 ($p = 0.42$) and the lipemic index increasing by +0.25 ($p = 0.23$). Lithium-heparin plasma exhibited no change in the hemolytic index (0.00, $p = 1.00$) and minor, non-significant changes in icteric and lipemic indices (+0.05, $p = 0.79$). Citrate plasma showed similar stability, with all variations yielding p-values above 0.19. Across all sample types, differences in HIL indices were clinically and statistically insignificant, confirming preanalytical sample quality preservation during drone transport.

CONCLUSIONS

Drone transport maintains stable HIL indices, supporting its reliability for medical logistics. Drones offer advantages such as bypassing traffic, enabling access to remote areas, and reducing transport times, while providing a sustainable alternative to traditional methods. By ensuring blood sample integrity, this study supports drone integration into healthcare as reliable, efficient, and eco-friendly solutions. Further research is needed to evaluate scalability and effects on additional diagnostic parameters.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0136

EVALUATION OF THE ANALYTICAL PERFORMANCE OF THE TOSOH G11 ANALYZER FOR HBA1C ASSAY

N. Mseddi [2], O. Salah [2], K. Ghniya [2], F. Khamassi [2], S. Hammami [3], S. Oueslati [3], W. Grouze [3], Y. Mansour [2], A. Bartkiz [1], B. Hammami [1], E. Talbi [3], R. Mahjoub [2]

[1]*Biochemistry Laboratory - Charles Nicolle Hospital; Tunis*

[2]*Clinical Biology Laboratory, Zouhair Kallel Institute of Nutrition and food technology, Tunis, Tunisia*

[3]*Research Unit UR17SP01 - "Zouhair Kallel" National Institute of Nutrition and Food Technology - Tunis, Tunisia*

BACKGROUND-AIM

HbA1c is a key biomarker for the diagnosis and monitoring of diabetes. This study aims to evaluate the analytical performance of the Tosoh G11 analyzer for HbA1c assay in terms of precision and correlation with another HPLC method: the Biorad's D10 system.

METHODS

Repeatability was assessed using whole blood pools with mean values of 4.87% for pool 1, 6.88% for pool 2, and 9.24% for pool 3. Reproducibility was evaluated using internal quality control samples provided by the manufacturer, with target values of 5.1% for level 1 and 10.2% for level 2. 104 patient samples were analyzed for the comparative study, which was statistically evaluated using the Bland-Altman plot and the Passing-Bablok regression curve.

RESULTS

For Tosoh G11 analyzer for HbA1c assay, the precision study revealed repeatability CVs of 0.64%, 0.50%, and 0.41% for pools 1, 2, and 3, respectively. For reproducibility, CVs were 0.72% and 0.49% for levels 1 and 2, respectively.
The comparative study with the D10 system (Biorad) showed a strong correlation, with a Spearman correlation coefficient of $r = 0.979$ ($p<0.0001$). The Passing-Bablok regression line indicated the absence of both systematic and proportional bias. The Bland-Altman difference plot showed a mean difference of 0.23% ($p<0.0001$) between the two methods, with matching limits of -0.2708 for the minimum and 0.7260 for the maximum.

CONCLUSIONS

The analytical performance of the Tosoh G11 analyzer for HbA1c assay is overall satisfactory, demonstrating excellent precision in line with recommendations from expert societies such as the SFBC, which recommends CVs <3.8% for repeatability and <5% for reproducibility. The strong correlation observed between the two analyzers across the entire range of tested values supports the interchangeability of results between the two systems.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0137

ANALYTICAL PERFORMANCE SPECIFICATIONS (APS) - ARE WE PROVIDING CLINICALLY APPROPRIATE APS FOR EXTERNAL QUALITY ASSESSMENT?

G. Davies [1], A. Thomas [1], C. Parfitt [1]
[1]*Weqas, Cardiff and Vale University Health Board, Cardiff, UK*

BACKGROUND-AIM

In terms of EQA, APS is defined as a range of values around the target which is considered acceptable for the performance of that test. A result outside the acceptable range should alert the laboratory that that their assay may produce results that are at risk of detrimentally affecting clinical decision making. It provides a simple tool to allow a rapid, standardized assessment of EQA results. Various strategies have been proposed over the last 25 years, including the Consensus hierarchy from the Stockholm Conference in 1999, and the simpler EFLM Milan strategy in 2014. The aim of the study was to review the strengths and weaknesses of the various models and compare with what was achievable.

METHODS

Performance data from Weqas was collected over the last five years across a wide clinical concentration for the common measurands in Clinical Biochemistry. The data covered 60 distributions using 240 samples, assayed by 200 laboratories for 10 measurands. Precision profiles were calculated for each of the major methods used for that measurand. These were represented as Standard Deviation (SD) and Coefficient of Variation (CV%). The profiles were compared with the optimal, desirable, and minimum APS based on biological variation (Model 2) and the methods with the best analytical quality identified.

RESULTS

For Sodium and HbA1c the minimum APS was not achievable and alternative models are proposed. For Potassium and Urate most methods achieved the optimal APS. For Cholesterol, Creatinine and Glucose desirable APS was achieved at, all concentration, > 100 µmol/L, and > 3.0mmol/l, respectively. For Calcium, the minimum was achieved by some methods and for HDL the minimum was only achieved at concentration > 1.0 mmol/L.

CONCLUSIONS

Although Model 2 was achievable for a number of measurands, it was rarely achievable across the full pathological range. The relationship between performance in terms of SD or CV and concentration was rarely linear, and a hybrid (mixed) model is proposed. APS should be designed to provide performance assessment that best meets the clinical utility of the test, whether used for screening, monitoring, or diagnosis. Where the measurand is used for different clinical utility then the more stringent model should be selected.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0138

DEVELOPMENT OF AN EXTERNAL QUALITY ASSESSMENT (EQA) PROGRAMME FOR A POINT-OF-CARE TEST (POCT) FOR PHOSPHORYLATED INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN-1 PHIGFBP-1

G. Davies [1], C. Parfitt [1], A. Thomas [1]
[1]*Weqas, Cardiff and Vale University Health Board, Cardiff, UK*

BACKGROUND-AIM

Preterm labour is defined as regular contractions of the uterus, resulting in changes in the cervix, starting before 37 weeks of pregnancy, affecting around 8 % of babies in the UK. Preterm birth is associated with short-term health problems, especially with breathing and feeding; as well as long-term physical and learning disabilities. phIGFBP-1 is produced in the decidua and as the cervix matures and labour approaches, the decidua and chorion detach and pIGFBP1 leaks into cervical secretions. Actim Partus (Alere, UK) is a qualitative POC test designed to detect phIGFBP-1 in cervical secretions during pregnancy and identify women at risk of preterm labour. In 2015, Weqas developed an EQA programme for phIGFBP-1 to assess and monitor performance of these tests.

METHODS

Semi-purified IGFBP-1 was sourced and validated using a quantitative immunoenzymometric assay (IEMA) in collaboration with Medix Biochemica. EQA material was produced covering a range of concentrations, including a true negative (diluent only); samples near the clinical cut off (10 μg/L); and at the upper limit of measurement (200 μg/L). Sample stability was assessed by storing samples at 20 °C, 4 °C and -20 °C. Homogeneity was assessed by repeated analysis of multiple pools. Participants received 2 samples on a bimonthly basis, with IEMA quantitative results used to determine the correct interpretation.

RESULTS

There was no significant deterioration in samples stored at 20 °C, 4 °C and -20 °C over a 7- day period, nor in samples stored at 4 °C and -20 °C over a 14-day period. Homogeneity was found to be acceptable over a range of concentrations of phIGFBP-1. Participant data has shown that although clinical sensitivity exceeds 85 % at phIGFBP-1 concentrations above 50 μg/L; it falls to 62 % at 19.6 μg/L. Thus a number of negative results are reported for a true positive sample at concentrations above the cut-off point.

CONCLUSIONS

The data reiterates the need for an ongoing assessment of performance especially near the cut- off. The Weqas Pre - Term Labour Marker programme is accredited to ISO 17043.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0139

EXTERNAL QUALITY ASSESSMENT FOR PLASMA URACIL MEASUREMENT: APPLICATION FOR THE DETECTION OF SEVERE TOXICITY OF FLUOROPYRIMIDINES-BASED CHEMOTHERAPY IN CASE OF DPD DEFICIENCY.

C. Narjoz [2], F. Thomas [3], B. Royer [4], I. Anglard [1], M. Zguindou [1], A. Vassault [1]

[1]*Asqualab, 8 rue Maria Helena Vieira Da Silva, 7014 PARIS, France www.asqualab.com*

[2]*Laboratoire de Biochimie, hôpital Europeen Georges Pompidou, Paris, France*

[3]*Laboratoire de Biologie médicale Oncologique. Institut Universitaire du Cancer. Toulouse. Oncopole. France. GPCO-UNICANCER group, France*

[4]*Laboratoire de Pharmacologie Clinique, CHU Jean Mermoz, 25030 Besancon, France. GPCO- UNICANCER group, France.*

BACKGROUND-AIM

Since 2018, evaluation of the risk for severe toxicity of fluoropyrimidines (FP) before chemotherapy, is mandatory in France consisting in previous screening for DPD deficiency based on DPD phenotyping using plasma uracil measurement ([U]). According to the results, decision for contra-indication in case of complete DPD deficiency associated with FP toxic deaths ([U]≥150 µg/L; ~0.08% of patients) and adaptation of FP dosage for patients with partial DPD deficiency (>16 µg/L, ~9% of patients) are undertaken.

METHODS

An External Quality Evaluation program was organized by ASQUALAB since 2018. 6 plasma samples per year were provided to the participating laboratories. Samples are prepared using human dialyzed plasma spiked with different known concentration of uracil (U) and lyophilized. All participating laboratories used liquid chromatography (n = 45) with either mass spectrometry (84%) or UV detection (12%).
The [U] results provided were evaluated as compared to the weighted target values, to the general mean and pair group mean according to acceptable limits (+/- 20%) as well.
Furthermore, Zscore were calculated (results were considered as satisfactory if Zscore <2, doubtful where 2< z-score <3 and unsatisfactory where z-score >3).

RESULTS

In 2018, 13 French laboratories took part to the evaluation whereas the EQA program were practiced by 51 European laboratories in 2024.
The results provided by the participants were assessed against expected weighted values.
For normal samples (U <16 µg/L) in 2024, results are found to be within the expected values by 86% (44/51) of the participants, they were only 77% (31/40) in 2020, exhibiting increasing performance.
For samples with partial deficiency (>16 µg/L to <100 µg/L), in 2024, 88% (45/51) results were found within the expected values, they were 89% (35/40) In 2020, demonstrating a constant performance.
For samples with complete deficiency (>150µg/L) in 2024, they were 92% (47/51), they were only in 2020 88% (35/40) showing an improvement of the evaluation.

CONCLUSIONS

The number of participating medical laboratories in EQAP greatly increased in Europe within 7 years. Data presented demonstrate the important role of EQAP for harmonization and improvement of the medical decision for the prevention of FP toxicity effects.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0140

NATIONAL TERTIARY PUBLIC HOSPITAL PERFORMANCE APPRAISAL: USING FOCUS-PDCA TO IMPROVE EXTERNAL QUALITY ASSESSMENT

C. Xie [1]

[1]*Department of Laboratory Medicine and Sichuan Provincial Key Laboratory for Human Disease Gene Study, Sichuan Provincial People's Hospital, University of Electronic Science and Technology of China, Chengdu, Sichuan, China*

BACKGROUND-AIM

To innovatively use the FOCUS-PDCA quality improvement strategy to establish an external quality assessment (EQA) working group to continuously improve EQA performance, an important indicator of the national tertiary public hospital performance appraisal.

METHODS

The project was carried out at the National Center for Clinical Laboratories. Using FOCUS-PDCA, which combines problem-focused steps (FOCUS) and improvement steps (PDCA), a project team was established to carry out improvement work. Root cause analysis was carried out to analyze the problems in quality control from EQA project application to results analysis and an improvement plan was implemented according to the steps of FOCUS-PDCA. The project was executed in three cycles from 2019 to 2021 to obtain more satisfactory results.

RESULTS

After implementing three cycles of FOCUS-PDCA, the EQA participation rate increased from 66.5% in 2018 to 100% in 2021, and the EQA pass rate increased from 94.9% in 2018 to 99.3% in 2021. Consequently, the hospital moved into the top 50 in performance assessment for the first time in 2020 and ranked 27th in 2021.

CONCLUSIONS

The use of the FOCUS-PDCA quality improvement strategy can improve the EQA performance of national tertiary public hospitals and help them achieve satisfactory results in the national examination.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0141

MACHINE LEARNING-BASED GENOME-WIDE METHYLATION PROFILING AND CLINICAL RISK SCORE CONSTRUCTION FOR ALZHEIMER'S DISEASE

T. Zhu [3], P. Zhang [1], Y. Wang [1], H. Wang [4], Z. Xu [5], Z. Lu [2]

[1]*Department of Clinical Laboratory, Shandong Provincial Hospital Affiliated to Shandong First Medical University, Jinan 250021, Shandong, China*

[2]*Department of Clinical Laboratory, Shandong Provincial Hospital, Shandong University, Jinan 250021, China*

[3]*Department of Clinical Laboratory, Shandong Provincial Hospital, Shandong University, Jinan 250021, Shandong, China*

[4]*Medical Neurobiology Lab, Inner Mongolia Medical University, Huhhot 010110, China*

[5]*Shandong Second Medical University, Weifang 261053, China.*

BACKGROUND-AIM

Epigenetics, particularly DNA methylation, plays a crucial role in the onset and progression of Alzheimer's Disease (AD). Machine learning-based genome-wide methylation analysis can provide insights into the pathology and diagnostic biomarkers of AD.

METHODS

This study obtained DNA methylation data from peripheral blood and brain tissue samples across four AD cohorts and applied machine learning methods to map genome-wide methylation sites to biological pathways and to identify pathways associated with AD. Modular analysis of these pathways was further conducted to identify modules related to AD. Finally, polymethylation scores (PMS) were calculated and evaluated for their potential as diagnostic biomarkers for AD.

RESULTS

In peripheral blood, pathway modules related to heart development, muscle function, bone morphogenetic protein (BMP) signaling, and tooth development were most associated with AD. In brain tissue samples, methylation changes related to cell dynamics regulation, metabolism and energy regulation, development and morphogenesis, gene expression regulation, and immune and defense mechanisms were closely linked to AD. PMS based on brain tissue demonstrated excellent classification performance (AUC: 0.78–0.84), while PMS based on peripheral blood showed relatively weaker predictive efficacy (AUC: 0.59).

CONCLUSIONS

Using machine learning to analyze methylation data and identify pathway modules in AD patients enhanced our understanding of AD pathogenesis. PMS demonstrated significant potential as a diagnostic biomarker for AD.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0142

CLINICIANS' PERSPECTIVES ON THE IMPACT OF A RANSOMWARE ATTACK ON THE CHEMICAL PATHOLOGY LABORATORY AT A TERTIARY HOSPITAL IN SOUTH AFRICA

A. Davids [1], A. Fataar [1], A. Zama [1], Z. Kadwa [1], C. Andrews [1], M. Morris [1], T. Jalavy [1], E. Kruger [1], A. Zemlin [1]
[1]*Department of Pathology, Division of Chemical Pathology, Faculty of Medicine and Health Sciences, Stellenbosch University, Cape Town, South Africa and Department of Pathology, Division of Chemical Pathology, National Health Laboratory Service, Cape Town,*

BACKGROUND-AIM

Cyberattacks on healthcare are not only costly but negatively affect patient care. Furthermore, laboratories and healthcare facilities are often unprepared for these cyberattacks. On June 22, 2024, the National Health Laboratory Service (NHLS) suffered a ransomware attack, which resulted in the inability to utilise information technology-related systems, including the laboratory information system. As a result, many automated processes reverted to manual operations, leading to a lack of access to both new and historical patient laboratory results. This transition caused delays in the turnaround time and made it challenging for clinicians to conveniently and promptly access both current and past laboratory results. This study aimed to explore clinicians' experiences at Tygerberg Hospital, South Africa and assessed the perceived impact of the disruption to chemical pathology laboratory services on patient care.

METHODS

A cross-sectional survey was conducted to evaluate clinicians' experiences during the June 2024 ransomware attack on the NHLS. Data were collected via an electronic survey and supplemented by test volume analyses for critical (creatinine) and non-critical (vitamin B12) tests.

RESULTS

Of the 58 completed surveys, 84% of respondents reported increased stress, and 78% noted delays in diagnoses. Test volumes decreased by 26.8% for creatinine and 34.1% for vitamin B12 compared to the same time in previous years, reflecting reduced testing during downtime. Clinicians highlighted challenges with result retrieval and disruptions to patient care, including delays in surgery and treatment decisions.

CONCLUSIONS

This study offers important insights into clinicians' views on the effects of a laboratory ransomware attack. It highlights the crucial role that information systems play in healthcare and points out the challenges faced in resource-limited settings. The findings emphasise the need for investment in cybersecurity and contingency planning to ensure patient safety and protect against potential future disruptions.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0143

IMPROVING THE EFFICIENCY OF QUALITY CONTROL WITH AN INTEGRATED PBRTQC SYSTEM BASED ON PATIENT RISK

X. Duan [3], T. Badrick [2], W. Shao [3], A. Bietenbeck [1], B. Pan [3], B. Wang [3], W. Guo [3]
[1]*MVZ Labor Poing*
[2]*The Royal College of Pathologists of Australasia. Quality Assurance Programs.*
[3]*Zhongshan Hospital, Fudan University*

BACKGROUND-AIM

Recent advances in information technology have led to a renewed interest in patient-based real-time quality control (PBRTQC) as an alternative to internal quality control (IQC). However, as regulations mandate IQC in many countries, PBRTQC can only be run separately. The extra labor PBRTQC brings for laboratory staff can lower enthusiasm and impede wide adoption. Therefore, laboratories need a more efficient system integrating the IQC with PBRTQC to implement the methods.

METHODS

A QC system that integrates the IQC with PBRTQC was proposed. The integrated system states that there is no fixed schedule for IQC; instead, alarms generated by the PBRTQC model were verified with QC. The maximum average number of patients with unacceptable analytical errors ($MaxANP_{TE}$) was proposed as the critical metric to benchmark the efficiency of the integrated PBRTQC system to the classic IQC system based on a modified Parvin patient risk model for laboratories not running under the bracketed continuous mode. The historical data of serum sodium (Na), chloride (Cl), alanine aminotransferase (ALT), and creatinine (CREA) from Zhongshan Hospital, Fudan University, in 2019 was used for simulation. The efficiency of the integrated system incorporating the simple PBRTQC model and the more advanced regression-adjusted real-time quality control (RARTQC) model were compared with the classic IQC system.

RESULTS

In most cases, the integrated system incorporating RARTQC models outperformed the classic system, where they could reduce QC events by up to 45%, 98%, 100%, and 86% for ALT, Na, Cl, and CREA, respectively. In an extreme case, the RARTQC model for Cl can run with no false alarm and still achieve superior quality assurance than the twice-daily IQC system. Two design procedures for the integrated systems were proposed: the Quality First Design Procedures (QFDP), which maintains the QC cost while improving quality assurance, and the Cost First Design Procedures (CFDP), which maintains the quality assurance while reducing the cost of QC materials.

CONCLUSIONS

The study demonstrated the improvement of efficiency of the integrated PBRTQC system over the classic IQC system. These insights can help laboratories make informed decisions on adopting PBRTQC models and provide evidence for revising regulations on IQC.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0144

BOOSTING HEMATOLOGY CELL COUNTER RELIABILITY WITH INNOVATIVE QC TECHNIQUES

U. Gosavi [1], K. Golvankar [1], P. Poladia [1], M. Tiwari [1], S. Kumar [1], S. Vaykar [1], J. Dalavi [1], A. Pagdhune [1], P. Chavan [1], R. Mohite [1], U. Gavhane [1]
[1]*ACTREC, Tata Memorial Centre, Kharghar,Navi Mumbai, India*

BACKGROUND-AIM

Introduction: Conventional quality control (QC) methods for hematology analyzers include performing precision with commercial control materials and setting accuracy by using calibrators. The Alternate QC approaches (AQA) includes duplicate testing, inter-instrument comparison, moving average analysis, retained sample testing, etc.
Aim-By developing predictive models of alternate QC approaches (AQA) based on retrospective analysis, this study aims to proactively identify systemic errors (SE) by using patient's samples.

METHODS

Study involves a data size of six months which was done to evaluate the effectiveness of AQA for detecting SE. A QC protocol for the AQA and their acceptability limits was developed by our laboratory in reference to NABL112, a specific criteria guideline.>30,000 patient samples were run on two calibrated cell counters (Advia2120i). Statistical evaluation includes mean, standard deviation (SD), % coefficient of variation (CV) for precision testing, ±2 SD of the mean bias for duplicate testing, linear regression analysis for inter-instrument comparison, and 3% of the target mean as the upper limit and lower limit for moving average analysis.

RESULTS

From the total runs in six months, SE detected by Replicate testing was 15.9%, with the maximum root-cause finding associated with daily maintenance. Inter-instrument comparison was 4.5%, where maximum times RBC flow cell cleaning was the root-cause.SE detected with moving average analysis was 1.2%, with the root-cause findings of a skewed patient population. The retained sample testing detected 8.3% errors with root- causes associated with errors in storage conditions

CONCLUSIONS

Alternate QC methods help in the detection of systemic errors in a very cost-effective manner in hematology cell counters

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0145

METHOD COMPARISON FOR FSH, PRL, TESTOSTERONE, AND PGN ON DIFFERENT IMMUNOASSAY PLATFORMS

E. Kapllani [3], L. Mino [3], M. Lika [2], A. Bulo [1]
[1]*Laboratory Department, University of Medicine, Tirana*
[2]*Laboratory Networks, "Mother Teresa" University Hospital Centre, Tirane*
[3]*Pegasus Med Laboratory, Tirane*

BACKGROUND-AIM

According to ISO 15189:2022, when a new laboratory instrument is introduced, it must be compared with the existing one to determine if the results obtained are consistent, thereby establishing whether the new method can replace or be used interchangeably with the old one. This study compares two immunoassay methods: the CLIA method on the Maglumi X3 platform by Snibe and the CMIA method on the Abbott Alinity ci and Architect ci8200 platforms, focusing on assays for Follicle-Stimulating Hormone (FSH), Prolactin (PRL), Testosterone, and Progesterone (PGN).

METHODS

We followed the EP09-A3 guideline for method comparison using patient samples. Forty patient samples were tested on the Alinity ci platform (CMIA method) for FSH, and the same samples were retested on the Maglumi X3 platform (CLIA method). The same procedure was followed for PRL and Testosterone. For PGN, we compared the results from the Maglumi X3 platform with those from the Architect ci8200 platform, due to compatibility in linearity. Statistical analysis was performed using Analyse-It software and the Student's t-test.

RESULTS

For FSH, PGN, and Testosterone, the results showed a p-value > 0.05, and the 95% confidence interval for the calculated bias included the value of 0, indicating no significant difference between the methods. For Prolactin, the p-value was < 0.05, and the 95% confidence interval for the calculated bias did not include 0, suggesting a significant difference between the two methods.

CONCLUSIONS

The comparison of the CLIA method (Maglumi X3) and the CMIA method (Alinity/Architect) demonstrated good correlation for FSH, PGN, and Testosterone, indicating that these methods are comparable and can be used interchangeably. However, for Prolactin, significant differences were observed, suggesting that reference value intervals for the new method should be reviewed and adjusted according to CLSI EP28 guidelines, as recommended in CLSI EP09-A3.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0146

APPLICATION OF A NEW MODEL TO REDUCE PEREMPTION OF PLATELET CONCENTRATES AT CHU UCL NAMUR: A BEFORE AND AFTER STUDY

L. Moreno Y Banuls [1], G. Detry [1], C. Mbende [1], F. Mullier [1]
[1]*CHU UCL Namur*

BACKGROUND-AIM

In Belgium, the shelf life of platelets concentrates (PC) is 5 days (AR28.01.2017) due to various factors, including the risk of bacterial proliferation and storage lesions.
PC stock management constitutes a real challenge for all bloodbanks due to the highly variable demand from clinicians and the short shelf life of these products. Stocks must be close to needs in order to avoid stock shortages and product loss.
The development of a tool to assess PC needs is a key priority.

METHODS

Our university hospital offers state-of-the-art care for patients with complex needs: hematology, traumatology, cardiac surgery,...
A calculation was developed in order to estimate PC needs based on consumption from previous weeks. Before this, desired stock of PC was empirical.
This comparison study aims to evaluate the effectiveness of this new method.
The study was divided into three phases : BEFORE from 2022/03/01 to 2023/02/28 ; EVALUATION from 2023/03/01 to 2023/08/31 and AFTER from 2023/09/01 to 2024/08/31.

RESULTS

The PC expiry rate during the three phases was respectively 4.0% for BEFORE, 0.5% for EVALUATION and 1.7% for AFTER implementation.
Since the implementation of this calculation, the quarterly expiry rate has fallen from an average of 4.2% in 2022 to 1.2% and 1.9% respectively in 2023 and 2024.
In 2024, a expiry rate of 4.2% was highlighted for the 3rd quarter, corresponding to a peak in July coinciding with the absence of the sector's managers and failure to update the tool.
Without considering this peak, the quarterly expiry rates in 2023 and 2024 are similar, at 1.2 and 1.1% respectively.

CONCLUSIONS

This tool has proven to be particularly effective and is implementation has enabled us to reduce the PC expiry rate in our bloodbanks, with a significant financial (approximately 8300€/quaterly) and ethical (wasted donation) impact.
The PC expiry rate will continue to be monitored on a quarterly basis, in order to identify any deviations in its effectiveness. Currently, this calculation is updated manually; we want to take advantage of business intelligence to collect, analyze and present transfusion data (without human risk factor: forgetfulness, errors, absence...) to quickly identify trends and correct any excessive wasting.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0147

THE IMPACT OF CIRCUIT OF PREOPERATIVE ANEMIAS FOCUSED ON KNEE AND HIP PROSTHESIS SURGERIES

A. Ruiz Ripa [1], S. Yáñez Soria [1], A.C. Ruiz Puig [3], C. Subirà Alsina [2], J. Mendez Gallardo [1], C. Roman Torralba [1], G. Rivas Cuevas [1]

[1]*Laboratori de Referència de Catalunya. Hospital de Mataró. Consorci Sanitari del Maresme.*
[2]*Servei Anestesiologia. Hospital de Mataró. Consorci Sanitari del Maresme*
[3]*Servei COT. Hospital de Mataró. Consorci Sanitari del Maresme.*

BACKGROUND-AIM

There is clear evidence linking blood transfusions to adverse outcomes, including an increased risk of mortality. Emerging studies show that Patient Blood Management (PBM) can be effective in reducing transfusions. One key component of PBM is establishing protocols for the detection and correction of preoperative anemia. This includes reviewing treatments to reduce anemia before surgery, monitoring hemoglobin recovery, and minimizing transfusions.

METHODS

We assessed the impact of the protocol on the number of patients receiving transfusions during knee and hip prosthesis surgeries. We compared transfusion data from 2022, before protocol implementation, with data from 2024, after implementation. Additionally, we analyzed the number of TS requests made by anesthesia and traumatology services during these periods.

RESULTS

The number of elective surgeries in 2022 was 558 (269 knee surgeries; 289 hip surgeries), and in 2024, it increased to 597 (290 knee surgeries; 307 hip surgeries), a 6.5% rise. In 2022, 98 patients (17.6%) required transfusions, compared to 61 patients (10.2%) in 2024, representing a 55.3% reduction in transfusion rates. For patients with corrected hemoglobin levels, no TS was required, leading to a reduction in TS requests from anesthesia and traumatology services from 938 in 2022 to 711 in 2024, a decrease of 31.9%.

CONCLUSIONS

Implementation of this protocol resulted in a significant decrease in transfusion rates: from 1 in 10 to 0.5 in 10 for knee surgeries, and from 2.5 in 10 to 1.5 in 10 for hip surgeries. The management of preoperative anemia thus had a positive clinical impact on transfusion rates, with economic and social benefits. The reduction in unnecessary TS requests also significantly impacted the laboratory workload. These outcomes highlight the importance of adopting strategies to improve blood utilization and patient safety.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0148

USE OF PATIENT MEDIANS AS A TOOL IN EQA

A.E. Solsvik [3], A.V. Stavelin [1], P. Fauskanger [2], E. Rønneseth [1], S. Sandberg [1]
[1]*Noklus, Bergen, Norway*
[2]*Noklus, Bergen, Norway; Department of Mathematics, University of Bergen, Norway*
[3]*The Norwegian Organization for Quality Improvement of Laboratory Examinations (Noklus), Bergen, Norway*

BACKGROUND-AIM

A large number of patient results are available in the laboratory information system (LIS). These results serve as an effective tool for monitoring equivalence between different measuring systems (MSs) and measuring procedures (MPs) since there are no commutability issues. Thus, an important challenge in conventional external quality assessment (EQA) programs is addressed. By participating in the Noklus Patient Median (NOPAM) EQA program, laboratories have the opportunity to compare their results to their peer group, as well as to other MSs. This study aims to present the results for selected analytes included in NOPAM.

METHODS

Daily patient medians reported to the NOPAM program are grouped by manufacturer and instrument, with the median of all medians calculated for each group. Data presented in this study are derived from the most prevalent MSs and include all results reported through 2024. These medians are compared across different groups to monitor equivalence and the degree of harmonization among the groups.

RESULTS

For glucose, the median of all daily medians for the Abbott Alinity group is 5.3 mmol/L (n=7161), Abbott Architect 5.4 mmol/L (n=8553), Siemens Atellica 5.4 mmol/L (n=5207), and Roche Cobas 5.3 mmol/L (n=51352). For FT4, the group median for the Abbott Alinity group is 12.5 pmol/L (n=9875), Abbott Architect 13.0 pmol/L (n=2970), Siemens Atellica 15.0 pmol/L (n=3709), and Roche Cobas 16.2 pmol/L (n=10764). Results for additional analytes will be included in the poster.

CONCLUSIONS

Glucose is an analyte seeming to be well harmonized, whereas FT4 is not.
The NOPAM program is designed for global accessibility, enabling laboratories worldwide to monitor improvement efforts and assess their impact over time. By comparing patient medians reported by routine laboratories, NOPAM provides a valuable tool for monitoring and supporting global harmonization initiatives.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0149

MANAGING INDIVIDUAL SOURCES OF MEASUREMENT UNCERTAINTY IN FIT COLON CANCER SCREENING: THE VIRTUAL LABORATORY CONCEPT AS A SOLUTION FOR EQUITY IN MEDICAL LABORATORY CARE

M. Van Schrojenstein Lantman [4], P. Van Der Groep [1], E. Kemper [3], R. Vossen [6], M. De Groot [2], M. Karin [5], E. Humer [1], A. De Jong [1], B. Franken [4], C. Speijers [4], J. Ten Kate [1], M. Frasa [1], M. Thelen [4]
[1]*BVO-NL*
[2]*ETZ*
[3]*IJsselland ziekenhuis*
[4]*SKML*
[5]*STAR-SHL*
[6]*Zuijderland ziekenhuis*

BACKGROUND-AIM

Faecal Immunochemical Testing for human haemoglobin (FIT) plays a crucial role in many national and regional screening programs to identify asymptomatic individuals with increased risk for colon cancer or its treatable precursors. In this setting quantitative FIT is used to identify those who are elicit for specific screening with colonoscopy.
The FIT screening approach has the intrinsic assumption that all individuals with the same amount of haemoglobin in their faeces have the same chance of referral for colonoscopy and subsequent follow-up. This assumption relies on the lack of systematic differences in FIT results over time and between screening locations.

METHODS

The FIT reference officer and participating 4 laboratories of the Dutch colon cancer screening program have identified the individual sources of FIT variability. For all sources, analytical performance specifications (APS) have been defined, together with policies to maintain performance within APS.
The Dutch screening organisation has calculated a plus minus 9.5 % variation in FIT performance at cut-off level as APS to achieve the desired maximum plus minus 0.5% variation in referral rate for colonoscopy. As sources of FIT variation were identified: 1. reagent/calibrator lot variation, 2. sampling buffer lot variation, 3. within analyser variation, 4. between analyser variation. Each source was assigned a variation budget of 4.75% which sum to the 9.5% total variation as the square root of the sum of the squares of the sources.

RESULTS

Reagent and calibrator lot variation is managed by coordinated simultaneous lot changes in the participating laboratories following pre-checks of all lots involved compared to value-assigned commutable materials. During the last 8 years this has resulted in the rejection of 6 of 28 reagent/calibrator lots. Buffer lot acceptance testing is currently in the implementation phase. Within and between laboratory variation is managed by operating as a virtual laboratory with central management of QC results of the same control materials used in all participating laboratories by the national FIT reference officer.

CONCLUSIONS

The presented approach maintains FIT performance within the set APS and referral variability within the set specification, independent of time and location of FIT screening.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0150

DEVELOPMENT OF AN ACCREDITED EXTERNAL QUALITY ASSESSMENT (EQA) PROGRAMME FOR RENAL CALCULI

N. Tooze [1], G. Davies [1], S. Jones [1], A. Thomas [1]
[1]*Weqas, Cardiff and Vale University Health Board, Cardiff, UK*

BACKGROUND-AIM

Renal stones (calculi), and renal stone disease (nephrolithiasis or urolithiasis), are a common problem worldwide with a prevalence of approximately 10% in men and 7% in women and an estimated 5-year recurrence rate of up to 50%.They are associated with systemic diseases such as Type 2 diabetes, obesity, dyslipidaemia, and hypertension. Stone analysis plays a valuable role in the diagnosis of kidney stone patients, specifically in infrequently encountered stones such as infection or drug-induced, ammonia urate stones and in the rare cystine and xanthine inborn errors.

METHODS

The chemicals and the ratio of chemical components in the samples were selected to cover the appropriate pathological range of calculi constituents that laboratories would encounter. 12 different chemical compositions and admixtures were produced. The appropriate amount of chemical was weighed gravimetrically and ground with a pestle and mortar until an even powdered consistency was obtained. Samples were analysed using FTIR spectroscopy and compared with a reference library to validate the chemical composition of each matrix. All samples were stored at -20°, and distributed to participants at ambient temperature. 6 rounds were distributed per year, with each round consisting of 4 different "stone" materials of combinations of pure and mixed chemicals containing 75-125 mg material.

RESULTS

The majority of participants correctly identified Calcium Phosphate and Uric Acid. 3 incorrectly reported Magnesium Ammonium Phosphate (MAP) and 2 incorrectly reported oxalate. For calcium carbonate, 93 and 61% identified calcium and carbonate respectively. For a mix of MAP & Hydroxyapatite, 96 % identified MAP, and 80% correctly identified calcium. 84% and 73% correctly identified Xanthine and Silicon Dioxide. Poorer performance was observed for wet chemistry kits for the rarer components.

CONCLUSIONS

The EQA programme allows for the ongoing assessment, education and improvement of the performance of calculi analyses in the laboratory especially when faced with unusual samples. The Weqas EQA programme for Renal Calculi is now fully accredited to ISO 17043 and will continue to provide performance monitoring in this area.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0151

APPLICATION OF PATIENT-BASED REAL-TIME QUALITY CONTROL IN THYROID FUNCTION TESTING

B. Van Deventer [1], C. Van Niekerk [3], D. Nowrungsah [2], T. Pillay [3]
[1]*National Health Laboratory Service (NHLS), TAD Pretoria*
[2]*Universal Pathology Laboratories, Durban*
[3]*University of Pretoria / National Health Laboratory Service*

BACKGROUND-AIM

Real-time quality control (RTQC) is critical in ensuring the accuracy and reliability of laboratory results. Patient-based quality control (PBQC) leverages patient data trends to monitor and detect assay deviations, offering a complementary approach to traditional quality control methods. This study evaluates the implementation of PBQC in thyroid function tests (TFTs), focusing on its ability to detect analytical errors in real-time. There have been very few PBQC studies performed using TFTs.

METHODS

A retrospective analysis of TFT data from more than 29 000 samples, including thyroid-stimulating hormone (TSH), free thyroxine (FT4), free triiodothyronine (FT3), was conducted from a high-throughput clinical laboratory in South Africa over 12 months. PBQC was implemented using moving average (MA) models. Optimal MA parameters, such as block size and weighting, were defined based on assay stability and patient population characteristics. PBQC performance was compared to traditional internal QC in detecting shifts and trends using simulations of systematic bias and imprecision. QC constellation was used to analyse the data.

RESULTS

PBQC detected analytical shifts as small as 3% within 5-10 patient results, significantly faster than traditional QC protocols requiring larger datasets. The MA models demonstrated high sensitivity (95%) and specificity (92%) for detecting assay errors. No significant false-positive alarms were observed when MA parameters were appropriately tuned. At the 2-98 percentiles, the truncation limits for TSH were 0.09-7.25 mIU/L. The optimal Estimated Weighted MA(EWMA) feature was at a lambda value of 0.3 and optimized L value of 3. A block size of 20 for EWMA produced an acceptable number of alarms.

CONCLUSIONS

PBQC using moving averages is a valuable adjunct to traditional QC in TFT analysis. It enhances real-time error detection, reduces the risk of reporting erroneous results, and aligns with the evolving focus on patient safety in laboratory medicine. Widespread adoption of PBQC in TFTs could improve the overall quality assurance framework in clinical laboratories. This is the first study in Africa on the use of TFTs in PBRTQC.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0152

AGE-DEPENDENT CUT-OFF POINTS FOR GFAP AND UCH-L1

M.I. Vazquez Tavero [2], L. Garcia Medina [2], G. Queipo De Llano Orellana [2], O. Ayllon Gatnau [1], S. Sanchez Asis [2], E. Montoro Jorquera [4], J. Ortega Pérez [5], A. Conesa Hernández [4], J.M. Sánchez Gil [4], F.M. Gómez Morales [4], M. Viles García [7], L. Torrijos [6], J.M. Bauçà [3], I. Llompart Alabern [3], D. Morell-Garcia [3]

[1]*Clinical Analysis Department, Manacor University Hospital, Palma de Mallorca, Spain*

[2]*Clinical Analysis Department, Son Espases University Hospital, Palma de Mallorca, Spain*

[3]*Clinical Analysis Department, Son Espases University Hospital, Palma de Mallorca, Spain Health Research Institute of the Balearic Islands (IdISBa), Palma de Mallorca, Spain*

[4]*Emergency Department, Santa Lucía University Hospital, Cartagena, Spain*

[5]*Emergency Department, Son Espases Universitary Hospital, Palma de Mallorca, Spain*

[6]*Radiodiagnostic Service, Santa Lucía University Hospital, Cartagena, Spain*

[7]*Radiodiagnostic Service, Son Espases University Hospital, Palma de Mallorca, Spain*

BACKGROUND-AIM

Recent studies show that Ubiquitin C-Terminal Hydrolase L1 (UCH-L1) and Glial Fibrillary Acidic Protein (GFAP) levels in serum can predict cranial CT findings in acute brain injury. Age may influence interpretation.
The objective of this study is to evaluate age-related differences in UCH-L1 and GFAP levels in patients with mild traumatic brain injury (TBI) to improve predictive capacity of the markers (since the manufacturer offers a single cutoff point not related to age for its interpretation) in relation to the findings found in the cranial CT.

METHODS

A prospective double-blind study from May 2022 to February 2024 in three hospitals included adults who came to the Emergency Department with mild TBI. Samples were analyzed using chemiluminescent microparticle immunoassay (CMIA) according to the manufacturer's instructions (Alinity i series, Abbott). Patients were classified by cranial CT findings and stratified by age groups starting from 40 years. Bivariate comparisons used the Mann-Whitney U test, with a 5% significance level. The median and 5th, 65th, and 95th percentiles of the markers were also calculated in the resulting groups.

RESULTS

Of 195 patients, 9 (5%) had positive CT findings, median age 63 years [43-69], GFAP 304.80pg/mL [120.50-352.60] and UCH-L1 643.50pg/mL [259.60-1031.00]; 186 (95%) had negative CT findings, median age 69 years [44-80], GFAP 56.20pg/mL [33.85-96.30], UCH-L1 395.90pg/mL [253.10-616.33]. Significant differences were found only for GFAP (p=0.00022).
Low concordance with negative CT (19% using commercial cutoff points) led to age group analysis, showing significant differences for all groups (≤40, 41-65, >65 years for GFAP; ≤80, >80 years for UCH-L1).
Median and percentiles 5th, 65th and 95th of GFAP for age groups proposed were respectively: 51.35, 14.02, 76.95, 268.61; 28.35, 8.55, 43.87, 157.91; 75.05, 31.78, 91.31, 212.13. UCH-L1 values for ≤80, and >80 years were: 365.60, 96.24, 465.16, 965.72; 496.70, 174.68, 685.82, 2591.40.
Using age-stratified values (65th percentile) improved concordance for negative CT scans to 58%, maintaining 100% concordance for positive CT findings.

CONCLUSIONS

GFAP and UCH-L1 values in mild TBI patients should be age-adjusted for better concordance with cranial CT findings, potentially doubling savings in imaging tests.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0153

EVALUATING THE "PLT CLUMPS?" FLAG FROM DIFFERENT CHANNELS OF SYSMEX XN HEMATOLOGY ANALYZER: A METHOD FOR RAPIDLY DISTINGUISHING BETWEEN TWO PRE-ANALYTICAL FACTORS AFFECTING PLT COUNTING IN CANCER PATIENTS.

D. Xu [1], L. Wang [1], N. Zhao [1], W. Tai [1], J. Yang [1], W. Cui [1]

[1]*National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, 100021, China*

BACKGROUND-AIM

This study aimed to investigate the accuracy of the "PLT Clumps?" flag triggered by different channels on the Sysmex XN blood analyzer in identifying two sample states, as well as to optimize the related platelet review strategy in cancer patients.

METHODS

570 samples flagged "PLT Clumps?" by CBC+DIFF mode were recruited. After excluding samples with visible clot, retesting was conducted using CBC+DIFF+PLT-F mode. The accuracy of "PLT Clumps?" flag from different channels and its correlation with sample states, PLT aggregation (PA) or fibrin precipitation (FP), were evaluated. Low-platelet samples were recalled for a second blood draw to confirm whether pseudothrombocytopenia (PTCP) occurred. The incidence and positive predictive value (PPV) of the "PLT Clumps?" flag across different tumors were analyzed.

RESULTS

Out of 85 verified cases (17 PA, 63 FP and 5 with visible clot), the overall PPV was 14.9% (85/570) in CBC+DIFF mode, WNR-only flag had a PPV of 3.5%, WDF-only 73.9%, and dual-channel flagging raised PPV to 94.4%. In CBC+DIFF+PLT-F mode, true-positive rate was 80.0% (64/80), false-positive rate was 0.2% (1/485), PA and FP accounted for 73.9% (17/23) and 26.1% (6/23) of PLT-F-only flagged samples, all WDF-only and dual-flagged cases were FP. Microscopic examination combined with CBC+DIFF+PLT-F mode flagging provides a strong indication of PTCP. Hepatobiliary tumors showed highest flagging rate (20.4%) but lower PPV than that of other tumors.

CONCLUSIONS

This study analyzed the correlation between "PLT Clumps?" flags from different channels and two common pre-analytical interference factors in PLT counting, further optimizing platelet review strategy for cancer patients.

Accreditation, Patient Safety, Risk management, Quality Assurance, Audit

P0154

VERIFICATION AND OPTIMIZATION OF REJECTION CRITERIA FOR HEMOLYSIS, ICTERUS, AND LIPEMIA INDICES IN BIOCHEMICAL METHODS ON THE SIEMENS ATELLICA ANALYZER

T. Žuran Vilčnik [1], I. Jurković Jakopanec [1]
[1]*Laboratory Diagnostic Department, General Hospital Ptuj*

BACKGROUND-AIM

A standardized, objective, and high-quality evaluation of hemolysis, icterus, and lipemia (HIL) indices plays a critical role in assessing the reliability of biochemical test results. At the Department of Laboratory Diagnostics, we conducted a comprehensive verification of HIL index measurements, evaluated the suitability of manufacturer-recommended thresholds for the Siemens Atellica analyzer, and optimized these indices based on collected data while considering both clinical significance and analytical acceptability.

METHODS

The quality of HIL index measurements was assessed through internal quality control, repeatability, and accuracy evaluations. For the most sensitive methods, the impact of interferences was examined using serum samples with standardized interference additions, following the CLSI EP07 protocol and acceptability criteria. We performed a retrospective analysis of rejection criteria for the most critical indice, H. The influence of H on parameters such as potassium, AST, LDH, and iron was analyzed by introducing hemolysate to serum samples without interference and measuring biochemical parameters before and after its addition.

RESULTS

Our analysis revealed high-quality measurement performance for HIL indices on the Siemens Atellica biochemical analyzer. Signal repeatability was observed at 63.3%, 7.8%, 2.4%, 1.1%, 3.1%, 2.3%, 2.2%, and 0.8% across eight hemoglobin concentration levels corresponding to H indice values from 0 to 3. Rejection criteria for indices I and L, based on manufacturer data, were found appropriate. However, some rejection criteria for indice H were identified as unsuitable in practice. Retrospective analysis indicated that interference from H would have led to at least one test rejection in 18.76% of biochemical samples. After optimizing the H thresholds, the rejection rate dropped to 5.76%, aligning with historical rejection rates in our laboratory.

CONCLUSIONS

A deep understanding of HIL indices determination, their evaluation, and their optimization significantly enhances the quality of biochemical test results. These efforts represent a pivotal step in mitigating risks associated with investigative procedures and ensuring reliable patient care.