Abstracts*)

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P001

THE EFFECTS OF AN AWARENESS CAMPAIGN TO REDUCE EDTA CONTAMINATION IN LABORATORY SPECIMENS

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Background: To ensure the accuracy of patient test results, we decided to focus firstly on pre-analytical phase specifically the potassium EDTA contamination and the order of draw of blood samples.
Objective: To check the prevalence of EDTA contamination and to evaluate an awareness campaign to decrease this frequent error.
Materials and methods: The study included 100 paramedical staff regularly involved in sample collection in different services in the hospital. An anonymous knowledge assessment was handed out to the cohort and the detection of EDTA contamination was checked in the laboratory. The EDTA contamination was defined as hyperkalemia (serum potassium level >5.8 mmol/l); hypocalcaemia (serum adjusted calcium <2.00 mmol/l), hypomagnesaemia (serum magnesium <0.66 mmol/l) with normal renal function. Then, we evaluated the one week awareness campaign. Chi-square test was used for the comparison of frequencies before and after the awareness campaign.
Results: The frequency of EDTA contamination before and after the awareness campaign has significantly decreased from 44.4% to 27.0%; p=0.024.
Conclusion: Education regarding correct blood collection technique is essential in preventing EDTA sample contamination. This involves the correct order of draw. Errors during the collection process are not inevitable neither eradicated but could be reduced by good practices and continuing education.

Key words: EDTA contamination; awareness campaign; spurious hyperkalemia; hypocalcaemia; hypomagnesaemia.

P002

PREANALYTICAL CONDITIONS IN SERUM HEPCIDIN MEASUREMENT

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Background: Hepcidin is a 25-amino peptide hormone that regulates iron homeostasis. Its serum quantification is necessary for the right therapeutic choice in iron-deficiency anemia and anemia in chronic diseases. Some studies have shown a diurnal secretion of the hormone.
Materials and methods: For a period of one year we collected blood samples for serum hepcidin quantification in 90 healthy controls. The samples were collected in vacuettes with serum separated gel at three different times during the day – 07.30-08.30; 11.00-12.00 and 15.00 – 16.00 hours. Hepcidin levels were measured with ELISA method.
Results: We found a significant difference in serum hepcidin levels during chosen three blood taking times. The normal ranges for Bulgarian population are 3.05 µg/L-37.75 µg/L. The measured levels were: at 07.30-08.30 hours 12.2 ± 4.2 µg/L (min 5.5 µg/L; max 23.6 µg/L); 11.00-12.00 hours 14.1 ± 4.4 µg/L (min 7.1 µg/L; max 27.2 µg/L) and 15.00 – 16.00 hours 16.5 ± 4.4 µg/L (min 9.9 µg/L; max 29.6 µg/L) [0.7 < r < 1; p > 0.5 between 07.30-08.30 and 11.00-12.00 hours and p < 0.05 between 07.30-08.30 hours and 15.00 – 16.00 hours and 11.00-12.00 hours and 15.00 – 16.00 hours]. No significant differences were found for transferrin saturation between measured groups [0.1 < r < 0.3; p > 0.5].
Conclusions: In order to obtain most correct results for serum hepcidin quantification (especially in border to referent ranges levels) in the preanalytical phase it is important to consider the time of blood sampling.

Key words: hepcidin, iron-deficiency anemia, anemia in chronic diseases, preanalysis

P004

MONITORING QUALITY IN THE PRE- AND POST-ANALYTICAL PHASES: A NEW UK NEQAS SERVICE

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The UK National External Quality Assessment Service (UK NEQAS) has developed an online system that allows participants to review and monitor the incidence of untoward events occurring in the pre and post analytical phases. This secure, online service extends quality surveillance beyond the analytical phase, providing a baseline of data against which users can benchmark their performance, with Sigma metrics. The initial stages of the service will be offered to blood sciences and microbiology only, although the intention is eventually to cover all pathology disciplines.

The service is entirely web based. Participants submit the number of failures or rejections, together with the total number of eligible patient requests, specimens or reports, for a range of up to 11 quality indicators. Participation may be at department, hospital or network level. Based on recommendations from the IFCC Working Group on Laboratory Errors and Patient Safety, the quality indicators were developed by UK NEQAS in conjunction with scheme advisors and include patient identification, specimen labelling, specimen collection and reporting errors. The feasibility of and participant preferences for the service have been tested in a pre-pilot distribution to 14 selected laboratories in the UK and the Republic of Ireland.

Initial feedback has demonstrated a high level of interest in the service from laboratories and national quality oversight bodies. The challenges encountered center on the practicability of data extraction from laboratory information management systems and the need for a glossary to ensure the standard description of terms used for data capture.

It is planned that the full service will be available from April 2015. It will be flexible and allow the addition or removal of indicators, including the collection of root cause analysis investigations of external quality assessment errors.
This service has been developed in liaison with the Association for Clinical Biochemistry.

Key words: Pre-analytical, Post-analytical, Quality

P005

EVALUATION OF AN ELECTRONIC GATE-KEEPING SYSTEM AS A MEANS OF ASSESSING DEMAND MANAGEMENT IN A TERTIARY CARE CHEMICAL PATHOLOGY LABORATORY IN SOUTH AFRICA

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Background: Demand management is defined as the use of health resources to maximize its utility within a health system. In an attempt to contain health care costs, our laboratory introduced an electronic gate-keeping (eGK) system in 2010 as a form of demand management control. Chemistry and haematology tests generate the highest costs and we therefore subjected them to eGK. Tests are automatically rejected according to a set of predetermined gate-keeping rules. In this study, we audited the number of chemistry tests rejected by this system and how many were subsequently restored. Additionally, we assessed the impact of this system on clinical outcomes and laboratory costs.

Material and Methods: We conducted a retrospective audit of the number of chemistry tests rejected by our eGK system and the number subsequently restored. We evaluated whether these rejections impacted on patient care and calculated the cost savings generated by this system.

Results: A total of 68480 chemistry tests requested over the specified time period were subjected to eGK. Of these, 6.7% (4605) were rejected. Following clinician request, 14.7% (679) of these rejected tests were subsequently restored and analyzed. We found that eGK had a minimal effect on patient care, yet generated a significant cost saving.

Conclusions: Only 14.7% of tests rejected by our eGK system were restored as requested by the treating clinicians, implying that most tests rejected were in fact unnecessary requests. We found that our eGK system was an effective demand management tool leading to cost savings without being detrimental to patient care. After the successful implementation of eGK in our laboratory, it is being rolled out to other laboratories in South Africa.

Key words: demand management, gate-keeping, patient care, cost saving

P007

SAMPLE HAEMOLYSIS RATES IN ED AND ICU SAMPLES – IS THERE A DIFFERENCE?

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Background: Sample hemolysis rates are a useful measure of sample quality. Similar hemolysis rates have been reported in emergency department (ED) and intensive care unit (ICU) samples but there is little data comparing rates between the two populations. This study compared the rates and distribution of hemolysis grades between ED and ICU samples using automated hemolysis index (HI) measurements.
Materials and methods: Tan Tock Seng Hospital performs serum HI measurement (reported as 0-10) automatically on all samples using the Beckman-Coulter DxC chemistry analyzer. Anonymized details of all HI measurements on all samples from ICU and ED patients between April and October 2014 were extracted from the laboratory information system. Sorting and statistical analysis was performed in Microsoft Excel & Access and SPSSv11.
Results: There were 28417 ED and 14681 ICU records. The % hemolysis rates for the various HI grades for ED and ICU were HI 0: ICU 61/ED 65.12; 1: 29.5/30.68; 2: 4.42/2.74; 3: 1.81/0.65; 4: 1.03/0.27; 5: 0.68/0.18; 6: 0.51/0.14; 7: 0.32/0.11; 8: 0.30/0.07; 9: 0.25/0.03; 10: 0.18;/0.03. Based on a HI cutoff of >=3 (100 mg/dL Hb), 5.07% of ED and 1.46% of ICU samples are hemolysed. Logistic regression to predict HI >= 100 mg/dL gives an odds ratio for ED vs ICU of 4.52 (p<0.001) when controlled for age and sex.
Conclusion: The hemolysis rate for ED samples at 5% is 3.5 higher than for ICU samples. Higher hemolysis rates for ED vs ICU samples are seen across all HI grades. ED samples are generally collected via 20 mL or larger syringes and forced into tubes by stabbing the needle through the rubber cap. ICU samples are generally collected using the evacuated tube system. The difference in hemolysis rate seen here underlines the importance of education and adherence to best practice in phlebotomy technique.

Key words: hemolysis, phlebotomy, emergency department, intensive care unit

P008

BIOCHEMISTRY SAMPLE REJECTION: REASONS, RATES AND RANKING

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Background: Clear criteria for specimen rejection are an essential element of a laboratory quality system. I describe the results of a retrospective audit of specimen rejection data for 2012 from the biochemistry laboratory of a 1400 bed general hospital in Singapore.
Materials and methods: The biochemistry laboratory at Tan Tock Seng Hospital handles all specimens (inpatient, outpatient, emergency department) collected onsite and receives over 2000 specimens a day. Unsatisfactory specimens are registered for a "rejection" test whose "result" is one of 31 predefined individual codes (R1-R31). The laboratory report issued to the requesting location contains the "rejection" test, together a textual explanation of the rejection code. The rejection report is thus part of the routine reporting system. A monthly report of the "results" of all "rejection" tests can easily be generated, allowing monitoring of the rates of different rejection reasons.
Results: During 2012, 705512 samples were received with an overall 0.57% annual rejection rate. Monthly rates varied from 0.50-0.68%. The top 10 reasons comprised 87% of rejections. In order, these were: insufficient specimen: 20.9%; no specimen received: 13.5%; arterial blood gas specimen clotted: 11.2%; no lavender top tube received for HbA1c: 10.7%; unlabeled specimen: 8.3%; mislabeled specimen: 6.9%; specimen leaked in transit: 6.0%; incorrect specimen received: 4.3%; specimen not sent on ice: 3.4%; no plain serum sample received: 1.9%. The 31 reasons for rejection can be categorized as: collection errors (type, volume) 70%; labelling/requesting errors 19%; transport errors 11%.
Conclusion: The biochemistry laboratory rejects approximately 1 in 200 specimens with sample collection errors (sample type, volume) comprising 70% of rejections. The phlebotomy procedure itself provides the greatest opportunity for error. The laboratory can improve control of this step through both direct (e.g. providing phlebotomy services) and indirect (e.g. education) management of the process.

Key words: rejection, phlebotomy, transport, labelling, audit

P009

AFTERNOON COLLECTION OF PRE-ORDERED OUTPATIENT FASTING GLUCOSE SPECIMENS – ARE THEY TRULY FASTING?

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Background: It is important to differentiate between random and fasting glucose specimens for correct interpretation. Our clinician order entry system requires clinicians to request random and fasting glucose samples separately in advance of outpatient visits. This cannot be altered at collection subsequently irrespective of actual patient fasting status. Whether patients are indeed compliant with the prolonged fasting for afternoon sampling is unknown. This study examined whether the glucose concentrations of outpatient fasting specimens collected in the afternoon are lower than afternoon random samples as evidence of true fasting status.
Materials and methods: Anonymized details, including collection time, of all fasting and random glucose requests on outpatients collected over 4 months were extracted from the laboratory information system for analysis in Microsoft Excel and Access. All glucose measurements were performed on Becton Dickinson SSTII gel tubes using Beckman Coulter DxC 800 chemistry analyzers.
Results: There were 8198 random and 1332 fasting glucose samples on outpatients collected between 7-18h. % of random and fasting samples collected from 7-10h was 40% and 90% and from 15-18h was 20% and 0.7%. The median glucose concentrations (mmol/L) were random glucose 7-10h: 6.1; fasting glucose 7-10h: 5.9; random glucose 15-18h: 5.9; fasting glucose 15-18h: 5.35. Using median tests, median glucose concentration for fasting 7-10h samples was lower than random 7-10h samples and median for fasting 15-18h samples was lower than random 15-18h samples. Similarly median glucose concentration for fasting 15-18h samples was less than fasting 7-10h samples while median for random 15-18h samples was lower than random 7-10h (p values <0.0001-0.0013).
Conclusion: Both fasting morning and afternoon glucose concentrations were less than equivalent timed random samples. The consistent relationship between fasting and random samples seen in morning and afternoon samples suggests that afternoon fasting samples are indeed fasting and justify separate reporting and interpretative comments.

Key words: glucose, diurnal, fasting, random

P010

IMPLEMENTATION OF PREANALYTICAL QIS WITHIN BALKAN AREA LABORATORIES

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Background: Although a model of quality indicators of pre-analytical phase was already developed by a working group of IFCC, still, there is no consensus among clinical laboratory regarding implementation of these indicators at local level.
Our network of laboratories adopted those recommendations through its clinical trials division and conducted during the year 2013 a pivotal study to calculate the preanalytical QIs and to analyze how the implementation of those can be conducted.
Materials and methods: Clinical Samples belonging to patients involved in clinical trials; Clinical Trials Procedure – preanalytical phase in clinical trials; Sample Collection Instructions
Defined formulas for a total number of 12 QIs;
Statistical Analysis;
Newly developed survey for clinical laboratories;
A total number of 11000 samples, belonging to patients involved in clinical trials were received in 2013. A unique set of QIs were defined. Indicators were calculated, using the same formulas, by a central unit only, using data reported by local lab units.
Results: Indicators shown an elevated percent of total pre-analytical errors, i.e., 25%, wherefrom three main categories of errors were identified, i.e.:
–   Lack of centrifugation;
–   Hemolysis;
–   Usage of wrong collection systems
Conclusions: Following our study, we developed a questionnaire, in order to assess the clinical laboratories capacity to collect data in order to calculate preanalytical QIs and to implement them in their laboratory management system. Additionally, the questionnaire has the purpose of assessing labs technical capacity to implement the hemolysis index.

This survey is submitted to analysis to EFLM preanalytical WG and its final form to be distributed in our country through the National Society.

Key words: clinical laboratories, indicators, questionnaire

P011

IDENTIFICATION OF ERRORS IN PREANALYTICAL PHASE IN LABORATORY EXAMINATION

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Background: Clinical Chemistry Laboratories as a part of the Healthcare System are susceptible to medical errors, which have a significant impact on the patient result. To prevent this, timely and effective action by employees is needed. From all laboratory errors, it is estimated that about 60% are related to the preanalytical phase. Gathering reliable data is very important, so the laboratory can study all steps of the testing cycle and implement improvements.

Materials and methods: This study was processed in a period of 3 months, with 2350 samples monitored in the whole working process. Quality Indicators Check Lists were created for different segments of the preanalytical phase and the data were summarized and evaluated.

Results: Most of the errors were as a result of the preanalytical factors 74.38%, 1.85% of the test requirements without referral, 3.70% were unlabeled, 3.40% insufficient quantity of serum, 1.85% had fibrin clots, 6.48% were coagulated, 2.47% with not received biological materials, 5.86% were with improper blood collection. Most of the preanalytical errors occurred in the biological material brought by the clinics (hemolysis) and only 1.64% of hemolysed samples were taken in our laboratory.

Conclusion: Full elimination of the laboratory errors is impossible, which highlights the importance of the good laboratory practice and adoption of strategies to prevent, monitor and decrease errors. With the advance of the medical techniques and computer science, the analytical errors are no more a major factor that impacts the correct laboratory result. The errors in the preanalytical phase stress the need of continuous education of all the staff involved in the laboratory examination process, to improve the quality of the whole patient care.

Key words: preanalytical phase, quality indicators, hemolysis

P012

COMPARISON OF LIND-VAC VACUUM TUBES FOR ROUTINE INVESTIGATIONS WITH GREINER TUBES

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Background: Vacuum tube systems have long been accepted for safe routine sampling of blood, particularly venous blood. New manufacturers appear on the market which justifies comparison with established systems. Recently Lind-Vac in Estonia has launched their system which prompts for a comparison with that regularly in use.

Materials and methods: Comparisons between tubes from Lind-Vac (Estonia) with those from Greiner (Austria) were carried out as described in CLSI GP34-A (Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection) and EP-9A (Method comparison and Bias Estimation using Patient Samples). Tube types were with clot activator (type 1) and with clot activator and gel (type 2). Type 1 was used for 14 analytes in 24 patients and type 2 for 13 analytes in 20 patients. Sample collections were made according CLSI H3-A6 (Procedures for the collection of Diagnostic Blood Specimens by Venipuncture) in two tubes of each type for each patient. Concentrations were measured using RX Imola Randox (Ireland) in duplicates from each sample.

Results: Results of comparisons of tubes type 1 an 2 did not show any significant difference of the concentration between samples from Lind-Vac and Grainer tubes (p>0.05). However, the repeatability in tubes without gel were higher for Lin-Vac (p<0.05) for alkaline phosphtase (ALP), total bilirubin (TB), creatin kinase (CK), and triglycerides (TG), and higher for Grainer tubes for (p<0.05): aspartate aminotransferase (AST), urea (U) and urate (UA). For tubes with gel repeatability was higher for Lin-Vac (p<0.05) for AST, amylase and TG, and for Grainer for (p<0.05): total calcium, CK, U and UA.

Conclusion: Greiner and Lind-Vac tubes comparison shows identical concentrations. Imprecision of the results from both types of tubes were of the same order of magnitude within quality goals and did not influence test interpretation.

Key words: vacuum tubes, comparison, venous blood, clot activator, gel

P013

THE DEVELOPMENT OF A LABORATORY QUALITY TRAINING PROGRAM FOR AFRICA FOCUSING ON PRE-ANALYTICAL ERRORS

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Background: The last decades have seen a decrease in analytical laboratory errors with the extra-analytical phases becoming more error-prone. The pre-analytical phase accounts for 46-68.2% of laboratory errors; mainly due to lack of standardized protocols for defining and measuring pre-analytical variables. Increased attention to patient safety and awareness that laboratory results impact on patient treatment has made it a priority for laboratories to reduce errors and promote quality. This led to the establishment of working groups devoted to pre-analytical errors. However in Africa many laboratories are in a dilapidated state, prompting organizations to attempt to improve the quality of results and strengthen capacity. We established the first audit and pre-analytical group in Africa and highlight its achievements.
Materials and methods: Following a needs analysis as part of a strategic initiative to improve the quality of laboratory services in the pre-analytical phase, we established the clinical audit and laboratory management committee. The objectives of this committee were to perform clinical audits of the pre-analytical phase, establish a laboratory management training program, strengthen laboratory management capacity, create awareness of pre-analytical errors and establish a network with other African countries.
Results: We developed a laboratory management training program and this course is compulsory for doctors and scientists training in Clinical Chemistry. It has attracted senior African laboratory professionals and has propelled training programs particularly in Nigeria, which has the most academic pathology laboratories in Africa. We assisted the Royal College of Pathologists to establish LabSkills Africa, which focuses on improving pre –analytical errors and laboratory interface in 5 African countries. Through a coordinated research program we have published numerous articles in peer-reviewed journals.
Conclusion: During the last five years, our institution has successfully introduced pre-analytical error training to various countries in Africa with tangible outcomes.

Key words: quality, Africa, pre-analytical errors, audit

P014

USER QUERY OF THE STATE OF THE SAMPLE IN THE PREANALYTICAL PHASE

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Background: Delays in Primary Care can be caused by the lack of analytical results, as a consequence of preanalytical incidents. This entails a new extraction after a consultation, in which the lack of tests for the diagnosis or treatment is confirmed.
Our goal is to establish a telematic system for the user to check the state of the analysis from the Hospital website, as well as the possible resulted incidents.
Materials and methods: In the Hospital website, a tab would be set to let the user query the state of the analysis by using the User-Password feature, after being registered in the Health Center by the time the day of extraction is requested.
With the request number given to the patient by the time of the extraction, the state of the analysis could be queried, as well as the possible associated incidents.
Depending on the type of incident detected, a printout of a request containing all the pending tests would be generated, in order to proceed to carry out a new extraction, with the consequent creation of a new appointment in the electronic request program, as well as the patient's possibility to choose the day and hour of the second extraction.

Results: During 2013, the preanalytical incidents registered requests were:
- 566 coagulated samples
- 448 insufficient sample
- 306 samples incorrectly brought to level
- 5462 samples not received
- 13260 hemolyzed samples

Conclusions: This system would allow to reduce the time from the first visit to the diagnosis, to improve the user and the Primary Care doctor's perception of the Laboratory, by stopping repeated consultations caused by preanalytical incidents, with the consequent decrease of the waiting lists. Besides, there'll be an efficient use of the resources by preventing the duplication of the whole request, where the involvement of the patients is essential.

Key words: preanalytical incidents, telematic system, samples

P016

STABILITY OF HEMATOLOGICAL ANALYTES DURING 48 HOURS STORAGE AT THREE TEMPERATURES

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Background: The complete blood count (CBC) is one of the most common tests requested by physicians. The results of this test are affected by storage temperature and time of incubation. This study was designed to evaluate the stability of hematologic parameters in blood specimens stored for 48 hours at three temperatures.
Materials and methods: K2 EDTA- blood was collected into Becton Dickinson tubes from 22 apparently healthy adults (11 males and 11 females). The Cell-Dyne 3700 hematology analyzer (Abbott Diagnostics) was used for the measurements. The CBC was performed immediately (0 time point; 0 TP) and at 4, 8, 12, 16, 20, 24 and 48 hours after storage at room temperature (RT), 4 °C or 10 °C. Changes in values of CBC parameters from the 0 TP were determined and reported as % of the initial value. Statistical comparisons were made using the paired-t test and the repeated measures ANOVA.
Results: The changes in RBC parameters during storage at 4 °C or 10 °C for 48 hours were <5%. Storage at RT resulted in changes of < 5% in some RBC parameters (RBC counts, Htc, MCH) at 48 hours, while the changes in Hb, MCV, MCHC and RDW were approximately 7-14% at 48 hrs. The changes in WBC and PLT counts were within 5% after 24 hours storage at all three temperatures, while WBC was reduced by 7.7%, 2.7% or 5.5%, and PLT was increased by about 9.3%, 8.7% or 5.5% at 48 hours after storage at 4°C, 10 °C or RT, respectively.
Conclusions: These data show that the main CBC parameters remain more or less stable during 24 hours storage at RT or colder. Storage at 4°C or 10 °C is may be necessary for longer periods.

Key words: Complete blood count, temperature, time of incubation

P018

COULD SAMPLES STORED AT ROOM TEMPERATURE FOR UP TO 24 HOURS BE ACCEPTED FOR SECOND-LINE COAGULATION TESTING?

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Background: Accurate coagulation test results depend on all phases of laboratory process. Besides sampling, transport and centrifugation, sample stability following blood collection is an important part of preanalytical phase, but it is still a matter of concern. Although samples for coagulation testing are routinely processed according to current guidelines, sometimes there are requests for performing additional tests in already analyzed fresh plasma samples, especially in critical care patients. The aim of this study was to examine whether fresh plasma samples stored at room temperature for up to 24-h after blood collection can still be accepted for second-line routine coagulation testing.
Materials and methods: We have measured prothrombin time (PT), activated partial tromboplastin time (aPTT), fibrinogen (Fbg) and antithrombin (AT) in citrated plasma samples in primary tubes within 4-h of blood collection and after storage at 25 °C for up to 24-h.

Additionally, plasma aliquots were separated from primary tubes and stored at 25 °C for up to 24-h. Stored plasma samples in primary tubes and aliquots were processed the next day under the same conditions. For each parameter, samples from 20–30 patients were investigated covering a wide range of normal and pathological results. Measurements were performed on the coagulation analyzer BCS XP by using reagents from Siemens Healthcare Diagnostics.

Results: The highest variation of results in stored samples was observed for aPTT (primary tubes: mean 11.8%, range 3.4–32.8%; aliquots: mean 15.5%, range 5.0–30.4%). For all other parameters the mean percentage change was below 10% either in primary tubes (ranging from 1.3–5.7%) or in aliquots (ranging from 1.1–3.6%).

Conclusion: No advantage of separating plasma from cells was observed. Samples stored in primary tubes for up to 24-h can be used for second-line routine coagulation testing, even for aPTT as changes of results were not clinically relevant.

Key words: routine coagulation tests, 24-h stability, room temperature

P019

IMPORTANCE OF PREANALYTICAL PHASE: A CASE OF CRYOGLOBULINAEMIA DETECTED ON A BLOOD SMEAR

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Background: Cryoglobulins are serum immunoglobulins (Igs) that precipitate at temperatures below 37°C and redissolve on warming. Cryoglobulinaemias may be idiopathic (10%), but typically develop in the context of malignancy, chronic infection or connective tissue disease. Cryoglobulins are subdivided: type 1 involves a monoclonal immunoglobulin, type 2 has mixed monoclonal and polyclonal and type 3 cryoglobulinemia involve polyclonal immunoglobulin precipitates. Cryoglobulins may assume amorphous, gelatinous and/or crystalline morphological forms *in vitro* in the patient serum/smear and require appropriate and very specific serum sampling and handling conditions.

Materials and methods: a 71-year-old male presented fever, cough and left pleural effusion. A CT scan showed up enlarged mediastinal, lumbo-aortic and celiac lymph nodes. Further investigation yielded a diagnosis of marginal zone lymphoma with cells positive for CD19/CD20 forte/CD45 and negative for CD10/CD5/CD38.

Results: Complete blood count showed Hb 132g/L, WBC count 4.45×10^9/L with a normal differential count, and platelets 204×10^9/L.

Laboratory work-up did show normal levels of Igs, but serum protein electrophoresis showed only a slight monoclonal band (beta region) and immunofixation identified two monoclonal proteins (IgA lambda and IgM lambda).

The peripheral blood smear revealed visible aggregates of amorphous particles, suggesting the presence of cryoglobulins, which was later confirmed after warming the blood (37°C × 2 hours) with the smear becoming free of microscopic deposits. It was decided to collect a new sample of serum this time kept at 37°C which revealed hypergammaglobulinemia with an increased amount of IgM (1103mg/dL), demonstrating protein precipitation when cooled to 4° C or room temperature. The latter was characterized by immunofixation to be an IgM lambda monoclonal protein.

Conclusions: The observation of cryoglobulins is very rare on a peripheral blood smear, but it is very important to be aware of its presence as it provides a window into the disease which can be later confirmed.

Key words: preanalytical phase, cryoglobulinaemia, blood smear

P020

RATE OF HEMATOLOGY SPECIMENS REJECTION

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Background: To calculate the rate of rejected specimens received in hematology laboratory stratified by area of collection and reason of rejection.

Materials and methods: Retrospective study conducted at Pamukkale University Hospitals in Denizli, Turkey, for twelve months period. Data on rejected hematological specimens in the laboratory information system from November 2013 to November 2014 were analyzed.

Results: A total 388259 specimens were considered and 7476 (1.93%) specimens were rejected based on our laboratory rejection criteria. The rejection rates were 3.38%, 2.42%, 1.46% for sedimentation, coagulation and CBC tubes, respectively. The most frequent reason for the rejection was the clotted specimen (69.37% of total rejections), followed by insufficient volume (17.54% of total rejections). Other causes of rejection observed were wrong specimen (3.34%), excessive sample volume (2.88%), hemolyzed specimen (2.66%), inappropriately labeled specimen (1.43%), inappropriate order (0.99%), damaged specimen (0.98%), empty container tube (0.56%), lipemic specimen (0.13%), and long interval after collection (0.12) respectively. The areas of collection as well as the reason of rejection were recorded and the results were as follows: The overall rejection rate ranges from 0.69% to 16.77%. Highest rejections seen from Neonatal Intensive Care (14.77%) followed by Inpatient Pediatric Surgery (8.25%), Inpatient Oncology Services (4.32%), Inpatient Pediatric Services (4.23%), Medical Intensive Care (3.98%), Inpatient Medical Services (3.64%), Inpatient Surgery Services (3.33%), Inpatient Hematology Services (2.81%), Emergency Unit (2.66%), Outpatient Pediatric Services (1.84%), Surgery Intensive Care (1.60%), Outpatient Phlebotomy Services (0.80%) and Outpatient Hematology Services (0.69%).

Conclusion: The most reasons of rejection of specimens in the hematology laboratory were mainly related to phlebotomy technique. Training of phlebotomist is important to reduce preanalytical errors.

Key words: Hematology, Rejection rate, preanalytical errors

P021

PREANALYTICAL ERROR OCCURRENCE RATE IN CENTRAL CLINIC LABORATORY OF A PUBLIC HOSPITAL IN TURKEY

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Background: The pre and post analytical phase in a testing cycle contributes up to 93% of total laboratory errors. However, pre-analytical phase is primarily responsible for errors. Hence, it is of precise importance for the laboratory to study error occurrence rates during the testing cycle and implement a quality improvement plan to release an accurate result.

Materials and methods: The present study was conducted during the period Jan-Nov 2014 in the Central Clinical Lab in Osmaniye State Hospital, Turkey. During period of 11 months, 626897 samples were monitored for major preanalytical problems at the receiving counter of the Central Clinical Laboratory.

Results: Among all preanalytical laboratory errors, 35.4% of the errors were associated with clotted sample, 25.5% errors with inadequate sample, and 25.3% errors with hemolysed sample in the laboratory. Assessment considering the departments showed that emergency unit had the highest error rates (hemolysis: 52.5%, lipemic: 42.9%, damaged: 34.6%, clotted: 34.2%, inadequate: 26.8%, wrong material: 17.6%, wrong barcode: 16.7%). There was significant difference among the departments in terms of preanalytical errors (p<0.001).

Conclusions: Based on these observations, major preanalytical errors are of great concern and needs corrective approach via proper educational programs to related personals. If this area is ignored, that can lead to negative patient outcome. However, a better specimen quality and patient satisfaction are achieved with the high quality personal-based education regarding pre–analytical errors.

Key words: Pre–analytical errors, biochemistry laboratory, hemolysis

P022 – SELECTED ORAL COMMUNICATION

A NOVEL METABOLOMICS-BASED QUALITY CONTROL ASSAY OF HUMAN EDTA PLASMA

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Background: Research in the healthcare area like identification and validation of new diagnostic biomarkers, drug target discovery and treatment monitoring approaches often starts with the analysis of existing biobank samples. The quality of these biobank samples can be impaired by various pre-analytical sample processing steps that will confound the analytical results and decrease the value of research if not identified and addressed properly. Metabolite profiling, also known as "metabolomics", is a well-suited technology to support the identification of

technical biomarkers for the quality assessment of biobank samples due to its high sensitivity plus the broad coverage of physiological and chemical processes.

Materials and methods: Human EDTA plasma samples obtained after applying defined pre-analytical confounding factors were subjected to mass-spectrometry based metabolomics including selected targeted platforms MxP® Broad profiling, MxP® Eicosanoids, MxP® Catecholamines and MxP® Lipids. Additionally, a targeted GC-MS based assay developed to control for such pre-analytical confounders, was applied.

Results: Pre-analytical confounders resulted in significant and reproducible changes of the human plasma metabolome with blood storage having the highest impact. Several metabolites suited as Quality Markers were identified and validated in independent data sets after Bonferroni-Holm correction of the false-positive rate with p-values being <0.001. Samples with insufficient pre-analytical quality were identified with high sensitivity and specificity.

Conclusions: High-level result interpretation of -omics studies requires a comprehensive knowledge of the impact of the pre-analytical phase on the results and their underlying physiological and chemical mechanisms. The newly developed assay enables pharmaceutical R&D, clinical research organizations, and biobanks to better understand the actual condition of human plasma samples, efficiently monitor SOP compliance in multicenter trials, deliver superior quality samples, and support evidence-based decisions for sample selection.

Key words: metabolomics, quality control, pre-analytical variation

P023

COMPARISON OF IMPROVACUTER™ TUBES WITH BD VACUTAINER™ TUBES FOR VARIOUS HORMONES IN THE ASPECTS OF STABILITY AND INFLUENCE OF GEL SEPARATORS

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Background: Validation of the blood collection tubes are important to determine the role of different collection tubes, which influences the assurance of laboratory results. We compared two different tube brands (Improvacuter™; (Guangzhou Improve Medical Instruments Co. Ltd., China) and Becton Dickinson (BD) Vacutainer™; (Becton, Dickinson and Company, UK)) and investigated the effect of gel and the storage time in comparison with each other.

Materials and methods: We compared the results of nine immunoassays (fT3, fT4, TSH, FSH, LH, progesterone, testosterone, estradiol and cortisol) performed on UniCel® DxI 800 Immunoassay System (Beckman Coulter Inc., USA) using blood samples collected into BD Vacutainer SST II Advance tube, Improvacuter Gel and Clot Activator tube, BD Vacutainer Clot Activator tube and Improvacuter tube. Analytes were measured in all tubes on three consecutive days to study the effect of long-term storage. Tubes were stored at 2-8 °C between analyses. Stability was also evaluated over 48 hours for each collection tube. Evaluation of clinical significance performed based on total allowable error (TE$_A$).

Results: Estradiol and testosterone concentrations obtained from Improvacuter Gel and Clot Activator tube and BD Vacutainer Clot Activator tube remained below the lower limits of analytical range for the same analytes while they were within the limits in BD Vacutainer Clot Activator tube and Improvacuter tube. The detected statistical significance of stability was not significant clinically for hormone parameters we tested in all four tubes.

Conclusion: Gel containing tubes (both BD and Improve) give comparable results with the tubes which do not contain gel except for estradiol and testosterone. The use of gel containing tubes for estradiol and testosterone are not recommended on UniCel® DxI 800 Immunoassay System according to our results. The change in the analyte concentrations over 48 hours remained within the TE$_A$ limits for the studied analytes. Improve tubes gave similar results with BD tubes.

Key words: blood tubes validation, hormones, stability

P024

REDUCE HEMOLYSED BLOOD SAMPLES: A CHALLENGE FOR EMERGENCY DEPARTMENT AND CLINICAL LABORATORY

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Background: The Valenciennes Hospital Emergency Department (ED) welcomes about 53500 patients per year. In the ED, the prevalence of hemolysed specimens was around 15,92% (January to May 2013), causing clinical, organizational and economical problems. The aim of the study was to identify remediable hemolysis factors and to design an effective strategy with laboratory staff to reduce sample hemolysis.

Materials and methods: During five months, an educational program based on a literature review including various factors of risks of hemolysis: venipuncture (needle vs catheter and location), needle gauge, tourniquet time, antiseptic used, tubes order, vigorous or no mixing, tubes under filled, transport temperature... was implemented. Also, a shift from regular (7 mL) to low volume blood collection tubes (5 mL) and a standardization of assessment of hemolysis index (HI) were operated. Free hemoglobin was used to identify hemolysed clinically significant samples with HI > 2+.

Results: Hemolysed specimens in our laboratory are occurring with a frequency comparable to that reported by others studies (12,5% to 23%). For reduce hemolysis sample, a real teamwork between the laboratory and the ED was achieved. A control of hemolysis once a month showed a significant decrease occurred from October 2013. A changed of the clinical staff behavior combined with others actions allowed to attain a reduction in hemolysis sample from 13,35% to 4,83% (p=0,0001).

Conclusions: Overall, combination of several factors showed a positive impact to significantly reduce rates of hemolysis sample. A Quality Indicator (IQ) was set up for the long-term control of hemolysis. Clinical and laboratory staffs satisfaction was palpable with improvement of work quality such as less repeat blood sampling. Future research should include an economic evaluation. Moreover, very good relations were developed between the clinical laboratory and the ED with communication improvement.

Key words: Hemolysis, Emergency Department, Quality Improvement

P025

DEPLOYMENT OF CAREGIVERS PRE-ANALYTICAL REFERENTS IN UNITS OF CARE: EXPERIENCE FEEDBACK FROM FRENCH GENERAL HOSPITAL

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Background: Strict control of the pre-analytical phase outside the laboratory is crucial for improve the safety of patients and reduce costs associated to poor quality samples. The aim of this work was to make an experience feedback on the implementation of pre-analytical referents in units of care.

Materials and methods: Since 2011, 30 nurses/midwives spread in 55 departments trained a theoretical and practical educational program (35 hours of training) on pre-analytical phase issues, and evaluated by questionnaires. In addition, a formation in the audit of practices according to French High Authority of Health (HAS) referential was performed.

The working group composed of pre-analytical referents meets 4 times a year and defines the actions which should be taken such as distribute questionnaires of knowledge to the nurses in the whole hospital, realize audits on the correct blood collection protocols and make a return of the results obtained with departments, write protocols of blood collection, follow quality indicators and elaborate information leaflets.

Results: Three audits in 4 years were performed with 172 observations in 26 departments in 2014. This audit highlighted an improvement of practices for used needles vs butterfly needles, tubes order and mixing tubes.

The rate of participation to questionnaires of knowledge in the departments was more of 62% (305/485), and allowed to identify points of training. It resulted from it, elaboration of information leaflets distributed in more of 75% of caregivers.

A connection between this working group and the hospital pharmacy was put in place in particular for test new blood collection systems.

Conclusions: The institution of this cross-sectional working group allowed to improve relations between departments of care and the laboratory. The various actions carried out show a positive impact on laboratory results for physicians and for patients. Long life to this dynamic working group!

Key words: Pre-analytical Referents, Pre-analytical Phase, Caregivers, Laboratory, Quality

P026

USING PDSA TO IMPROVE REDRAW RATES AND REDRAW TURNAROUND TIMES IN THE EMERGENCY DEPARTMENT

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Background: Patients in the Emergency Department (ED) routinely require intravenous (IV) access and blood collection. Blood sample collection during IV placement will minimize the discomfort of a separate venipuncture, however is associated with increased incidence of specimen hemolysis, which may delay treatment. The aim of this study was to both decrease the frequency of redraws and improve turnaround time for specimen recollection using Plan, Study, Act, Do (PDSA) methods.

Materials and methods: We reviewed redraw rates and the time required for blood specimen recollection and result posting (redraw turnaround time) for ED patients at St. Mary's Hospital (Rochester, MN) from July 2012-March 2014. Baseline and post-process improvement data were obtained from the laboratory information system. Statistical analysis was performed using GraphPad. This study was exempt by the Mayo Clinic Institutional Review Board.

Results: The baseline redraw rate in the ED was 4.1(0.5)% (n=10 months). During a 45-day period, 7.6% (n=490) of blood samples in the ED were collected during IV placement, with 4.5% (n=22) resulting in redraw despite a training intervention aimed to improve specimen quality. A subsequent intervention restricted blood sample collection during IV placement. The frequency of blood sample collection during IV placement decreased to 5.3% (n=213), and the overall redraw rate decreased to 1.5% and was maintained at average (SD) 1.8(0.3)% over nine months. Redraw turnaround times were <60 minutes for 9.6% and <120 minutes for 67.1% of samples (n=73, July 2012). PDSA methodology was used to change the process of notifying the phlebotomist of a redraw and mean (SD) turnaround times improved with 80.6 (7.1)% (p<0.0001) within <60 minutes and 91.5 (5.3)% within 120 minutes (p<0.0001, n=17 months).

Conclusions: PDSA and quality indicators were employed to successfully improve and maintain redraw rates below 2% and turnaround times <60 minutes.

Key words: redraw rate, quality indicator, IV start blood collection, process improvement, PDSA

P027

MANAGING LABORATORY TESTS UNDER REQUEST: AUTOMATIC COMPUTER-AIDED ALGORITHM INTERVENTION FOR AN IMPROVEMENT IN HYPERPARATHYROIDISM (PHPT) DETECTION: 30 MONTHS STUDY

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Background: In collaboration with GPs an automatic strategy to identify appropriate samples to be tested for serum calcium, was designed, established and evaluated, for an improvement in hyperparathyroidism (pPHT) detection.

Materials and methods: Laboratory Information System (LIS) added serum calcium (s-Ca) to every primary care patient above 45 years, without s-Ca requested in the previous three years. If results ≥ 9.9 mg/dl (2.5 mmol/L) serum albumin was automatically added by LIS, and if s-Ca corrected per albumin value was above 10.2 mg/dl (2.6 mmol/L), parathyroid hormone (PTH), 25-hydroxy vitamin D [25(OH)D] and phosphate were also automatically added by LIS in the same sample. If PTH results >65 pg/mL, was recommended to send the patient to endocrinology for study, through an automatic comment in laboratory report. By reviewing medical records (MR) we calculated the number and cost of each pHPT patient diagnosed through the strategy, taking into account the reagent costs of added s-Ca, albumin, PTH, phosphate and 25(OH)D.

Results: From January 1st 2012 to October 30th 2014 (except the period between November 2013 and February 2014), 35460 s-Ca were added automatically by LIS, resulting in 172 hypercalcemia results. 20 hypercalcemia results were justified by a previously diagnosed pHPT, malignancy, chronic renal failure, or drug therapy. 62 resulted in a diagnosis of pHPT and 42 are currently in study for a pHPT. Despite their

abnormal and unexpected s-Ca test results, in 55 patients the primary cause of hypercalcemia was not still assessed. Each case of pHPT diagnosed represented a cost of 113.4€.

Conclusion: The opportunistic screening to detect pHPT seems cost-effective. This self-regulating intervention may be exportable to any setting. The number of additional s-Ca requests would depend on the previous demand.

Key words: Serum calcium, Primary hyperparathyroidism, outcome results; patient safety, laboratory test utilization.

P028

MANAGING LABORATORY TESTS OVER REQUEST: FIVE YEAR EVALUATION THROUGH INDICATORS

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Background: Studies on regional differences in the laboratory tests utilization in Spain refer over requesting in Primary Care. Over requesting can produce negative effects not only because economic expenses but also by means of adverse effects of false positive results, making necessary to design strategies to be evaluated through monthly intra-laboratory indicators.

Materials and methods: In collaboration with General practitioners (GPs) automatic strategies through laboratory information system (LIS) were designed and established, to diminish IgA antigliadin antibody (GP-IgA), aspartate aminotransferase (AST), free thyroxine (FT4), γ-glutamyltranspeptidase (GGT), iron, phosphate, transferrin and total bilirubin (tBil) requests. AST, phosphate and transferrin were automatically added again if alanine aminotransferase (ALT) and calcium results were above reference ranges and ferritin levels above 400 ng/mL.
FT4 if thyrotropin (TSH) above or below reference ranges, after carefully patient medical record evaluation.
GP-IgA was replaced with IgA antitransglutaminase antibody (TG2-IgA) if patients were older than 2 years.
tBil was measured only if the icteric index value was above 34.2 mmol/L (2 mg/dL). Ratios of related test requests AST/ALT, FT4/ TSH, GP-IgA/ TG2-IgA, GGT/ALT, iron/ferritin, phosphate/calcium, transferrin/ferritin, urea/creatinine were calculated each month and the ratio measured tBil/requested tBil. Also if some indicators targets were achieved, was also evaluated (0.25 for AST/ALT, 0.25 FT4/TSH, 0.20 GGT/ALT).

Results: From December 1st 2009 to November 30th 2014, a subsequent diminution of every ratio was observed and maintained over time, related to the date the strategy was established, being statistically significant in every case when comparing pre and post intervention periods. AST/ALT and FT4/TSH indicators targets were achieved in January 2012 and March 2010, GGT/ALT did not reached the indicator goal.

Conclusions: From the laboratory, in collaboration with the requesting clinicians, and making use of the LIS, automatic computer-aided algorithm interventions that are maintained over time can be designed and established.

Key words: Clinical Laboratory; Laboratory Management; Patient Safety; Outcome Results; Test Request Appropriateness

P029

MANAGING LABORATORY TESTS UNDER REQUEST: AUTOMATIC COMPUTER-AIDED ALGORITHM INTERVENTION FOR AN IMPROVEMENT IN DIABETES (DM) DETECTION

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Background: In collaboration with General Practitioners (GPs) an automatic strategy to identify appropriate blood samples to be tested for HbA1c, was designed, established and evaluated, for an improvement in DM detection.

Materials and methods: Laboratory Information System (LIS) added HbA1c to every primary care patient above 45 years, without an HbA1c in the previous three years, CBC requested and serum glucose concentration between 100 and 125 mg/dl. If results ≥ 6.5% (48 mmol/mol) a second request was recommended in a 3-6 month period, through automatic laboratory report comment. Patient's medical records with

HbA1c values ≥ 6.5% were evaluated to investigate DM confirmation. We calculated the cost (reagent cost) of each patient diagnosed through the strategy, and when requested by GPs.

Results: From 1st March 2013 to 31 May 2014, there were 11030 patients older than 45 years without HbA1c requested in previous three years. 3803 had a glucose result between 100-125 mg/dl. In 1946 HbA1c was requested by GPs and in 1857 was added automatically by LIS, resulting in 190 HbA1c values ≥ 6.5% (48 mmol/mol) in the first group and 65 in the second. 22 and 18 patients diagnosed as DM in the first and second group respectively. GPs requested HA1c to 6418 patients with glucose values lower than 100 mg/dl and 5 DM patients were diagnosed. Each case of DM diagnosed was 97.3 euros in patients with serum glucose results between 100 and 126 mg/dl when requested by GPs, 113.5 when registered by means of the strategy, and 1412.0 when low serum glucose values.

Conclusion: The strategy detected new DM cases at low cost. When GPs requested HbA1c in patients presenting low serum glucose values, the cost of detecting DM was tenfold higher.

Key words: Diabetes mellitus; HbA1c; outcome results; patient safety; laboratory test utilization.

P030

EFFECT OF DAILY FEEDBACK IN THE DIMINUTION OF SAMPLES INCIDENCES IN PRIMARY CARE CENTERS

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Background: Laboratory pre-analytical quality regarding samples incidences is still a big topic to be solved by laboratory professionals. It can produce analytical interferences and additionally patient discomfort.

Materials and methods: We collected pre-analytical errors from the tests requested for hematology, coagulation and chemistry samples. When an incidence occurs, a specified codified result is registered in laboratory information system (LIS) as test result that indicates the samples have not been received, or coagulated, insufficient or hemolyzed, and a new phlebotomy is necessary. Historically a daily LIS search has been done looking for incidences and after supervision by laboratory nurse supervisor, the laboratory administrative staff telephoned the primary care centers (PCCs) administrative personnel that contacted the patient for a second phlebotomy, to avoid the patient going to the physician's office without a complete laboratory report. In view that the incidences were maintained over time, and in an attempt to improve sampling procedure, it was decided the laboratory nurse supervisor to be in charge of the procedure. From September 2014 it is her that personally is sending an email to the PCC coordinator nurse where the sample incidence has occurred to inform about the error, indicating the convenience of a second phlebotomy. To avoid seasonal variability in sample incidences, errors in November 2013 (pre-intervention period) and 2014 (post-intervention period) were compared.

Results: The number of daily incidences related to samples not received, or coagulated, insufficient or hemolyzed in hematology, coagulation and chemistry specimens has significantly decreased from 7.73 to 3.2 per day.

Conclusions: Continuous education is key and also continuous communication and daily feed-back between personnel in charge of the sample procedure in laboratory and PCCs.

It is imperative to design and establish the necessary tools in a daily basis for its detection and solution, and also the proper barriers for future prevention.

Key words: patient safety, pre-analytical phase, phlebotomy, quality in laboratory

P031

PATIENT PREPARATION BEFORE ANALYSIS: EVALUATION THROUGH SURVEYS BEFORE BLOOD COLLECTION

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Background: Minimizing pre-analytical errors through careful evaluation of the pre-analytical variables is a main task of clinical laboratory professionals for a more reliability of tests results and hence a better clinical decision making. Patient preparation before analysis is key, however not very often evaluated.

Materials and methods: In order to investigate the proper patient preparation before blood sampling every patient that came to the hospital laboratory for a phlebotomy was invited to fulfill a questionnaire. It consisted of 4 questions to check both, the information received when lab tests are requested, and also the real conditions he arrives for the procedure regarding fasting, exercise and medication. The results of the questionnaires were analyzed using Excel 2007.

Results: In one month period, 350 patients (38% male, 62% female) were included in the study (mean age 51.3 years). 12% of the patients recognized not having received information regarding the necessary conditions previous lab tests. 2% of the patients did not follow the fasting requirements before blood sampling. 12% of the patients had taken medication the morning before phlebotomy procedure. 19% of respondents reported having done exercise the 3 days before blood collection.

Conclusions: A tight collaboration between laboratory and requesting clinicians is required for a 100 per 100 patient's information regarding previous conditions necessary to be taken before the analysis. Most patients came to the laboratory for a phlebotomy in the required fasting conditions. In view of the amount of patients having medication before the phlebotomy, a more detailed study regarding medication interferences is needed in order to design and establish in collaboration with requesting clinicians the real necessary conditions previous to the analysis: Which medications are necessary to be avoided depending on tests requests. More studies are needed regarding possible interferences in patients having previous vigorous exercise.

Key words: laboratory errors, patient safety, pre-analytical phase, phlebotomy, quality in laboratory

P032

EFFECT OF SAMPLE TYPE, CENTRIFUGATION AND STORAGE CONDITIONS ON VITAMIN D CONCENTRATION

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Background: Studies about vitamin D [25(OH)D] stability in plasma are limited and preanalytical variables such as tube type may affect results. We aimed to evaluate effect of storage conditions, sample type and some preanalytical variables on vitamin D concentration.

Materials and methods: Blood samples from 15 healthy subjects were centrifuged at different temperatures and stored under different conditions.
Serum and plasma 25(OH)D difference, effect of centrifugation temperature and common storage conditions were investigated.

Results: There was no difference between serum and plasma vitamin D concentration. Centrifugation temperature had no impact on vitamin D concentration. 25(OH)D is stable under common storage conditions: 4 hours at room temperature, 24 hours at 2-8 °C, 7 days at -20 °C, 3 months at -80 °C.

Conclusion: Vitamin D does not require any special storage conditions and refrigeration. Both serum and plasma can be used for measurement.

Key words: centrifugation; temperature; stability; vitamin D; preanalytical phase

P034

EVALUATION OF EFFECTS OF PNEUMATIC TUBE TRANSPORT ON ROTEM® ANALYSES

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Background: Rotational tromboelastometry (ROTEM®) can be used for quick monitoring of the blood coagulation status of patients in emergency situations. For a rapid analysis the blood samples can be transported to the central laboratory in our hospital via a pneumatic tube system. This study has been performed to evaluate possible effects of pneumatic tube transport on several ROTEM® parameters in blood samples of cardiothoracic surgery patients of the Intensive Care Unit.

Materials and methods: Blood samples of 30 patients were transported to the central laboratory either by pneumatic tube system or by walking. All samples were used for ROTEM® INTEM, EXTEM, FIBTEM and HEPTEM analyses.

Results: Our results show that the ROTEM parameters that are included in the in house protocol for hemostatic therapy (EXTEM CT, EXTEM A10 and FIBTEM A10) have a bias of less than 5%. The measured within-run and between-run analytical variation of these parameters was less than 5% with the exception of EXTEM CT (maximum of 8%), which is in accordance with the manufacturer's specifications.

Conclusions: In conclusion, the pneumatic tube system in our hospital can be used to transport blood samples to the central laboratory for ROTEM® analyses. In the future, this provides the opportunity for various other departments in our hospital to include ROTEM® analyses in their treatment protocols.

Key words: Pneumatic tube system, ROTEM

P035

WHEN DOES LIPEMIA AFFECT CALCULATED OSMOLALITY?

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Background: Lipemia may be an important interference source for osmolality as well as routine chemistry test parameters. The aim of this study was to evaluate the effects of lipemia on measured and calculated osmolality.

Materials and methods: Measured and calculated osmolality were compared in native ultralipemic material (NULM)- and intravenous lipid emulsion (IVLE)-added sera. NULM was prepared from lipemic sera by high-speed centrifugation. Five different pools were prepared in which triglycerides concentrations ranged from 1.37 to 23.41 mmol/L. Osmolality was measured with an osmometer and calculated from the electrolytes measured by direct and indirect potentiometry. Lipemia indices of the samples were determined. All measurements were also performed after high-speed centrifugation.

Results: Lipemia did not significantly affect measured osmolality in both lipemic groups (p >0.05). There was a significant decrease in calculated osmolality due to decreased sodium measured by indirect potentiometry, but direct potentiometry in the highly lipemic group. Contrary to the expectations, measured osmolality was increased in IVLE-added sera.

Conclusions: Measured osmolality is not affected by lipemia in native lipemic specimens; but calculated osmolality is affected by lipemia at high triglyceride concentrations due to decreased sodium measured with indirect potentiometry. If measurement of osmolality is not possible, high speed-centrifugation or sodium measurement with direct potentiometry is proposed for calculated osmolality in highly lipemic specimens. IVLE spiking is not suitable for studies of lipemia interference.

Key words: Lipemia, interference, osmolality, potentiometry

P036

REGISTRATION OF PREANALYTICAL ERRORS IN SAMPLES SENT FROM PRIMARY CARE TO LABORATORIES IN NORWAY

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Background: To see a possible effect of an intense educational effort to reduce preanalytical errors in GP offices, nursing homes and other primary care centers, Noklus and NKK initiated a project where Norwegian medical laboratories counted preanalytical errors in samples received from primary health care (PHC).

Materials and methods: Medical laboratories in Norway that accepted to participate, registered four different preanalytical errors during one month in samples received from PHC.

Preanalytical errors registered:

– Incorrect / missing identification of patient
– Details of the sample prescriber or copy recipient is missing or incomplete
– Sampling time is not on the request form when it is required
– The sample material is incorrect, insufficient or missing.

The frequency of these preanalytical errors was returned to Noklus/NKK together with some basic information about the laboratory, e.g. accreditation status, use of electronic request forms, etc.

Results: 94 of 97 invited medical laboratories in Norway accepted to participate and registered the four different errors from PHC. Error III was the most frequent error over all, closely followed by error IV, error I and error II. Laboratories with systems to help prevent errors, like having electronic requesting, being accredited or a system to register preanalytical errors, received the fewest errors.

Conclusions: A successful registration of four preanalytical errors has been carried out in Norwegian medical laboratories. Laboratories with systems to help prevent errors recorded the fewest errors. Noklus will intensify education to PHC concerning preanalytical errors. Same registrations will be carried out in medical laboratories in 2015 and 2016 to look for a potential improvement, and to evaluate if this can be established as an ongoing Norwegian EQA-program.

Key words: Preanalytical errors, survey, medical laboratory, primary health care and quality.

P037

PREANALYTICAL SURVEYS AS A TOOL TO REDUCE PREANALYTICAL ERRORS IN PRIMARY HEALTH CARE (PHC) IN NORWAY

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Background: Noklus was established in 1992. Today 99% of Norwegian general practice (GP) offices, and 95% of nursing homes participate in Noklus' External Quality Assessment (EQA) scheme. Noklus started preanalytical surveys among their participants in 2013 in order to identify areas in need of improvement.

Materials and methods: In November 2013 and April 2014, free preanalytical surveys were distributed to Noklus' PHC participants. The surveys were questionnaires containing multiple choice questions about their routine and procedures concerning preanalytical issues. In 2013, the topic was mainly patient identification, and in 2014, capillary sampling. The participants got a written feedback with their own results compared to all participants. The report had recommendations of best practice and contained referrals to procedures and guidelines in the current topic.

Results: 2123 participant in 2013 and 2193 in 2014 received the survey, and 52% and 54% responded respectively. Both surveys showed lack of good practice regarding patient identification, labelling specimens and documenting the results in patient record. Point of care testing, was more often performed without proper training in nursing homes than in GP offices.

Conclusions: The surveys have identified routines and procedures that can cause preanalytical errors in Norwegian PHC. Based on the results, Noklus will intensify the guidance of their participants concerning patient identification. Training and education in correct capillary sampling in effort to reduce errors, particularly to nursing homes, will be a priority. Noklus plan to perform yearly surveys with different pre-analytical aspects in order to identify and reduce preanalytical errors in PHC. The preanalytical surveys can also be used to monitor changes caused by better guidance in different priority areas.

Key words: Preanalytical errors, survey, medical laboratory, primary health care and quality.

P038

THROMBIN-ACCELERATED QUICK CLOTTING IMPROVEMENTS IN PREANALYTICAL PHASES OF CLINICAL LABORATORY: IMPROVED INSTRUMENT DOWNTIME

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Background: Preanalytical variable improvement, with increasing performance expectations from the clinical laboratories particularly in critical analytes, has closely been focused on. The needs for preanalytical improvements have forced innovation of sample tubes. Thus, the plain (with no additive for clotting) have evolved into vacutainer serum separator tubes with silica-activated clotting, and finally, the latter have been innovated into serum tubes with thrombin-activated clotting. Thrombin-accelerated quick clotting has provided many improvements in preanalytical and analytic phases of clinical laboratory processes, including reduced serum indices (serum quality), reduced turn-around time, and increased serum yield (serum amount obtained). The aim of the study is to investigate the effect of serum tubes with thrombin-activated clotting (RST, BD) on instrument downtime.

Materials and methods: Thus, we carried out this study on the performance improvement of BD vacutainer rapid serum tubes (RSTs) compared to BD vacutainer serum separator tubes (SSTs). The effect of RST usage on instrument downtime was tried to estimate by using ion selective electrode slopes. For this purpose, the data obtained from laboratory information system and from the computers of two clinical chemistry analyzers (Beckman Coulter AU 5800) used in the lab, one (SA-CC: standalone clinical chemistry) in emergency section and the other (PP-CC: power processor-linked clinical chemistry) in routine section, were used.

Results: The RST-using SA-CC analyzer has higher sodium and chloride slope values (P<0.05 for both) than those of PP-CC analyzer, and higher but not-significant potassium slope values (P>0.05).

Conclusions: Our data analyses have shown that the improved downtime of the analytic system was achieved using RST in the analyzer employed in emergency department, which is important in reporting the reliable, fast laboratory test results of urgent patients because the higher the slope values, the lower the maintenance period for analyzer and the lower the downtime of it.

Key words: Downtime, Turnaround time, Serum indices

P039

THROMBIN-ACCELERATED CLOTTING IMPROVEMENTS IN PREANALYTIC PHASES: IMPROVED SERUM INDICES, SHORTENED TURNAROUND TIMES

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Background: The reduction of turnaround times of the analytes is the central, major goal especially in emergency departments of clinical laboratories. Serum tubes with thrombin-activated clotting have significantly reduced turnaround times for result reporting. With increasing performance expectations from the clinical laboratories particularly in critical analytes, preanalytical variable improvement has been focused on.

Materials and methods: This study has been carried out on the performance improvement of BD vacutainer rapid serum tubes (RSTs) with thrombin-activated clotting compared to BD vacutainer serum separator tubes (SSTs) with silica-activated clotting. The investigated parameters included serum indices, turnaround time, serum amount obtained, and the effect on some analytes. The selected analytes were analyzed in Clinical chemistry analyzer (Beckman Coulter, AU 5800).

Results: Data from the study showed that the results of some selected analytes were comparable between RSTs and SSTs. However, the results of alanine aminotransferase, aspartate aminotransferase, lactate dehydrogenase, direct bilirubin, and calcium in the samples of SST were higher when compared to those of RST (P<0.05), the result of only total bilirubin in the samples of SST were lower than those of RST (P<0.05). In spite of this, all the results obtained for both RST and SST were within reference range. No change was seen in creatinine, gamma-glutamyltransferase, alkaline phosphatase, amylase, sodium, and potassium levels between the two tubes. The decreased serum hemolysis index (P<0.05), shortened turnaround times (P<0.05), and increased serum yield (P<0.05) were achieved in RST when compared with SST.

Conclusions: RSTs offered savings in the time required for the accelerated test results and provided high quality and high amount of serum, all of which are important in reporting the high quality laboratory results of urgent patients. However, this situation should not eliminate the current usage of SSTs, which have very compatible test results with RSTs.

Key words: TAT, serum indices, fast clotting

P041

DETERMINATION OF METAMIZOLE INTERFERENCE ON MEASUREMENTS OF SELECTED BIOCHEMICAL ANALYTES IN ACCORDANCE WITH CLSI STANDARD EP7-A2

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Background: Analgin (Novalgin, Dipyrone) is a widely used analgesic drug. After discovering a strong influence of its active substance metamizole on enzymatic creatinine assays, we tried to determine metamizole interference on selected biochemical assays in accordance with CLSI standard EP7-A2 (Interference testing in Clinical Chemistry; Approved Guideline-Second Edition).

Materials and methods: Two different serum pools with high and low concentration of a selected analyte were prepared either from healthy volunteers and spiked to the concentration as declared by CLSI standard, or from hospitalized patients not receiving medicamentation. From

each pool, 10 control samples and 10 test samples were prepared. Test samples were spiked with metamizole substance to the concentration of 2.0 g/L. Pools were prepared for 23 different biochemical parameters and measured on Siemens Healthcare Dimension Vista analyzer. A bias between control and test average result was set as interference criterion for each assay with the help of Westgard total error (TE) specifications and the help of TE based on laboratory data.

Results: In both pools, 9 of selected analytes exceeded the set interference criterion of Westgard TE specifications: creatinine (enzymatic assay), uric acid, cholesterol, HDL, LDL, triglycerides, Ca, albumin and total protein/poole1, GGT/pool 2. 12 analytes in pool 1 and 14 analytes in pool 2 exceeded the limit when TE of laboratory data was used. The interference was always negative, results of the test pool were lower than from the control pool.

Conclusions: Metamizole, the active substance of Analgin, interferes with many biochemical analytes in serum samples when measured on Dimension Vista analyzer. Application of one Analgin ampulla (2.5 g metamizole) strongly lowers enzymatic creatinine and uric acid values and significantly affects lipid measurements as well as some other analytes. Attention must be kept to collect blood before application of the drug.

Key words: Metamizole; biochemical analytes; interference testing.

P042

OPTIMISING THE PREANALYTICAL PHASE WITH A TARGETED APPROACH USING BD LABORATORY CONSULTING SERVICES

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Background: The majority of errors that can lead to incorrect laboratory results are generated in the preanalytical phase, before the sample reaches the laboratory. However, the preanalytical phase is complex and difficult to control. We used BD Laboratory Consulting Services (BD LCS) to improve preanalytical processes and the quality of blood samples.

Materials and methods: In 2009, we analyzed the blood collection and sample processing practices using a BD Preanalytical Review. Fifty-two blood collections were observed, additionally, 351 samples were visually inspected. After the review, an improvement plan was developed including: dedicated phlebotomists on selected wards, tailored training for all persons involved in the preanalytical phase and the introduction of lower draw volume tubes. In 2013, the review process was repeated, 29 blood collections were observed and 254 samples visually inspected.

Results: There was a significant improvement in practices and sample quality over the period. During the audits disinfection errors were eliminated. Compliance to hospital procedures for tube labelling after blood collection increased from 81% to 97%. The introduction of lower draw serum tubes together with training resulted in a reduction in underfilled tubes from 39% to 8%. Adherence to sample mixing increased from 18% to 62% of the tubes, and a subsequent decrease in fibrin formation in serum specimens from 19% to 1%.

Conclusions: By using BD LCS, it is possible to improve practices and sample quality and consequently, patient care.

Key words: BD Laboratory Consulting Services, Improvement, Fibrin

P043

OPTIMISING SAMPLE QUALITY IN AN EMERGENCY UNIT USING BD LABORATORY CONSULTING SERVICES

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Background: Erroneous laboratory results can lead to hospital workflow inefficiencies, delayed diagnosis and even inappropriate therapy. Studies have shown that the preanalytical phase with its inherent complexity and variation is the prime cause of errors in the laboratory. The studies have also shown that these errors occur more frequently in emergency departments, where factors such as patient condition & pathology, the need for quick diagnosis and administration of potentially lifesaving interventions combine to create a demanding working environment and consequently greater opportunity for error. We used BD Laboratory Consulting Services (BD LCS) to identify optimization potential in the preanalytical phase.

Materials and methods: We analyzed the blood collection practices in the emergency unit using BD Preanalytical Quality Check and identified potential areas for improvement in equipment used and blood collection practice. These changes included the introduction of partial draw serum tubes and lower draw volume coagulation tubes and the use of a pre-attached Luer-Lok holder for catheter draws. The hemolysis rates over a period of 1 month before and after the intervention were recorded and analyzed.

Results: Before intervention, 41.9% of all the hospitals hemolytic serum samples were from the emergency unit, decreasing to 27.4% after intervention. The introduction of partial draw serum gel tubes (5 mL draw, 13x100 mm moving to 6 mL, 16x100), resulted in a decrease of the hemolysis rate from 8.5% (n=3793), to 4.0% (n=3711) for emergency samples. For the coagulation tubes (2.7 mL draw to 1.8 mL) a decrease from 10.5% hemolysis (n=1810) to 5.0% (n=1766) was observed. Further potential improvements were identified for sample identification to ensure compliance with hospital requirement to label all tubes prior to collection, appropriate use of a tourniquet and mixing of the tubes.

Conclusions: By using BD LCS, it is possible to improve sample quality and consequently, patient care.

Key words: BD Laboratory Consulting Services, Improvement, Hemolysis, Partial draw

P044

IDENTIFICATION ERRORS IN LABORATORY DIAGNOSTICS IN A NORWEGIAN UNIVERSITY HOSPITAL

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Background: Accurate and secure identification of patients is central within patient safety.
Identification errors involve misidentification of a patient or a specimen. Identification errors can occur during any part of the test cycle. Still most errors are presumed to occur in the preanalytical phase.

Materials and methods: We have evaluated the frequency and types of preanalytical mistakes found at Haukeland University Hospital, a 900-bed university hospital. Misidentification events reported in an electronic error reporting system (Synergi) from January 2011 to October 2014 were systematically reviewed.

Results: A total of 386 patient-related misidentifications had been reported during the study period. 197 reports were related to preanalytical work in laboratory diagnostic, the majority of them were related to blood sampling (n=113).
Misidentifications or mislabeling of samples occurred in 197 events, categorized as Misidentifications (n=12), Wrong patient ID (n=43), Missing wrist band identification (n=15), Missing or wrong control of identification (n=21), Mislabeled specimen (n=47), Sample from wrong patient (n=13), and/or Misidentification with laboratory allocation/distribution (n=46).
156 of the errors (78%) were discovered by the laboratory staff. Most deviations/errors (115 of 197) were caused by health professionals in clinical departments (58%). 65 (33%) of the errors had direct (or more indirect) consequences for patients. Misidentification or mislabeling were related to clinical chemistry samples (n=113), transfusion medicine (n=20), blood gas (n=17), microbiology (n=13), histology (n=10), urine (n=6), or CSF (n =3).

Conclusions: Hospitals are complex organizations, reflected by this significant number of errors related to missing patient identification or blood sampling. The majority of events did not result in direct harm to the patient or have more unknown severity. Once misidentification is detected, rejection and recollection is the most suitable approach to manage the specimen.
Preliminary results shows that the errors reported are complex and that the reporting system is challenging. More details will be discussed.

Key words: patient safety, blood sampling, misidentification, mislabeling, error reporting system

P045

PREVALENCE AND TYPE OF PRE-ANALYTICAL PROBLEMS FOR PATIENTS SAMPLES IN COAGULATION TESTS

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Background: Total quality in coagulation testing is a necessary requisite to achieve clinically reliable results. Evidence was provided that poor standardization in the extra-analytical phases of the testing process has the greatest influence on test results, though little information is available so far on prevalence and type of pre-analytical variability in coagulation testing.

Materials and methods: The present study was designed to describe pre-analytical problems on patients routine and stat samples recorded at Tepecik Training and Research Hospital in coagulation laboratory over a 1-year period.

Results: During the 1 year period, a total of 36.588 blood collection tubes were considered. Overall, pre-analytic problems were identified in 2.14% of the specimens. Although the highest frequency was observed for internal medicine departments, in no case was the comparison of the prevalence among the different hospital departments statistically significant. The more frequent problems could be referred to samples clotting (52.7%), inappropriate volume (33.6%) and improperly labelled samples (13.7%). The present investigation demonstrates a high prevalence of pre-analytical problems affecting samples for coagulation testing.

Conclusions: Coagulation tubes used in first order of blood draw and more vulnerable to in appropriate mixing and fulfilling of tubes causing to clotted and insufficient volume of specimen errors. Full implementation of a total quality system, encompassing a systematic error tracking system, is a valuable tool to achieve meaningful information on the local pre-analytic processes most susceptible to errors, enabling considerations on specific responsibilities and providing the ideal basis for an efficient feedback within the hospital departments.

Key words: Coagulation, prevalence, preanalytical errors

P046

IDEA OF A COMPETENCE CENTER FOR PREANALYTICS, AND A LABORATORY FOR BIOMEDICAL LABORATORY SCIENCE IN VAASA TEACHING HEALTH CENTER

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In Finland there are 3555 different clinical laboratory tests, and most of the samples for these tests are taken by biomedical laboratory scientists. Biomedical laboratory scientists have a long (20 credits) education in preanalytics, and this prevents errors in the preanalytical phase. From a patient's point of view, quality in the preanalytical phase and the clinical laboratory process is about getting sufficient information about the laboratory test and how to prepare for the phlebotomy, uncomplicated booking for phlebotomy, convenient waiting rooms for adults and children, a professional and kind encounter with the biomedical laboratory scientist, consideration of individual needs or desires, correct and appropriate communication, proper and safe phlebotomy, getting sufficient information about the results of the tests, and proper treatment of disease. Usually the patient does not see much of the analytic phase, because the clinical laboratory is not open to visitors. However, visiting the laboratory and making acquaintance with the laboratory work could benefit the patient in many ways. Especially children could find it interesting to visit the laboratory, and this could motivate them to be brave in the phlebotomy.

The city of Vaasa is planning a new teaching health center with a competence center for preanalytics, and a teaching laboratory for biomedical laboratory science in the same facilities. The idea is to gather and provide preanalytical competence for all medical and health care workers, and to have a teaching laboratory for biomedical laboratory students in the immediate vicinity to the sample collection department. The open access laboratory could serve curious patients giving insights into a laboratory world that is usually hidden.

Key words: competence center for preanalytics, preanalytics and the patient, biomedical laboratory science, open access clinical teaching laboratory

P047

PRE-ANALYTICAL PHASE – PORTUGUESE EQAS (PNAEQ) SINCE 2007 TO 2014

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Background: The main objective of implementing a program on pre-analytical phase is to evaluate the performance of clinical laboratories nationwide on these matters in order to improve their performance.

Materials and methods: Between 2007 and 2014 laboratories enrolled in the Evaluation in Pre-Analytic Phase program had to respond to 2 surveys/year until 2013 and 1 survey in 2014. Questionnaires, samples, case studies, medical request simulation and sample handling simulation were distributed to the participants.

The results were statistically analyzed and frequency charts were performed.

In each survey was prepared a report with the overall results with PNAEQ's comments.

Results: In 8 years of this program 116 laboratories were enrolled with 40% average of participation. 53% enrolled only once and 16% maintained their registration in four or more years. The highest percentage of answers received was in surveys that included shipment of samples with simulated clinical history (61% to 72%) or case studies (44% to 49%). In surveys that include error monitoring (with a participation of 27% to 50%), the percentage of reported errors is consistent with those described in the literature.

For questions about patient registration and error detection participants submitted their comments on the most appropriate form. For questions about control records and reagent preparation and biosafety situations, we have not had significant response.

Conclusion: The first year of the programme implementation had a good reception but the number of inscriptions decreased 1/7 since 2007 to 2013, with a slight rising in 2014. We are working on laboratories' sensibilization trying to highlight the importance of recording errors in pre-analytical phase and with an important role in formative part. This should warn and encourage the participants to monitoring errors that may occur at the beginning of the analytical process, because not reporting errors does not mean their absence.

Key words: pre-analytical, PNAEQ, monitoring errors

P048

INFLUENCE OF CENTRIFUGATION TEMPERATURE AND STORAGE OF SAMPLES IN DIFFERENT CONDITIONS ON THE VALUES OF PROTHROMBIN TIME (PT) AND INTERNATIONAL NORMALIZED RATIO (INR)

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Background: Determination of prothrombin time (PT) is an analysis that is often used in the diagnosis and control of hemostatic disorders. Recent studies have shown that different temperature and storage conditions of samples affect the change in value of prothrombin time. The aim of this study was to determine the effect of centrifugation temperature and storage of plasma samples on the values of prothrombin time.

Materials and methods: The study was conducted in 50 healthy subjects. Total number of subjects was 29 women and 21 men, aged 20-64 years. From all patients samples were taken in duplicate for determination of prothrombin time. Samples were centrifuged in a centrifuge with and without the thermometer, and the PV value and the INR are determined within 2 hours, and then determined after storage of samples in room and at temperature of +4 degrees after 24h.

Results: The results of this study showed no statistically significant differences in the values of PT of the tested samples compared to centrifugation in a centrifuge with and without thermometer (p value> 0.05). The values of PT samples storaged at room temperature after 24 hours (14.39 ± 1.06 and 14.41 ± 0.95) were significantly elevated compared to the value of PT analyzed within 2h (13.83 ± 0.94 and $13\,92 \pm 0.95$). In the samples stored 24 hours at a temperature of +4 degrees, the PT values were significantly lower (13.57 ± 0.79 and 13.44 ± 0.80) compared to the values within 2h.

Conclusion: Although the plasma samples for determination of PT can be used up to 24h, regardless of whether stored at room temperature or in the refrigerator, we believe that it is desirable to determine the value of PT within two hours of sampling.

Key words: prothrombin time, INR, storage conditions, plasma

P049

CONTINUOUS QUALITY CONTROL OF THE BLOOD SAMPLING PROCEDURE USING A STRUCTURED OBSERVATION SCHEME

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Background: An important preanalytical factor is the blood sampling procedure and its adherence to the guidelines, i.e. CLSI and ISO 15189, in order to ensure a consistent quality of the blood collection. Therefore, it is critically important to introduce quality control on this part of the process. As suggested by the *EFLM working group on the preanalytical phase* we introduced continuous quality control of the blood sampling procedure using a structured observation scheme to monitor the quality of blood sampling performed on an everyday basis.

Materials and methods: Based on our own routines the EFLM auditing questionnaire was altered giving an observation scheme containing 19 observation issues. Using this scheme three blood samplings from two phlebotomists was observed twice a week (at the blood sampling unit and at a hospital ward, respectively), giving a total of 12 blood drawings observed per week. All observations were performed by the same person (TLS).
Results: Already after three months critical issues can be pinpointed, where correction or educational steps are necessary, for example hand hygiene. However, at the meeting we will be able to present results from a six-month observation period.
Conclusion: It is possible to establish a continuous quality control on blood sampling. It has been well accepted by the staff and we have already been able to identify critical areas in the sampling process. We find that continuous auditing increase focus on the quality of blood collection which ensures consistency and high quality and also increases alertness from those performing the blood sampling. The latter is important in order to contain the focus on high blood sampling quality and to enable introduction of new sampling procedures.

Key words: Blood sampling, quality control, observation scheme

P050

USING UTILIZATION MANAGEMENT APPROACH TO REDUCE INAPPROPRIATE USE OF HIGHLY DIFFERENTIATED COAGULATION TESTS

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Background: Efficient managing of laboratory test utilization is required as overutilization of diagnostic laboratories is constantly increasing. The implementation of hospital information system has improved the communication between laboratory and clinic, but at the same time has enabled uncontrolled placing of electronic laboratory orders even for highly differentiated coagulation tests. The aim of this study was to determine whether testing for fibrinogen (Fbg) and antithrombin (AT) antigen concentration is ordered appropriately.
Materials and methods: A two-step procedure was employed in the study. First we performed the analysis of all requests for the determination of Fbg and AT antigen in a 1-year period by searching through the laboratory information system. The appropriateness of each request was evaluated in the second step by analyzing if determination of functional activity was required prior to requesting the determination of specific antigen concentration.
Results: In the investigated period, a total of 48 requests for Fbg:Ag and 72 requests for AT:Ag were identified. Among them, 27/48 requests for Fbg:Ag and 10/72 requests for AT:Ag were inappropriate as functional activities were not performed in those patients. The determination of Fbg:Ag was not performed in 7/48 patients and of AT:Ag in 35/72 patients because functional activities were within the reference intervals. We provided this comment with each report so that physicians may understand why the requested test was not performed. Finally, due to decreased functional activities, Fbg:Ag and AT:Ag were determined in 14/48 and 27/72 patients, respectively, and were clinically indicated.
Conclusions: According to obtained results, the majority of requests were inappropriate, especially for Fbg:Ag as physicians were actually requesting the determination of fibrinogen functional activity. Probably this was the consequence of the availability of requesting functional activity and antigen concentration for Fbg and AT in the same computerized laboratory order with no restriction.

Key words: utilization management approach, laboratory test utilization, coagulation tests

P051

PREANALYTICAL QUALITY INDICATORS CALCULATION

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Background: Every clinical laboratory accredited for medical laboratories is obligated to systematically monitor and evaluate its quality indicators (QI). The number of indicators depends on largeness of laboratory, but the most important questions are: what to measure, how to collect data and how to express results. The aim of this study was to introduce and evaluate several preanalytical QI in our medical lab (middle type), to quantify the frequency of errors and to undertake corrective or preventive actions.
Materials and methods: During the study period of 9 months data were collected by documenting the frequency of the following QI for preanalytical errors:

– Percentage of "Number of requests without physician identification/Total number of requests" (QI-1)
– Percentage of "Number of requests with errors concerning patient identification/Total number of requests" (QI-2)
– Percentage of "Number of requests without suspecting diagnosis/Total number of requests" (QI-3)
– Percentage of "Number of samples hemolyzed (hematology)/Total number of samples" (QI-4)
– Percentage of "Number of samples hemolyzed (chemistry)/Total number of samples" (QI-5)

Results: Calculating the frequency of errors depending on the quality indicator the following results were obtained: 0.4% (QI- 1), 0.6% (QI- 2), 1.7% (QI- 3), 0.8% (QI- 4) and 1.8% (QI- 5).

Conclusions: Although the number of QIs in this study is limited to only 5, we can conclude that preanalytical errors prevention requires good communication and cooperation among the whole health care team. In order to minimized the preanalytical errors our laboratory works to provide the necessary education, instructions, materials, and resources to assist in educating the teams.

Key words: quality indicators, preanalytical errors, hemolyzed samples.

P052

EFFECT OF HEMOLYSIS ON NON ROUTINE LIPID PARAMETERS

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Background: The main source of laboratory errors still are caused by pre-analytical factors. Analytical interference caused by hemolysis is the prevailing problem. The influence of hemolysis on routine clinical chemistry testing has been previously evaluated, but there are insufficient data for non-routine and research tests only.

The aim of this study was to examine the influence of certain degrees of hemolysis on results for lipoprotein a (Lp a), apolipoprotein A1 (Apo A1) and apolipoprotein B (Apo B).

Materials and methods: Pool serum and hemolysate were prepared from twenty healthy volunteers. Seven aliquots, prepared by serial dilutions of hemolyzed sample, with final hemoglobin concentration ranging from 0.06 to >4.51 g/L were done. In all seven samples of different degrees of hemolysis these biochemical parameters were done in triplicate. Lysis was achieved by osmotic shock. The significance of the differences between samples was assessed by paired t-test, and level of significance was set as $P < 0.05$.

Results: Our results showed that the concentration of Apo A1 and Lp(a) were significantly decreased when the concentration of free hemoglobin reached 3.01 g/L and > 4.51 g/L (1.69 g/L *vs.* 1.54 g/L and 1.27 g/L, $P = 0.004$ and $P = 0.002$ for Apo A1 and for Lp (a) 0.39 g/L *vs.* 0.35 g/L and 0.28 g/L, $P = 0.004$ and $P = 0.002$). Results for Apo B were significantly decreased only at free hemoglobin concentration of > 4.51 g/L (1.00 g/L *vs.* 0.75 g/L, $P = 0.02$).

Conclusion: Higher concentrations of free hemoglobin have influence on the result of examined tests by making the false lowering results. That can lead to an incorrect interpretation of the results. Therefore it would be desirable to seek re-sampling when there is a strong hemolysis in the sample.

Key words: pre-analytical errors, hemolysis, lipoproteins

P053

SIMPLE, EASY AND ACCURATE METHOD FOR THE COMPARASION OF BD, RADIOMETER AND HOME-MADE SYRINGES IN BLOOD GAS ANALYZERS

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Background: Most inaccuracies in the blood gas analyses are due to pre-analytic phases. To improve the pre-analytical phase quality, choosing the right equipment is an important criteria. During product performance evolution it is common to use patients' blood sample for quality

check however it is not easy to find pathologic blood samples regarding to both ethical and medical issues. Our objective was to compare different types of blood gas syringes by using instruments' original high, medium and low levels control material.

Materials and methods: We compared 3 different types of syringes; 1) Home-made (according to standards, insulin syringes manually coated with heparin which has diluted in serum physiologic) 2) Becton Dickinson BD A-line, 3) Radiometer Pico 50. We used Radiometer and Techno Medica Gastat analyzers and their original control material. We run Level 1-2-3-4 vials directly as a reel value and then we draw these control liquids to syringes. We re-capped syringes immediately and run randomly. We run pCO_2, pH, pO_2, ctHb, sO_2, FO_2Hb, FCOHb, FMetHb, FHbF, cK^+, cNa^+, iCa^{++}, Cl^-, Glucose, Lactate, Bilirubin in Radiometer analyzer and K^+, Na^+, Ca^{++}, Cl^-, pCO_2, pH, pO_2 in Gastat analyzer.

Results: There were no statistically differences between reel values and measured three types of syringes values for all parameters except oxygen and carbon dioxide results.

Conclusions: Our study showed that blood gas instruments' original control vials can be used for comparison of different types of syringes and analyzer performance during product performance evolution processes.

Key words: Blood gas, pre-analytic phase, blood gas syringes.

P054

PATIENT SAFETY AND ASSESSMENT OF PRE-ANALYTICAL PROCESS IN CLINICAL LABORATORIES: QUALITY INDICATORS

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Background: In clinical laboratories total testing process consists of 3 sub-processes. Pre-analytical process which is the duration between the clinical request of the clinician and the beginning of the analysis effects test reliability and therefore patient safety considerably (46%-68.2%). The variables that effect pre-analytical process must be kept under control. Variables are sources of errors. These errors are waste of time and money which are; improper labeling, hemolyzed samples, lipemic samples, clotted samples, inappropriate container, insufficient sample and damaged sample. Based on these errors quality indicators are determined. Process performance is evaluated by comparing calculated quality indicators with target values. In this study, our aim is to evaluate common errors in pre-analytical process and use them as quality indicators.

Materials and method: Pre-analytical process error data between July 2014-November 2014 were obtained from the laboratory information system. For every type of error monthly percentages have been calculated and evaluated according to the Quality Indicators (QIs) developed by the IFCC Working Group on "Laboratory Errors and Patient Safety" (WG-LEPS).

Results: Quality indicators calculated according to each error type in pre-analytical process have been detected above "optimum performance" level according to quality targets. "Clotted sample" was in the first, "hemolyzed sample" was in the second place among the highest error rates. The lowest error rate was " damaged sample".

Conclusion: Our results showed that quality indicators may be useful for evaluation of pre-analytical process. According to the quality indicators that could not achieve the target, the origin of the errors can be determined, corrective and preventive actions can be carried out. Also monthly trends can be evaluated and precautions can be taken for the prevention from the errors that mostly effect the patient safety (educations, development of instrument, etc.).

Keywords: Clinical laboratory, pre-analytical process, patient safety, quality indicator

P055

THE EFFECT OF PREANALYTICAL ERRORS ON THE IDENTIFICATION OF MYELODYSPLASTIC PHENOTYPES BY FLOW CYTOMETRY

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Background: Myelodysplastic syndrome (MDS) is a heterogeneous hematopoietic neoplasm. Although the diagnosis and prognosis of MDS are based on morphologic and cytogenetic examinations, several studies (e.g., Wells et al., Ogata et al.) suggest that flow cytometry (FCM) can also be a useful diagnostic tool by detecting phenotypic alterations compared to normal cells. Time-dependent immunophenotype changes—as a phenotypical variable—might influence results.

Material and methods: We examined five normal bone marrow samples collected in EDTA and investigated by eight-color staining. Forty-nine different immunophenotypic variables were recorded in each case for four days and mean florescence intensity (MFI) values were recalculated and results were compared to day-0 values.

Results: We detected continuously decreasing intensity of myeloid side scatter (SSC) and MFI of several markers (e.g., CD45, CD15, CD33, CD11b on granulocytes, CD64, CD14, CD300e, CD11b on monocytes, CD117 on myeloblasts). Yet there were also some markers where MFI's were increased (e.g., CD13 on granulocytes).The ratios of myeloblasts, lymphoblasts, preB cells were decreased. We identified an increased ratio of other rare events (e.g., mast cells, plasma cells) and decreased MFI of the relevant markers (CD117, CD33, CD38). The MFI of CD71 was slightly decreased, while the CV of CD71 was increased on erythrocytes. We calculated the scores of the patients according to different FCM scoring systems. None of the patients reached the diagnostic cut-off of the scoring systems on the first day, however, after 24 hours all patients were assigned to the high-risk MDS group according to the Wells scoring system but none of them could be considered as MDS cases based on the Ogata scoring system.

Conclusion: Due to delayed sample processing, considerable MDS-related immunophenotype alterations were detected not only on myeloid but also on erythroid cells and rare populations, which can cause false interpretation of the results. Therefore well-defined, standardized sample handling and appropriate interpretation of FCM results are essential.

Key words: preanalytical errors, myelodysplastic syndrome, flow cytometry

P056

VISUAL AND AUTOMATED DETECTION OF MILD HEMOLYSIS IN SERUM SAMPLES

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Background: Hemolysis is a critical problem which leads to medical errors in routine biochemical tests. Our aim was to check whether our ALT and AST results change after a minimal visual hemolysis with no automatic warning alarm for hemolysis.

Methods: This study was performed on serum samples. Automated detection was performed using the Cobas 6000 analyzer. Samples with severe hemolysis were not included. We assessed comparability of visual and automated detection of hemolyzed samples, Students' t-test was used to compare the groups. We had two groups after visual inspection: control group without any reddish coloration and hemolysed group with mild reddish coloration but without any warning of hemolysis on our automatized system.

Results: The hemolytic indices between normal and hemolysis group were 7.94±5.08 and 99.77±41.32 (p=0.00). AST values of normal and hemolysis group were 20.73±11.29 and 44.41±26.8 (p=0.015). ALT value of normal and hemolysis group were 20.75±11.29 and 45.23±63.35 and (p=0.023). There was significant difference in ALT and AST levels between the groups.

Conclusions: We designed the study to check the possible changes in AST and ALT levels after mild hemolysis that could be inspected visually but not exceeding the warning level of automatic detection. Due to our results, we concluded that visual inspection of samples may be reliable in mildly hemolysed samples, so the warning level of hemolysis detection for those analyses may be re-evaluated to be decreased for automatic detection systems. But this is our preliminary study, we will do further analyses with a larger study group.

Key words: Hemolysis, hemolytic index, AST, ALT

P057

THE RELEVANCE OF SAMPLING TIME IN PROLACTIN DETERMINATION

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Background: The prolactin concentration displays diurnal-nocturnal biorhythm i.e. it shows a decrease during the course of the day and increase during sleep with maximal value in the early morning hours. The aim of this study was to determine percentage of decrease in prolactin values and the time of reaching waking-baseline levels.

Materials and methods: The study enrolled 31 healthy subjects (25 women and 6 men). Samples were drawn at 7:00, 8:00, 9:00 and 11:00 hours after 15 minutes of resting period. Prolactin had been determined by electrochemiluminiscence method performed on Cobas e601 (Roche Diagnostics). Expected values (2.5-97.5th percentiles) with this method for non-pregnant women and men are 102-496 mIU/L and 86-324 mIU/L respectively.

Results: In 11 of 31 subjects (35.5%) we found prolactin levels above upper normal limit at 7:00. All of those subjects were found to have normal prolactin levels at later sampling times. Mean values at 7:00, 8:00, 9:00 and 11:00 for women were 485 (171-1346), 300 (115-627), 194 (85-379) and 188 (89-369) respectively. Mean values at 7:00, 8:00 and 9:00 for men were 338 (172-1009), 127 (85-187) and 101 (65-130) respectively. Percentage of decrease in individually prolactin values 7/8h and 7/9h for women were 43.1% and 56.2% respectively. Percentage of decrease in individually prolactin values 7/8h and 7/9h for men were 54.1% and 53.9% respectively. Difference between mean value at 9:00 (194) and 11:00 (188) was not significant.

Conclusions: Regarding the significant decrease in prolactin levels in samples drawn at 8:00, 9:00 and 11:00 and the fact that waking-baseline levels are mostly only reached 1-2 h after waking, the blood collection should be carried out 3-4 h after waking, i.e. between 8:00 and 10:00 a.m.

Key words: prolactin, sampling time, waking-baseline level

P058

CHEMICAL MODIFICATION OF PLASTIC BLOOD COLLECTION TUBES (BCTS) TO ACHIEVE HYDROPHILIC INTERIOR SURFACES TO MINIMIZE INTERFERENCE IN CLINICAL ASSAYS

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Background: Recent studies have demonstrated that BCT surfactant interferences on certain clinical assays have not been fully resolved. The objective of this study was to evaluate poly(ethylene terephthalate; PET) BCTs that have been chemically-modified to be hydrophilic (Chemo-PET) on cortisol; total triiodothyronine (TT_3) and thyroxine (TT_4); and other chemistry tests.

Materials and methods: To develop ChemoPET tubes, ethylene glycol (EG) and 1,5,7-triazabicyclo[4.4.0]dec-5-ene (TBD) were mixed at specified concentrations, poured, and incubated in BCTs at room temperature. After incubation, the BCTs were rinsed with water and air-dried. These tubes were assessed for tube wall hydrophilicity and their performance compared to other commercially available BCTs with quality control (QC) and serum specimens for hormone and chemistry analytes. A Student t-test and ANOVA were used to analyze QC and serum specimens test results among the different BCTs. All P values were adjusted for multiple comparisons using a Bonferroni correction.

Results: The non-aqueous reactions with EG and TBD produced a dramatic change in BCT surface wettability. The contact angles were ~70° for unmodified PET tubes and ~30° for ChemoPET tubes. For QC materials, ChemoPET showed significantly lower relative biases (+1.9% and +5.1% for cortisol; –3.3% and –2.2% for TT_3; –5.0% and –2.5% for TT_4, respectively) than other BCTs (e.g., for SST, +19.4% for cortisol; +15.0% for TT_3; +21.4% for TT_4, respectively; p < 0.0001). For serum samples, the ChemoPET tubes showed lower relative biases (–3.8% and –1.2% for cortisol; +5.7% and +7.9% for TT_3; +0.2% and –2.7% for TT_4, respectively) than other BCTs (e.g., for SST, +5.9% for cortisol; +17.0% for TT_3; +12.9% for TT_4, respectively; p < 0.0001). No clinically significant differences were observed among different BCTs for the chemistry analytes.

Conclusions: It is hoped that ChemoPET tubes can be used instead of current BCTs with problematic surfactant to eliminate interferences on clinical assays.

Keywords: surfactant, tube, interference, immunoassay, triiodothyronine

P059

INTERFERENCE IN MEASUREMENT OF HEMOGLOBIN CONCENTRATION – DON'T OVERLOOK LIPEMIA

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Background: Parenteral lipid emulsion administered to inpatients can affect the accuracy of hemoglobin concentration measurement on hematology analyzers. The interference of lipemia occurs due to increased turbidity of the sample. The aim of this study was to assess the interference of lipemia on hemoglobin concentration in EDTA blood samples after addition of exogenous lipid emulsion.

Materials and methods: The analysis was performed in 10 routine blood samples with hemoglobin concentrations ranging from 76 to 168 g/L. Each sample was split into six aliquots. In the first aliquot Coulter® DxH diluent was added (dilution 1:10) while in the other five aliquots increasing amounts of lipid emulsion (SMOFLIPID® 20%, Fresenius Kabi, Australia) were added (dilution 1:10). Final triglyceride concentrations (TG) were 3, 5, 10, 20 and 40 mmol/L. All samples were analyzed in triplicate on two hematology analyzers Beckman Coulter UniCel® DxH800 (Fullerton, CA, USA).

Results: Statistically significant differences in hemoglobin concentrations were observed starting from a TG concentration of 3 mmol/L (P = 0.002) on both analyzers. The average differences of hemoglobin concentrations ranged from 5 to 65 g/L. For TG=3 mmol/L differences were 3-7 g/L; for TG=5 mmol/L differences were 5-10 g/L; for TG=10 mmol/L differences were 13-18 g/L; for TG=20 mmol/L differences were 27-35 g/L and for TG=40 mmol/L differences were 64-68 g/L. The highest bias was observed in samples with lower initial hemoglobin concentrations: the bias was 83,4% at hemoglobin concentration of 76 g/L, whereas at hemoglobin concentration of 168 g/L the bias was 38,4%.

Conclusions: The goal of laboratories is to assure accurate results that can be safely used for patient management. In order to minimize laboratory errors caused by lipemia, an established procedure of recognizing lipemia and reporting correct results is crucial.

Key words: lipemia, interference, hematology, hemoglobin measurement

P060

ERRORS IN THE PREANALYTICAL PHASE OF EXAMINATIONS IN THE LABORATORY BISTRICA IN THE PUBLIC HEALTH SERVICE "NOVI SAD"

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Background: Errors made in the preanalytical phase account for up to 70% of the problems which occur in the laboratory diagnostics. The aim of this paper is to establish the most frequent causes of the preanalytical errors in the laboratory, with the purpose of improving the quality of laboratory services.

Materials and methods: This retrospective study was conducted in the Bistrica laboratory, during the period from the 1st April to 31st October 2014. We registered the total number of the blood samples on daily basis, which included: biochemical, hematological and hemostatic research and the total number of samples of urine and fecal matter. We also registered the unacceptable samples, which occurred as the consequence of the preanalytical error. They were classified as: hemolysed samples, clotted samples, samples with inadequate anticoagulant ratio, unmarked samples, samples which were not received insufficient samples quantity and repeated samples.

Results: During the period of the data collection the total number of 80,696 samples was received in the laboratory. In the preanalytical phase the total number of errors was 415, which accounts for 0.51% of the total number of the received samples. Of the total number of preanalytical errors, 31.8% were hemolysed samples, 27.9% samples showed an inadequate anticoagulant ratio, 20% were clotted samples, 12.7% were repeated samples showing to the laboratory error, 5.3% were unmarked samples, 1.2% samples had insufficient sample quantity.

Conclusions: Taking all the samples received in the laboratory into account, the percentage with the mistake in the preanalytical phase was 0.5%. In order to improve the quality of laboratory services, it is necessary to comply with the standard laboratory procedures.

Key words: preanalytical phase, error, laboratory.

P061

SPECIAL ASPECTS OF THE PREANALYTICAL PHASE IN HIGH THROUGHPUT CLINICAL LABORATORIES

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Background: Regional laboratories with huge analytical capacity and with multiple sampling sites located in considerable geographical distance face new challenges in the preanalytical (PA) phase. Thus, the Hungarian Society of Laboratory Medicine (HSLM) has initiated pilot studies in two laboratories.

Materials and methods: The Department of Laboratory Medicine at the University of Debrecen represented university laboratories, while the laboratory of the County Hospital in Nyíregyháza represented large regional laboratories. The effect of a long-distance pneumatic tube system (PTS) transport on laboratory results was evaluated at the university laboratory. Quality indicators of the PA phase were established and monitored at both participating sites.

Results: Transporting samples by the longest laboratory PTS of Hungary covering all clinical wards was investigated and only clinically non-significant elevations of lactate dehydrogenase activity and mild platelet activation were found.

At the university site the PTS transport resulted in shorter turnaround times compared to conventional couriers. Transporting times to the county laboratory from regional phlebotomy sites of general practitioners ranged between 2-6 hours which indicate the necessity of the reorganization of sample transport. Samples were rejected in PA phase most frequently due to hemolysis and lipemia in both participating laboratories (0,50%-1,77% of sera). In anticoagulated samples clot formation was the dominant cause of rejection (0,46% and 0,27% of citrated samples, 0,25% and 0,11% of EDTA samples in university and county laboratories).

Conclusions: These results revealed that PA phase has special aspects in high analytical throughput laboratories, which suggests the need for special education. Monitoring quality indicators in PA phase is an important contributor to the improvement of the total testing process, and should be introduced nationwide. Coordination of trainings and development of quality indicator database regarding PA phase at the national level is in the focus of the future strategy of HSLM.

Key words: preanalytical phase, pneumatic tube system, quality indicators

P062

STABILITY OF 43 COMMON BIOMARKERS IN WHOLE BLOOD STORED UP TO 96 HOURS AT ROOM TEMPERATURE

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Background: As laboratory for general practitioners Star-MDC is faced with long transport times before samples arrive for (clinical chemical) analysis. Since results for preanalytical stability in literature are often conflicting or do not match our situation, we set out to investigate the limits of transportation time.

Materials and methods: 6 serum tubes (BD vacutainer SST II Advance) were drawn from 7 volunteers each. The samples were centrifuged and analyzed immediately (0-sample) or after 8, 24, 48, 72 and 96 hours. Samples were kept at room temperature, 43 biomarkers were measured in all samples. Results were compared with the 0-sample. A deviation smaller than the desirable bias based on biological CV or actual analytical imprecision was accepted.

Results: For 6 biomarkers a transport time up to 8 hours was acceptable. 18 biomarkers were stable up to 96 hours and can therefore be sent to the laboratory by mail. Most notably potassium was stable up to 24 hours and bilirubin even for 96 hours. In the case of potassium individual variance in stability was noted. Total- and LDL cholesterol levels increased significantly after 24 hours, HDL and triglyceride levels also increased but stayed within the desirable bias.

Conclusions: transport times up to 24 hours are acceptable for most biomarkers including potassium. Due to the limited number of samples results should be confirmed in a larger study before implementation.

Key words: stability, whole blood, room temperature

P063

PRESENCE OF FIBRINOGEN INTERFERENCE ON A CAPILLARY ELECTROPHORESIS

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The objective of this work is to check on the presence of fibrinogen in a patient with IgG gamma component of monoclonal gammopathy and a beta wide band of new appearance. To demonstrate that we used two aliquots of the patient serum, treating one of them with ethanol and the other with thrombin/CaCl2. After the treatment a capillary electrophoresis was done confirming the disappearance of splitting in beta2, corresponded to the fibrinogen interference, maintaining the monoclonal component peak in gamma.

P064

DIFFERENCES BETWEEN CAPILLARY AND VENOUS BLOOD VALUES OF ALPHA-FETOPROTEIN IN HEALTHY ADULTS

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Background: Alpha-fetoprotein (α1-fetoprotein, AFP) was initially found in the human fetus, fetal yolk sac, liver and intestine. Except benign conditions (pregnancy, infancy, hepatic diseases, hereditary disorders) elevated AFP level is considered as abnormal in adults. It's used for screening or monitoring hepatocellular carcinoma, yolk sac tumor, some other tumors and most commonly used tumor marker in pediatric oncology.
A review of available literature showed that there have been no similar research results that could involve differences of capillary and venous samples for AFP.
Materials and methods: From all 43 healthy subjects (27 female and 16 male); median of age 40 with range 23–66 years; were taken venous (6 ml Vacuette; red cap; 21G needle) and capillary (ring finger; 1ml Microtainers; red cap; MiniCollect Safety lancet, depth 2,0mm) blood samples according to standards of good laboratory practice. Materials were from Greiner (Greiner Bio-One, Austria) and measurements were performed within 4 hour of blood sample collection. AFP was determinated on immunoassay analyzer Cobas e411 (Roche Diagnostics, Germany) with electrochemiluminance method, original reagent, calibrators and controls.
Serum AFP level >5.8 IU/mL was defined as AFP-positive according to the manufacturer's instructions with lower detection limit 0.50 IU/mL.Statistical analyses of descriptive analysis, correlation and Wilcoxon test for paired samples were performed using statistical software MedCalc version 10.4.
Results: Data were not normally distributed and non-parametric Wilcoxon test presented no significant difference between capillary and venous samples (P=1.00). AFP median for capillary blood was 2.72 (95% CI=2.30-3.42) and for venous 2.69 (95% CI=2.23-3.57), with high correlation coefficient r=0.995 (P<0.0001).
Conclusion: There are no relevant differences between AFP in healthy adult donors obtained from venous or finger-prick blood samples. Therefore capillary sampling for AFP can be used for sampling of elderly patients, oncology patients, those with severe burns, extreme obesity, or susceptibility to thrombosis, etc.

Key words: alpha-fetoprotein, capillary, venous, blood specimen collection

P065

IMPACT OF UNDER-FILLED BLOOD COLLECTION TUBES CONTAINING K_2EDTA AND K_3EDTA AS ANTICOAGULANTS ON AUTOMATED HBA$_{1c}$C TESTING

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Background: According to Clinical Laboratory Standard Institute (CLSI) guidelines and manufacturer's regulation (Becton Dickinson), under-filled blood collection tubes may cause errors in laboratory testing resulting in potential misinterpretation of patient results.
The aim of our study was to assess impact of under-filled blood collection tubes to HbA$_{1c}$ monitoring in patients with diabetes mellitus in two different anticoagulant tubes.
Materials and methods: Blood samples from 29 patients were drowned into K_2EDTA anticoagulant blood collection tubes with different volumes (4mL, as declared by the manufacturer, 2mL and 1mL) and tested for HbA$_{1c}$ levels. Specimens from another 26 patients sampled in K_3EDTA anticoagulant tubes, underwent the same procedure. All samples were analyzed with an automated immunoturbidimetric procedure (TinaQuant-Integra 400Plus, Roche Diagnostics, USA). Statistical analysis was done using Deming regression in MedCalc 9.4.2.0 statistical software (MedCalc Software bvba, Mariakerke, Belgium).
Results: There was no significant difference in group with K_2EDTA anticoagulant between recommended volume of 4 mL blood and under-filled volume of 2 mL and 1 mL [regression equation (4mL and 2mL): y=0.5329+0.9282x, intercept A=0.5329, 95%CI=-0.08632 to 1.1520, slope B=0.9282, 95%CI=0.8382 to 1.0182; regression equation (4mL and 1mL): y=0.3180+0.9584x, intercept A=0.3180, 95%CI=-0.05893 to 0.6950, slope B=0.9584, 95%CI=0.9041 to 1.0127]. Results obtained from K_3EDTA tubes were showing the same trend [regression equation

(4mL and 2mL): y=0.02842+0.9900x, intercept A=0.02842, 95%CI=-0.3107 to 0.3675, slope B=0.9900, 95%CI=0.9449 to 1.0352; regression equation (4mL and 1mL): y=0.1177+0.9802x, intercept A=0.1177, 95%CI=-0.1253 to 0.3607, slope B=0.9802, 95%CI=0.9479 to 1.0126]. Although we found a slight deviation in bias for some results ($\pm$ 0.3% NGSP/DCCT units), all of them were within established limits of clinical decision ($\pm$ 0.5%).

Conclusions: Despite general recommendations, under-filled K_2EDTA or K_3EDTA blood collection tubes have no impact on HbA_{1c} level analysis.

Key words: under-filled blood collection tubes, K_2EDTA, K_3EDTA, HbA_{1c}

P066

INCORRECT MEASUREMENT OF ERYTHROCYTE SEDIMENTATION RATE DUE TO MALNUTRITION

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Background: Patient's nutritional condition is one of the main determinants of accuracy of the result among preanalytical variables. In this study, we discussed the effect of protein-energy malnutrition and its complications on erythrocyte sedimentation rate. Our case report is about a patient with a known chronic inflammatory disease having undetectable erythrocyte sedimentation rate (ESR).
Materials and methods: A 59-year-old female patient with a known diagnosis of Crohn's Disease (CD) was admitted to emergency ward with abdominal pain and constipation. She was not using any drugs. ESR, C-reactive protein (CRP), complete blood count, routine clinical chemistry parameters were ordered by the clinician. ESR was undetectable. Another sample from the patient was requested to repeat the test. ESR could not be detected. ESR was measured with Test-1THL automated ESR analyzer (ALIFAX®S.p.A., Polverara, Italy).
Results: Abnormal result of ESR analysis led us to scan through all other laboratory results and patient's medical record. Although ESR was undetectable, CRP was increased (3.15 mg/dL). Her albumin and prealbumin levels were low (2.08 g/dL and 4,02 mg/dL, respectively) and she was anemic (Hb: 7 g/dL). She had hypoglycemia (59 mg/dL), hypocalcemia (7.41 mg/dL). Her total protein was also low (3,63 g/dL). She had ketone positive urine. Her D-Dimer level was high (1.322 mg/L), implicating an increase in fibrinogen degradation products. According to serum protein electrophoresis, she had hypoproteinemia and decreased albumin/globulin ratio (0.99). She had very low BMI (15.23 kg/m^2) and history of intestinal obstruction as CD attack. She had been deliberately refusing to eat for several months to protect herself from CD attacks. During her follow-up in one year, her condition was treated and her ESR was measured as 36 mm/hr.
Conclusions: CD is a chronic inflammatory systemic disease and ESR is expected to increase during a CD attack. However, low fibrinogen level due to malnutrition may be the reason why ESR was undetectable. Considering nutritional status of patients should be a solution to solve cases with abnormal ESR results.

Key words: Erythrocyte sedimentation rate, malnutrition, preanalytical phase, case study

P067

EFFECT OF STORAGE AND TRANSPORT CONDITIONS ON ROUTINE BLOOD CELL COUNT IN DISLOCATED LABORATORIES

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Background: We aimed to evaluate the effect of storage and transport conditions on routine blood cell count in long distance laboratories.
Materials and methods: 100 blood samples were collected from patients during a month period. All samples were drawn according to the recommendations of national guidelines for phlebotomy by Working Group for the Preanalytical Phase under the auspice of The Croatian Society for Medical Biochemistry and Laboratory Medicine. For routine blood cell count the blood was collected into 3.0 mL K_3 EDTA vacuum tubes (BD Vacutainer® DPlymouth,UK) (Ref.No.368857) and were performed using Coulter HmX – 5 diff Hematology Analyzer (Beckman Coulter LH 780; Miami, FL, USA). The samples were analyzed first in the laboratory LabPlus Zagreb then they are stored on 4-8°C and transported to dislocated laboratory LabPlus Split (411 km far away from Zagreb).

Results: The comparison of results demonstrate good correlation and no statistically significant differences were observed for all cells count: WBC r=0,999 P=0,81; Neutro % r= 0,987 P=0,87; Eo % r=0,983 P=0,80; Ba % r=0,937 P=0,29; Ly % r=0,996 P=0,94; Mo % r=0,970 P=0,12; RBC r=0,984 P=0,28; Hb r=0,990 P=0,89; Hct r=0,979 P=0,20; MCV r=0,975 P=0,85; MCH r=0,981 P=0,17; MCHC r=0,989 P<0,0001; RDW r=0,969 P=0,3; PLT r=0,986 P=0,99.

Conclusion: Storage and transport may have strong influence on sample stability. With the aim to decrease the chance for errors and obey the guidelines for phlebotomy, high quality storage and transport of samples proved to be very important. According to this recommendation we did not observe any effects of storage and transportation on the obtained results in this study.

Key words: dislocated laboratories; storage and transport; guidelines

P068

THE INFLUENCE OF A MEAL TO DETERMINATION OF ANTIOXIDANT DEFENSE PARAMETERS IN PLASMA AND RED BLOOD CELLS

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Background: The aim of this study was to examine the influence of a meal to the values of antioxidant parameters: superoxide dismutase (SOD), SE-dependent glutathione peroxidase (Se-GPx), glutathione reductase (GR) and Total Antioxidant Status (TAS) in 20 healthy blood-donors aged of 20-28 yrs.

Material and Methods: The first blood sample was collected between 8:00 and 8:30 a.m. after an overnight fast, using Li-heparinized tubes. Immediately after blood collection, the blood-donors consumed a light meal, containing standardized amounts of carbohydrates, protein, and lipids. Subsequent blood samples were collected at 2 h after the end of the meal. The activity of Se-GPx were determined in whole blood samples, SOD was determined in blood hemolisate, while GR and TAS were determined in plasma obtained after 10 minutes centrifugation at 3000 rpg.

Results: Statistical processing data revealed significantly increased antioxidant parameter values SOD, Se-GPx, GR and TAS 2 h after meal consummation (p<0.05) compared to the values after over-night fast. The average percentage increase for SOD was 26.9%, for Se-GPx, 37.1%, for GR was 14.55% and for TAS was 18.6%.

Conclusions. Based on the obtained results it may be concluded that meal consummation could have a significant influence on increased production of reactive oxygen species leading to an increase activity of antioxidant parameter values.

Key words: antioxidants defense parameters, blood, determination, meal, plasma

P069

PREANALYTIC ERRORS TRACKING IN THE MEDICAL LABORATORY OF UNIVERSITY MEDICAL CENTRE MARIBOR

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Background: Our aim is a presentation of the differences between manual and electronic preanalytical errors recording.

Materials and methods: We started to record some preanalytical errors manually in 2006. We reported them as quality indicators to our hospital management. Based on the results we also trained our phlebotomists. From 2009 till 2013 we recorded: identification error, missing data, no material, insufficient material, sample collection error and sample quality error. We also classified errors according to the medical department where they appeared. At the end of 2013 we started to record errors directly into LIS. There are 15 types of errors.

Results: From 2009 to 2013 we did 24300 orders per month. On average there were (per month) just 2 identification errors (1,1%), 1 missing data (0,7%), 8 insufficient materials (4,2%), 4 sample collection errors (2,4%), 46 no material errors (26,7%) and 117 sample quality errors (64,9%). Total number count of errors also decreased from 2303 errors in 2009 to 1867 errors in 2013 (-18.9%). At the end of 2013 we started the new way of recording. The results for the first eight months in 2014 have shown that although the number of orders is the same, the number of errors increased dramatically from 180 in the past to 489 today (+171%) as did the types of errors.

Conclusion: In the past years we had good quality indicators results. Our total numbers showed progress. But the new way of errors tracking where every single error is recorded shows that in the past we perceived just the iceberg of the problem. So we have to find a new way for preanalytical errors management.

Key words: preanalytical errors, manual recording, electronic recording, LIS

P070

LIPEMIA PREVALENCE AMONG CHILDREN OF EARLY AGE

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Background: As it is known, lipemia is one of the main interfering factors on a patient's blood results. The fasting sample is basic preanalytical standard for preventing a postprandial lipemia. But the physiology of young children impossible the sampling to take place on an empty stomach. Postprandial lipemia usually remains in the circulation for up to 8-9 hours with breastfeeding, and up to 5 hours with artificial feeding.
Materials and methods: Blood samples were researched in Consulting and Diagnostic Center for Children for the period of January – December 2013. Lipemia is hardly visible to the naked eye and its' detection can be subjective. For that reason measurement of an Lipemia Index (LI) on analyzers of the Cobas (Roche Diagnostics) was taken. On analyzers Cobas c 501 and Cobas Integra 400 plus LI was measured in lipemia units and compared to the optical behavior of the lipid substitute Intralipid.
Results: Median in first group of children less than one year old (n=478) was 21, [10-90P: 4-67]; in second group of children aged from 1 year till 3 years (n=1013) median was 7, 10-90 P: 0-17, (P <0.05 vs. first group), in third group of children aged from 4 year till 7 years (n=2366) median was 7, 10-90 P: 0-14, (P<0.05 vs. first group).
Conclusions: Our results indicate that due to the physiological processes of children in their first year of life, it is almost impossible to receive a sample of serum that is not influenced by a postprandial lipemia. The quantitative assessment – measurement of the LI – shows the influence of lipemia on the result.

Key words: interference; child; lipemia.

P071

ASSESSMENT THE EFFECT OF BD VACUTAINER® RAPID SERUM TUBE AND LUER-LOCK ADAPTER ON THE RATES OF HEMOLYSIS IN THE EMERGENCY DEPARTMENT

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Background: Hemolyzed specimens are a common occurrence in laboratory practice and it is associated with variety of factors including collection, handling, transportation, processing, and storage of blood specimens especially in the emergency department (ED). Hemolysis is a great challenge to ED where blood is drawn from intravenous catheters (IVCs). The aim of present study was to assess the effect of the using of tubes, a rapid-clotting serum tube, BD Vacutainer® Rapid Serum Tube (RST™), and luer-lock adapters with pre-attached holder (BD) on the rates of hemolysis in serum samples in the ED.
Materials and methods: The study was divided into three observational periods of 45 days each. In first period, blood was collected by using BD Vacutainer SST II plastic serum tubes. In second period, BD Vacutainer RSTs were used and in last period, RSTs and luer-lock adapters were used together. Hemolysis was quantified as serum index by using a Beckman Coulter AU5800 analyzer. A hemolysis index of ≥ 0.5 g/L was used to define hemolysis.
Results: The total number of hemolyzed serum specimens and theirs percent in the periods were 916/3776 (24.26%), 763/3582 (21.30%), 464/3795 (12.23%), respectively. Percent changes of hemolysis rate between first and second periods was 12.2%, between first and third periods was 49.6%, and between second and third periods was 42.6%. These observed differences among the periods were found to be statistically significant (P <0.05).

Conclusions: The use of luer-lock adapters with pre-attached holder showed a predominant effect on the reducing of the rate of hemolysis index compared to using RST. It was suggest that using of luer-lock adapter and RST during sampling in ED may be effective strategy to reduce the rate of hemolysis.

Key words: Hemolysis, rapid serum tube, Luer-lock adapters, emergency department

P072

WHAT DO PATIENTS THINK ABOUT EXTRAANALYTICAL PHASES OF LABORATORY PROCESS?

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Background: Patients are very important participants of extraanalytical phases of laboratory investigations. Extraanalytical phases include preanalytical and postanalytical parts. Patient reflection of lab service can effectively help to assess quality of laboratory process from user's side.
Materials and methods: We used method of social questionnaire among patients who received laboratory service in St.-Petersburg, Russia.
Results: Results were handled using general statistics. Majority of patients (71%) made laboratory tests because of physician's prescription, 13% – by their own decision or recommendations of their acquaintances, 9.4% – for prophylactic purposes, 4.4% – for pregnancy monitoring and 2.2% needed to receive a document about health status for employers. Two thirds of respondents (67.2%) received information about their preparation for sample collection from their physicians, one third (32.8%) – from laboratory staff. Nevertheless 8.6% did not accomplish this recommendation. Process for appointment to lab tests were not satisfactory for 20.7%. More patients served in private laboratories (92.9%) estimated phlebotomy in high level compared with state service (61.4% in outpatient clinics and 60.0% in hospitals), p<0.05. 30.7% of patients had emotional discomfort staying in the queue before sample collection. 20.7% patients did not like timing of orders for their tests results especially in state medical institutions. 32.4% patients had problems during their testing process. The most often problems in testing process were: timing of orders for tests results (7.9%), remote location of laboratory service (6.4%), queues and discomfort in place of sample collection (5.7%), difficulties in ordering for lab tests (4.3%), lack of attention of medical personnel (3.6%).
Conclusions: Patient questionnaires allowed to analyze problems of extraanalytical phase of laboratory process and to optimize correction actions in improving quality of laboratory service in Health Care.

Key words: extraanalytical phases, preanalytical phase, patient reflection, phlebotomy, sample collection.

P073

ANOTHER PERSPECTIVE ON REDUCING PREANALYTICAL ERRORS- NURSE EDUCATION

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Background: The preanalytical phase shows the highest prevalence of errors in laboratory diagnostics. In Croatia, nurses present an important bond between patients and the laboratory since they perform blood sampling in hospital wards and primary care dispensaries. Laboratory of General Hospital Dubrovnik conducts nurse education trough written instructions. The aim of this paper is to analyze nurse experience in previous education and suggestions about additional education in the area of preanalytical phase.
Materials and methods: Anonymous, voluntary questionnaire containing 5 questions was filled out by 101 of 380 nurse employed in General Hospital Dubrovnik (response 27%). Subjects were distributed according to school education and work experience. The differences in frequency distributions of qualitative variables were analyzed by Fisher exact test and chi-square test, with a significance level of P<0,05.
Results: Results showed that 73/101 nurses acquired most of their knowledge of the preanalytical phase by learning from more experienced nurses in their workplace. Written instruction from the laboratory used 32/101 nurses, but only 10/101 consider that most of their knowledge originated from those instructions.
It is considered that school education was insufficient and that additional training is required (64/98). Of 64 respondents who believe that the additional training is required, 77% suggested using written instructions from the laboratory, 51% suggested organizing workshops, and 43% suggested organizing lectures and courses. Implementing the part of their internship in the laboratory is considered useful by 70/100 nurses. For all questions answered no significant difference regarding school education and work was found.

Conclusions: Although nurses most frequently suggest using written instructions from the laboratory for education, survey showed that a small number of nurses actually used them for education. It is considered to be useful ensuring continuous education of new nurses by the laboratory staff or implementing part of internship in the laboratory.

Key words: preanalytical phase; nurse; education

P074

ROLE OF THE SOCIETY OF MEDICAL BIOCHEMISTS OF SERBIA IN THE STANDARDISATION OF THE PREANALYTICAL PHASE OF LABORATORY DIAGNOSTICS

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Background: The Society of Medical Biochemists of Serbia (SMBS) has a working group for preanalytics that functions within the Committee for Laboratory Work Organization and the Standardization Committee.
The SMBS has its own corresponding member in the EFLM Working Group on the Preanalytical Phase (EFLM WG-PRE) through which the SMBS participates in all the activities of this working group, and has also taken part in numerous published research.
Materials and methods: Preanalytical activities of SMBS are: organization of meetings, developing national recommendations, participation in the project of the IFCC WG "Laboratory Errors and Patient Safety" entitled Model of Quality Indicators, conduction of surveys, participation of EFLM WG-PRE projects and etc.
Results: The SMBS has conducted surveys related to the activities in preanalytical phase of laboratory diagnostics (570 biochemists were involved). Survey on Collaboration between Clinicians and the Laboratory was conducted by the SMBS in 2014 in five countries of the region (257 biochemists and 1532 clinicians from 105 health care institutions in Serbia took part).
The SMBS has organized a large number of educational sessions dedicated to the proper application of vacuum systems, and is engaged in introducing the use of vacuum systems as mandatory systems in health institutions of Serbia.
On behalf of the SMBS, Centre for Medical Biochemistry, Clinical Centre of Serbia (CCS), between 2011 and 2013 interviewed 4500 patients about their satisfaction with the work of the reception laboratory at the Polyclinic of the CCS, for which it received two Republic awards for quality and user satisfaction.
Conclusion: The SMBS has been working continuously for many years on the implementation of ISO 9001, ISO 17025 and ISO 15189 and the promotion of medical laboratories accreditation. The SMBS encourages and includes university students in all its activities related to the field of preanalytics.

Key words: SMBS, preanalytical phase

P075

ACCREDITATION PROCESS AND EXPERIENCE OF THE BIOCHEMICAL ANALYSES LABORATORY

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Background: Institute of medical and experimental biochemistry is leading educational institution in the field of medical biochemistry in the Republic of Macedonia. Biochemical analyses laboratory (BAL), within the Institute, is the first and only public laboratory accredited according to ISO 17025. BAL is in the process of accreditation according to ISO 15189. Accreditation scopes of our laboratory were: clinical chemistry, hematology, virus immunology and drugs of abuse. The total number of accredited tests is 48. External QC is not mandatory and there is no national proficiency testing program but BAL participates in EQAS since 2011.
The objective is to present the Quality Management framework of the BAL which includes: Quality planning (QP), Quality laboratory process (QLP), Quality control (QC), Quality assessment (QA) and Quality improvement (QI).
Methods: The five -Q framework defines how quality can be managed using PDCA cycle (plan, do, check and act). QP provides the planning step, QLP establishes standard processes for doing things, QC and QA provide measures for checking how well things are done, and QI

provides a mechanism for acting on those measures. Quality assurance program (QAP) consists of broad spectrum of practices, plans and procedures that will assure that the quality will be maintained.

Results: Key components of the Quality Management System are: top quality of the services and products; top management commitment in defining quality goals; continuous improvement based on the indicators of key processes and activities; rapid response to customer needs and customer-driven and process-oriented product development; evidence-based decision making; continuous education and training...

Conclusions: Every laboratory should perform quality improvement projects. The new standard and regulation should be designed and applied to all laboratories to increase the quality of laboratory service in Macedonia.

Key words: accreditation, biochemical laboratory, quality management system

P076

PROSPECTIVE MODEL-BASED COMPARISON OF DIFFERENT SAFETY-ENGINEERED PROTECTION MECHANISMS FOR BUTTERFLY BLOOD COLLECTION NEEDLES

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Background: Needle-stick injuries are still a major risk for health care employees, although safety-engineered protection mechanisms have been introduced. Characteristics and usability of different safety-engineered protection mechanisms for butterfly blood collection needles have not been investigated. We hypothesized that there would be marked differences in the application of different safety-engineered protection mechanisms for butterfly blood collection needles.

Material and Methods: In this randomized controlled study, 33 inexperienced 3rd year medical students performed venipuncture in a simulation model (IV Arm Model, Laerdal) using butterfly blood collection needles with four different safety-engineered protection mechanisms: (i) Venofix® Safety (B. Braun Melsungen AG), (ii) BD Push Button (BD), (iii) Safety-Multifly® (SARSTEDT), and (iv) Surflo® (TERUMO). The sequence of venipuncture procedures was: uninstructed first handling, instruction according to operating manual, first trial, and second trial. Venipuncture procedures were filmed for detailed analysis using a multi-camera video system. Primary endpoints included time up to safety mechanism activation, single-handed activation, correct activation of safety mechanism, possibility of safety mechanism deactivation, and preferred safety mechanism.

Results: Median time up to safety mechanism activation was 7 s (Venofix® Safety), 2 s (BD Push Button), 9 s (Safety-Multifly®), and 7 s (Surflo®). Single-handed activation during second trial was 18% (Venofix® Safety), 82% (BD Push Button), 15% (Safety-Multifly®), and 45% (Surflo®). Correct activation of safety mechanism during second trial was 3% (Venofix® Safety), 64% (BD Push Button), 15% (Safety-Multifly®), and 39% (Surflo®). Possibility of safety mechanism deactivation was 0% (Venofix® Safety), 12% (BD Push Button), 9% (Safety-Multifly®), and 18% (Surflo®). 11 medical students preferred Venofix® Safety, 17 BD Push Button, 5 Safety-Multifly® and none Surflo®.

Conclusions: BD Push button has the significantly shortest time up to safety mechanism activation and highest single-handed activation rate, and is the preferred safety-engineered protection mechanism. Our findings support the hypothesis, that there are marked differences in the application of different safety-engineered protection mechanisms for butterfly blood collection needles.

Keywords: butterfly blood collection needles, needle-stick injury, safety mechanism

P077

A SURVEY ON CLINICIAN AWARENESS OF THE IMPORTANCE OF PREANALYTICAL FACTORS AND COMMUNICATION WITH LABORATORY

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Background: Since laboratory errors are mostly due to the extra analytical processes, interaction between laboratory and clinicians is an important issue for patient safety. In this context, we designed a pilot study for determination of the clinician awareness of importance of preanalytical factors, and their confidences to the laboratory process.

Materials and methods: We prepared a questionnaire that contains 20 items each, and delivered to Internal Medicine, Surgery clinics and Emergency Units of 10 hospitals which have approximately 30.000 outpatients daily. The questionnaire is planned to determine of clinician awareness of preanalytical variables, importance of communication with laboratory, and the thoughts of clinicians about training on all laboratory process. The SPSS Version 21 Statistical Package was used for statistical analysis. The reliability of questionnaire was found acceptable with the Cronbach's alpha coefficient 0.68.

Results: 158 clinicians were participated. Related to preanalytical phase: 93% of clinicians are informing patients about the preparation for specimen collection; 47% know the importance of specimen storage conditions, while 36% don't have any knowledge; 83% are aware of the importance of specimen collection time and 78% have knowledge of biological variation while 18.3% don't know; 35% assure the effectiveness of quality control and 63% are confident for the laboratory results; Related to laboratory directors: 50-51% have satisfaction from easy communication with laboratory directors and their interpretation of the test results; Related to training: 87% agree with training, but 54% are thinking clinicians must participate in trainings; 72% are thinking participation of only phlebotomists is enough.

Conclusions: Although validity should be improved in this pilot study, it can be concluded that, training of staff, including clinicians on extra analytical variations is invaluable tools and the contribution of laboratory directors by interpretation of test results is needed.

Key words: awareness, clinician, laboratory, preanalytical factors

P078

THE IMPACT OF PREANALYTICAL ERRORS IN DETERMINING THE RESULTS OF DIAGNOSTIC PARAMETERS OF HEMOSTASIS, INR AND APPT

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Background: We investigated influence of preanalytical errors in sample insufficiently (incorrectly) taken blood while designing INR, APTT with prescribed ratio of blood and anticoagulant 1:9 (4.5 ml blood/0.5 anticoagulant), and whether, or to what percentage it leads to such erroneous testing results.

Material and methods: Material is a sample of venous blood taken in a test tube with an anticoagulant-Na3 -105 mmol. Patients were treated in Laboratory for coagulation and homeostasis, Department KCUS. Method is coagulometric (SIEMENS CBS); Detection clot optical principle.

Results: The respondents were divided into two groups. First group (10) formed control group. Results INR of 0.9 to 1.06, and APTT values ranged from 27.9 to 34.4 with. Second group consisted of subjects with consigned diagnosis whose samples were double tested, properly and improperly taken, with half blood ratio of 1:5(2:25 blood/ anticoagulant 0,5). For proper samples the INR results are in range from 0.90 min to 3.89 max, and midbond is 1,55. APTT results at this group are in range (min-26.1,max-63.3) and midbond is 36.6. Improperly collected samples, INR was 0.95 min; and max 4.46. The midbond value is 1,90. Values of APTT ranged (min-36,8,max -106.7)and average is 55,1. Standard deviation of INR control group is (SD 0.04); for duly taken samples it is (SD 1.02), for improper one (1.38). Standard deviation of APTT in control group was (SD 2.34), for samples taken properly (SD 11.02), and for the improper (SD 23.33). In one case the INR had more values to improper samples comparing to properly take one (10%) and APTT at all 10 improperly taken showed significantly higher values (100%). Coefficient of variation between determination of CV-1.2-2,2%.

Conclusion: The compliance with regularity in taking blood for testing parameters of coagulation INR and APTT, is very important in obtaining valid test results.

Key words: PV = INR (prothrombin time international normalized ratio), APTT (activated thromboplastin time), preanalytical errors.

P080

CAPILLARY BLOOD GAS ANALYSIS IN POCT: PRE-ANALYTICAL PHASE ERROR CORRECTION BY USING MAGNETIC MIXER

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Background: Identification of reliable quality indicators in pre-analytical phase and corrective action is a key to ensure quality of laboratory services. This study was performed to identify blood clotting as quality indicator among pediatric samples of capillary blood gas analysis during point of care testing (POCT) and the impact of corrective action.

Materials and methods: This one year study was performed between January 2013 and December 2013 at King Khalid University Hospital, Riyadh. Capillary blood gas samples were assessed as POCT in pediatric intensive care unit, neonatal intensive care unit and labor room. The quality indicator chosen was blood clotting that was expressed as percentage of samples discarded due to clotted blood sample. The initial corrective action implemented was regular training sessions by nursing coordinator for the nurses collecting samples followed by introduction of magnetic mixer for prevention of blood clotting after a period of three months.

Results: The mean number of samples tested for capillary blood gas analysis during the twelve months period was 9589 ± 1448. During the initial period of three months of training sessions alone the mean percentage of discarded samples was $11.4 \pm 0.4\%$ after the introduction of the use of magnetic mixer along with the training sessions the mean percentage of discarded samples was $7.7 \pm 1.8\%$ followed by $5.5 \pm 0.5\%$ and $4.7 \pm 0.1\%$ in the third and fourth quarters respectively.

Conclusions: Pre-analytical phase error correction by using magnetic mixer for pediatric capillary blood gas analysis over a period of one year was associated with over 50% reduction in the number of discarded samples.

Key words: Per-analytical, error, POCT, blood gas.

P081

A STUDY TO DECREASE THE PREANALYTICAL ERRORS

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Background: In this study, we aimed to analyze the preanalytical errors among the samples from inpatients and outpatients sent to our core laboratory and investigate the role of training courses in preventing these errors.

Materials and methods: In order to identify the sources of preanalytical errors, data were collected via LIS for 4 months. According to this data, the departments which have the most number of preanalytical errors and the most common sources of preanalytical errors were identified. A training course was planned for these departments to improve the preanalytical quality. After ten months, the error rates before the course and after the course were compared.

Results: The total preanalytical error rate in the pre-training period was 0.155% and the most common preanalytical errors among the total errors were hemolysed sample (29.9%), clotted sample (20.9%) and insufficient sample (19.7%). The departments, which have the most number of preanalytical errors, were department of pediatrics outpatients-inpatients and blood sampling unit, respectively. Training course was planned about the preanalytical error sources for these departments. After these courses, total error ratio was decreased from 0.155% to 0.124%. The most common errors among the total errors after training were clotted sample (48.9%), insufficient sample (16%) and hemolysed sample (14.2%). The decrease in hemolysed samples was appreciable after training course.

Conclusions: Hemolysed and clotted samples were found to be the most common sources of preanalytical errors in our hospital, likely with other studies. These preanalytical errors, can be decreased with training courses. Training courses should be planned periodically for the staff in blood sampling units and other departments to improve the quality indicators in long term.

Key words: Preanalytical errors, hemolysed sample, quality indicators

P082

SAMPLE REJECTION DUE TO PRE-ANALYTICAL PHASE ERRORS AND THE IMPACT OF CORRECTIVE ACTIONS

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Background: Up to 70% of total laboratory errors occur in the pre-analytical phase. Rejection of unsuitable samples not only affects patient care but can also increase turnaround time.

Objective: This study was performed to evaluate pre-analytical phase errors leading to rejection of specimens sent to clinical chemistry laboratory and the impact of corrective actions.

Methods: This study was performed in a period of one year between Jan. and Dec. 2013 at King Khalid University Hospital, Riyadh to investigate the reasons for specimen rejection. The indicators used were sample collection errors using inappropriate collection tubes, incomplete requisition forms and miss match of information on the collection tubes and the accompanying requisition forms. The corrective actions in terms of regular meetings with the concerned staff, emphasis on strict compliance to published laboratory guidelines and instant correction of the errors were introduced in the second quarter of the year.

Results: A total of 347734 specimens were received in clinical chemistry laboratory during the study duration of which 318 were rejected with a rejection rate of 0.091%. During the first quarter of the year the mean number of specimens rejected because of errors of collection was 15.3±1.5, for incomplete requisition form was 16.6±2.8 and for miss matched information was 8.6±1.1. After the implementation of corrective actions there was a gradual decline in the number of rejected specimens during the study period approaching to 4 for errors of specimen collection, 5.3±1.1 for incomplete requisitions and 4 specimens for miss matched information during the last quarter of the year.

Conclusion: Evaluation of pre-analytical phase errors due to factors out of laboratory premises resulting in sample rejection can have a negative impact on patient care that can be significantly reduced by a careful scrutiny of the specimens in the laboratory and implementation of corrective actions.

Key words: Pre-analytical, errors, rejection.

P083

PREANALYTIC LABORATORY ERROR ANALYSES IN A CLINICAL LABORATORY

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Background: It is estimated that more than 70% of clinical decisions are based on information derived from laboratory test results. Preanalytical variables account for 32-75% of laboratory errors and encompass the time from when the test is ordered by the physician until the sample is ready for analysis. Aim of this study is to evaluate the preanalytical laboratory errors of a private hospital in Istanbul.

Materials and methods: From April 2014 to October 2014, a total of 139.281 routine venous blood specimens were received in specimen admission unit of the clinical laboratory (including biochemistry and microbiology lab analyses) of the private Gayrettepe Florence Nightingale Hospital.

Results: According to the predefined criteria, 39 preanalytical errors were identified and recorded in a 7-month observational period with a 0.03% frequency of error rate (39/139.281). Our obtained data of preanalytical errors reveal the distribution of 38.5% (15/39) hemolyzed sample, 25.6% (10/39)clotted sample, 7.7% (3/39) incorrect identification, 7.7% (3/39) insufficient sample, 5.2% (2/39) incorrect patient, 5.2% (2/39) incorrect sample, 5.2% (2/39) incorrect labeling, 2.6%(1/39) lack of label and 2.6% (1/39)overfilled sample.

Conclusions: The present study elicits that our preanalytical errors were related with specimen collection that is the most critical controllable preanalytical phase variable. It is clear that improvements in this area will deliver the greatest incremental gains in the overall quality of clinical laboratory services in our hospital.

Key words: preanalytical, phase, error.

P084

A SURVEY STUDY; EVALUATION OF THE COMPLIANCE WITH PHLEBOTOMY GUIDANCE FOR THE PHLEBOTOMIST

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Background: Phlebotomy is a complex procedure and includes a high number of steps. Besides there may be a large heterogeneity in the understanding or compliance of medical staff performing phlebotomy which may result in increased number of preanalytical errors. Preanalytical phase includes a series of factors closely associated with the phlebotomists: a) questioning fasting time b) tourniquet application c) order of draw d) incomplete filling e) inadequate mixing of the tubes. The aim of this survey study was to evaluate the compliance of the staff (performing phlebotomy) with 'CLSI/NCCLS H03-A6-Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture' in our hospital.

Materials and methods: We carried out a survey including 23 questions about the phlebotomy practice (including procedures recommended by CLSI/NCCLS H03-A6) on the 201 staff performing phlebotomy in outpatient and inpatient clinics.

Results: Remarkable findings of the survey study are shown as percentages of the answers: 1) Questioning the patient identification (98.5%); 2) applying tourniquet between 5-10 cm above the venipuncture site (%84.5); 3) Applying tourniquet for longer than one minute (59.2%); 4) Releasing the tourniquet as soon as blood starts to fill the tube (47.8%); 5) Following the recommended order of draw (20%); 6) Mixing cycle for one full inversion of the tube (53.7%); 7) Questioning patient's fasting status (66.7%); 8) Filling the tube until blood flow ceases (37.3%).

Conlusions: The estimated compliance with phlebotomy guidance for the phlebotomists in our hospital was moderate and should be improved. Evaluation of the survey results can warn us about the hidden poor compliance points. Surveys may help assessing and improving the quality of blood sampling practices.

Keywords: Survey, Phlebotomy, Preanalytical phase

P085

DO UNDER-FILLED BLOOD COLLECTION TUBES CONTAINING K_2EDTA AS ANTICOAGULANT HAVE AN EFFECT ON ACTH MEASUREMENT?

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Background: It has been reported for some assays that insufficient sample volume can lead to increased final EDTA concentration in the sample-reagent mixture, causing chelation of metallic cations, and this can affect the activity of the alkaline phosphatase label used in the chemiluminescent reaction. This study aimed to investigate whether under-filled tubes have an effect on Siemens IMMULITE 2000 XPi ACTH analysis.

Materials and methods: Fasting blood samples from ten healthy volunteers (5 male and 5 female) were collected into prechilled tubes containing 5.4 mg dipotassium ethylenediaminetetraacetic acid (3 mL K_2EDTA BD Vacutainer, UK) at 08:30-09:00 a.m. Four tubes of whole blood were drawn from each individual. First tube was full-filled (up to nominal fill indicator) and considered as 100% volume (Reference group, G_R). The other three tubes were filled up to the different volumes according to reference tube [25%(G25), 50% (G_{50}), and 75%(G_{75}), respectively]. After blood collection, samples were handled according to manufacturer's instructions. Differences between the groups were compared using Friedman test. Percent differences were calculated by the following formula: % difference =[(Concentration Group-Concentration Group reference)/Concentration Group reference]*100. Royal College of Pathologists of Australasia Allowable Limits of Performance limits were used for the interpretation of the results.

Results: Concentrations of ACTH were estimated as median and inter-quartile range (IQR); 14.65 pg/mL (10.96-19.80), 14.75 pg/mL (11.79-18.78), 14.68 pg/mL (12.24-18.59), and 14.03 pg/mL (10.51-18.31) for G_R,G_{75},G_{50}, and G_{25}, respectively. There was no statistically significant difference at ACTH concentrations between the groups (p=0.066). Percent difference values were in acceptable limits.

Conclusions: We suggest that filling EDTA-sample tubes to ≥25% do not affect ACTH measurements by the Siemens IMMULITE 2000 XPi ACTH assay.

Key words: ACTH, under-filled collection tubes, EDTA.

P086

HOW DOES CENTRIFUGE TEMPERATURE INFLUENCE SOME LABORATORY ASSAYS?

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Background: Preanalytical variables including specimen collection, transportation, centrifugation, as well as storage and temperature can all affect clinical laboratory test results. The aim of this study was to investigate the effect of centrifuge temperature on routine chemistry and immunoassay tests.

Materials and method: Blood samples were collected from 48 patients into two serum separator tubes (Vacuette, Greiner Bio-one, Germany) (tube A,B). The tubes from each patient were gently mixed. Tube A centrifuged at 1500*g* for 10 min at 4°C (group 1), tube B centrifuged at 1500*g* for 10 min at room temperature (25°C) (group2). We monitored temperature of centrifuges with Ventura Temperature Tracking System and we observed that the temperature of centrifuges have raised to maximum 25°C, temperature of refrigerated centrifuges were max 6°C. After centrifugation, samples were analyzed immediately. Routine biochemistry test measurements were performed by Siemens Advia2400 autoanalyzer;

immunoassays were performed by Siemens Advia Centaur XP. Test results were reported as mean ± SD or median ± IQR. Differences between the groups were compared using Paired-t test or Wilcoxon Signed Rank Test (p< 0.05). Percent (%) difference for each analyte was estimated [(Group 2- Group 1)/Group 1]*100. *Desirable analytical quality specifications for bias* were used for the interpretation of the results.

Results: We observed no statistically significant differences for ALT, Total Cholesterol, HDL- Cholesterol, LDL- Cholesterol, GGT, Phosphorus, Iron, TIBC, Uric Acid, BUN, Hs CRP, ALP, Albumin, fT3, TSH and Parathyroid Hormone assays (Except for Na, K, Cl, AST, CK, Creatinine, Bilirubin Direct, Bilirubin Total, Glucose, LDH, Magnesium, Triglyceride, CK-MB Activity, Calcium and fT4 assays). Na, Cl and Ca analytes were not within desirable *analytical quality specifications for bias*.

Conclusion: Centrifugation temperature variations may have a significant effect on some routine parameters. Hence, laboratories should standardize and strictly monitor centrifugation temperature.

Key words: Centrifuge Temperature, Preanalytical Variables, Routine Chemistry and Immunoassay tests.

P087

DO RST TUBES PROVIDE COMPARABLE TEST RESULTS OR IMPROVED STABILITY WHEN COMPARED WITH SST TUBES?

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Background: For some analytes test results can be affected by choice of blood collection tubes. A few number of studies comparing the new BD Vacutainer® Rapid Serum Tubes (RSTs) with the BD Vacutainer Serum Separator Tubes (SSTs) for routine chemistry and immunoassay tests have been published. Moreover, published studies have not investigated Insulin, C-peptide and High Sensitivity C-Reactive Protein tests. The aim of this study was to evaluate the comparability of some laboratory tests and rates of hemolysis using RSTs and SSTs, also investigate the stability on serum storage time.

Materials and methods: Blood specimens were collected into RSTs and SSTs from 97 participants. After clot formation, all tubes were centrifuged at 1500xg for 10 minutes. Serum from each tube was tested for Insulin, C-peptide, High Sensitivity C-Reactive Protein (hsCRP), parathyroid hormone (PTH), 25-OH vitamin D, glucose, potassium (K), phosphorus, aspartate aminotransferase (AST), magnesium (Mg) and lactate dehydrogenase (LDH) measurements. Detection of hemolysis was carried out by a spectrophotometric method. Paired blood specimens (n=15) were stored at 4°C and retested at 4 hr and 24 hr for the evaluation of specimen stability. The significance of the differences between samples was assessed by paired-t test or Wilcoxon test. The mean percentage difference was calculated. Desirable analytical quality specifications and total change limit were used for the interpretation of the test results and the stability of analytes, respectively.

Results: Although the results for measured analytes showed statistically significant differences between the two tube types (p<0.05), the mean percentage differences (except for LDH) were within the current desirable allowable bias. No serum samples in the study were hemolysed (≥0.5 g/L) and most of the analytes investigated remained stable (24 h at 4°C) for both tube types.

Conclusions: This study suggests that BD RST tubes are suitable for collection of blood and storage of serum for common laboratory analytes including Insulin, C-peptide, hsCRP.

Key words: Blood collection tubes, stability, hemolysis

P088

ARE ELECTROMECHANICAL COAGULATION ANALYZERS REALLY A BETTER CHOICE FOR PERFORMING ROUTINE COAGULATION ASSAYS IN LIPEMIC SAMPLES?

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Background: It is widely accepted that lipemic coagulation samples can be reliable analyzed with mechanical methodology. In order to minimize the interference of turbidity caused by lipemia, some photo-optical coagulation analyzers provide the application for assaying PT, aPTT and fibrinogen on an additional wavelength. This study aimed to determine whether electromechanical methodology is superior to photo-optical methodology, for obtaining reliable results in lipemic samples.

Materials and methods: The influence of lipemia on routine coagulation assays was studied in plasma pools with normal (pool-N) and pathological values (pool-A), after addition of increasing concentrations of 20% lipid emulsion (SMOFLIPID®, Fresenius Kabi). Six aliquots of each pool were prepared, and saline was added in the first aliquots (dilution 1:10). In the remaining five aliquots, measured triglyceride (TG) concentrations were 3, 5, 10, 15 and 20 mmol/L. In each aliquot PT, aPTT and fibrinogen were performed in triplicate on the photo-optical analyzer BCS-XP on 405-nm and 570-nm (Siemens Healthcare Diagnostics), and on two electromechanical analyzers STA-R Evolution and STA Compact Max (Stago).

Results: Although Stago analyzers provided reliable PT, aPTT and fibrinogen results in both pools for all TG concentrations, decreasing aPTT values with increasing TG concentrations were observed in pool-A, compared to baseline values (bias=4,8-25%). No valid PT and aPTT results were obtained on BCS-XP in both pools on 405-nm, at TG concentrations 15 and 20 mmol/L, while reliable PT and aPTT results were obtained on 570-nm. The most pronounced influence of lipemia on BCS-XP was observed for fibrinogen, as no valid results were obtained even on 570-nm (pool-A at TG concentration of 10 mmol/L, pool-N at TG concentration of15 mmol/L).

Conclusions: Although electromechanical analyzers have demonstrated to be superior for Fbg measurement in lipemic samples, the application of 570-nm on BCS-XP allows reliable PT and aPTT determination even at high TG concentrations.

Key words: lipemia, routine coagulation assays, electromechanical coagulation analyzers, photo-optical coagulation analyzers

P089

RELIABILITY OF ROUTINE COAGULATION ASSAYS IN HEMOLYZED PLASMA SAMPLES ASSAYED WITH COAGULATION ANALYZERS WITH DIFFERENT CLOT DETECTION METHODOLOGIES

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Background: It is well known that in contrast to electromechanical clot detection, turbidity may affect the measurement of routine coagulation assays on photo-optical analyzers. However, limited information of the influence of hemolysis on routine coagulation assays, measured with different clot detection methodologies, are available.

Materials and methods: The influence of hemolysis on PT, aPTT, fibrinogen was assessed in plasma pools with normal (pool-N) and pathological values (pool-A) after addition of known concentrations of blood cell lysate. In addition to baseline samples with no addition of lysate, five aliquots of each pool were prepared, with final hemoglobin (Hgb) concentrations 0.5, 1.0, 2.5, 5.0 and 10.0 g/L. Hemolysis was also assessed in all samples by measuring free plasma Hgb concentrations, and by determining serum hemolysis indices on Roche Cobas c6000 analyzer. Routine coagulation assays were measured in triplicate in each aliquot, on two electromechanical Stago analyzers (STA-R Evolution and STA Compact Max) and on the photo-optical analyzer (BCS XP, Siemens Healthcare Diagnostics) on 405-nm and 570-nm.

Results: PT and fibrinogen results measured on Stago analyzers were unaffected at all Hgb concentrations, whereas the addition of blood cell lysates resulted in slight underestimation of aPTT results in pool-A, being most pronounced at Hgb concentrations of 10 g/L (23.2 and 25.5%). The greatest influence of blood cell lysates on BCS-XP was observed for APTT, resulting in substantial overestimation of aPTT results in both pools, starting from Hgb concentration of 1 g/L (13.2-147.6%). In contrast, underestimation of PT (9-30.0%) and fibrinogen (12-16.3%) was observed starting from Hgb concentration of 5 g/L.

Conclusions: Obtained results indicate that hemolysis has the strongest influence on aPTT results on both type of analyzers, being more pronounced on the photo-optical analyzer. The influence on PT and fibrinogen is less pronounced, except for the highest Hgb concentration on the photo-optical analyzer.

Key words: routine coagulation assays, hemolysis, clot detection methodology

P090

ESR STABILITY AT DIFFERENT TIMES IN K$_2$EDTA TUBES

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Background: The erythrocyte sedimentation rate (ESR) remains the most widely used laboratory test for monitoring infections, inflammatory diseases and some types of cancer. Micro TEST-1 (Alifax Padova, Italy) fully automated analyzer for the determination of ESR which uses EDTA

anticoagulated blood, thereby making use of the full blood count sample. The aim of this study was to evaluate the storage stability of whole blood preserved with K_2EDTA at room temperature (RT) or 4°C.

Materials and methods: The study was performed Diskapi Yildirim Beyazit Training and Research Hospital. The ESR of 100 'randomly selected patients' blood samples anticoagulated with K_2EDTA (3.0 mL, K_2EDTA 5.4 mg, Becton Dickinson, Plymouth, UK) was measured by Micro TEST-1 method at 0, 4, 6, 8, and 24 hours after collection. Fifty samples were stored at RT and the others at 4°C between analysis.

To evaluate stability, the Acceptable Change Limit (ACL) and the mean percentage deviation were calculated. The mean percentage deviation was compared to the ACL according to ISO 5725-6. The ACL for interpreting a measured difference is based on the analytical imprecision (CVa), using the formula ACL=2.77 CVa. We accepted that a mean percentage deviation greater than 2.77 CVa was reduced in stability.

Results: Compare the mean percentage differences with the ACL, with a "+" for an increase and a "−" for a decrease. ESR was remained stable only for 6 hours at RT and for 8 hours at 4°C in K_2 EDTA tubes.

Conclusions: At the room temperature, compared to the refrigerator, the results are changing earlier. Waiting room temperature containing EDTA blood sample should be measured within 6 hours after collection.

Key words: ESR; EDTA; stability

P091

PRE-ANALYTICAL FAECAL STORAGE CONDITIONS IN THE DIAGNOSIS OF COLORECTAL CANCER

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Background: The detection of the fecal occult blood represents a fundamental step in making an early diagnosis of colorectal cancer and the pre-analytical storage conditions of samples must to be accurately standardized. The aim of the present study was to compare the stability of hemoglobin in feces collected with two sampling devices specific for the fecal immunochemical tests, FOB Gold Tube Screen (SCREEN) and OC-Sensor DIANA (OC) respectively.

Materials and methods: 15 true positive fecal samples were collected with both devices. A pool from each sample was made, portioned and stored at + 4°C, + 21°C and + 32°C for 10 days. One aliquot of each pool stored at the specified temperatures was tested at five time intervals between sampling and analysis (1, 3, 6, 8 and 10 days).

Results: The percentage of cumulative fecal hemoglobin decrease (HbCD%) has been evaluated. At + 4 C, HbCD% was lower in pool collected using OC in comparison to that observed using SCREEN devices (p = 0.05), being maximum HbCD% equal to 10.3% observed 10 days after collection using OC device in comparison to 18.8% in samples collected using SCREEN device. No significant difference between collection devices (p=0.06 and p=0.83 respectively) were found for sample stored at + 21°C and + 32°C.

Conclusion: At + 4°C OC preserves the fecal hemoglobin better than SCREEN device, while at room and high temperatures, the devices demonstrated comparable storage performance. The refrigerate temperature represents the more suitable condition for fecal sample storage, although the hemoglobin degradation occurs immediately from the first day after collection. Therefore the delivery of fecal samples to the laboratory must to be done as soon as possible.

Key words: Fecal occult blood; fecal immunochemical test; colorectal cancer

P092

NEWLY DEVELOPED UNFENCED ROBOTS WORKING SIDE BY SIDE WITH TECHNICIANS IN THE PREANALYTICAL HANDLING OF BLOOD SAMPLES IN A HOSPITAL LABORATORY

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Background: Robots in hospital laboratories are usually placed in cages to protect technicians for being physically hurt by the robot during its movement. Within the last few years a new type of unfenced robots has been developed. The robots have sensors that upon resistance immediately stop their movements minimizing the risk of physical damage to nearby persons. With vision technology the robots may alleviate some of the preanalytical manual handling procedures of blood samples in a hospital laboratory.

Materials and methods: A circular horizontal plate with a diameter of 50 cm that dials and stops and dials and stops, continuously receives all blood samples from the wards and the outpatient clinics. Based on fast photos of the samples and their screw caps the robot picks up each sample by a suction device, the barcode is read and the sample placed in one of two different racks or in one of two different containers. The racks are subsequently manually carried a few meters to the appropriate analytical equipment.

Results: The robot has now been in use for more than 6 months. It handles approximately 2000 tubes/day with a capacity of 7-8 tubes/minute. The laboratory has been able to absorb an increase of 200 samples/day compared with the same period last year with the same number of technicians and without a reduction in turnaround time. Less than 1 hour after the samples are received in the laboratory 90% of the results are delivered to the clinicians.

Conclusion: The new generation of unfenced robots appears helpful in the preanalytical handling of blood samples in a hospital laboratory when space, economy or availability do not permit installation of standard bulk loaders. The robots increase the capacity of the lab, may reduce turnaround time and are well received by the technicians.

Key words: Unfenced robots, Sorter, Automation, Loading of racks

P093

PREANALYTICAL CONSIDERATIONS IN PROLACTIN ANALYSIS

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Background: Almost 40% of pituitary adenomas are prolactinomas, which secretes prolactin in different degrees. Prolactin follows a circadian rhythm. The patient must keep vigil time prior to the extraction of two hours. This is a critical factor in the determination of prolactin in order to avoid preanalytical errors. Furthermore, hyperprolactinemia could be induced not only by drugs but other conditions. The aim of the work is to evaluate the false positives after have informed the clinician about the noncompliance of 2 hours previous to the extraction.

Materials and methods: Prolactin levels were analyzed by immunochemiluminescence (ADVIA Centaur XP, Siemens Healthcare Diagnostics). Active prolactin is obtained after precipitating with 25% polyethylene glycol solution. If the value is over 40% of the total prolactin, it discards macroprolactinemia. Active prolactin > 600 and 400 UI/mL are considered pathologic for women and men respectively. We investigated those patients who had 2 prolactin determinations performed in < 3 months, and we studied the influence of compliance of the preanalytical conditions.

Results: The study enrolled 10.380 samples analyzed in 2013 in our laboratory (Virgen-Macarena University Hospital, Seville), of which 1311 were duplicates of the same patients. According to the first determination 13.7% were pathologic and only 9.2% with the second determination. For studied the number of false positives, we selected those patients presenting hyperprolactinemia in the first determination, and who showed normal values in the second determination. They resulted in 8.2% (63) of all patients studied with duplicate values.

Conclusions: Preanalytical phase is essential to avoid errors in clinical laboratory measurements. A correct extraction of the sample 2 hours after being awake could avoid psychological damage and setback to the patient. Moreover, we could decrease total prolactin repetitions in a short times and active prolactin determinations, what would suppose a great economic saving for our laboratory.

Key words: Prolactin, preanalytical phase, interference factors

P094 – SELECTED ORAL COMMUNICATION

EFFECT OF INACTIVATION PROCEDURE OF EBOLA VIRUS ON ROUTINE BIOCHEMISTRY PARAMETERS

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Background: Latest Ebola breakthrough encouraged a study of the effect of recommended procedure for inactivation of hemorrhagic fever viruses on routine biochemistry parameters.

Materials and methods: Recommended inactivation protocol consist of use of detergent 20% Triton X-100 and 20% tri-(n-butyl)-phosphate in final concentration of 1% and one hour incubation period of sera on 45°C. Effect of inactivation procedure on biochemistry parameters was tested using routine patient samples (n=31). Determination of sodium, potassium, chloride, urea, creatinine, aspartat aminotransferase (AST), alanin aminotransferase (ALT) and C-reactive protein (CRP) prior and after simulated inactivation was done on a Beckman Coulter AU680 analyzer (Beckman Coulter, Tokyo, Japan) using original reagents and applications recommended by manufacturer. All statistical

analysis, including descriptive statistics, Kolmogorov-Smirnov test for normal distribution, paired t-test, Passing-Bablok regression analysis and Bland-Altman plot was done using MedCalc, 12.5.0 (Ostend, Belgium).

Results: Paired t-test showed statistically significant difference in all parameters before and after inactivation procedure (creatinine, P=0.001; AST, P=0.010; ALT, P=0.001; CRP, P=0.004 and for other parameters, P<0,001). Passing-Bablok regression analysis showed constant and proportional difference between native and inactivated samples for following analysis: AST, y= -14.7(95% CI -32.8 to -6.0) + 1.8(95% CI 1.3 to 2.7)x; CRP, y= -0.3(95% CI -0.8 to -0.1) + 0.7(95% CI 0.7 to 0.8)x; chloride, y= -45.7(95% CI -80.3 to -21.8) + 1.3(95% CI 1.1 to 1.7)x. Bland-Altman analysis showed a clinically significant difference for following parameters (mean difference as%, ±1.96SD): ALT (35.2%, 5.4 to 64.9), AST (-10.0%, -10.61 to 86.1), CRP (51.3%, -40.1 to 142.8), potassium (11.7%, 5.6 to 17.7), chloride (13.0%, 6.3 to 19.6), sodium (8.4%, 3.3 to 13.6), creatinine (10.6%, -18.0 to 39.2) and urea (8.5%, -1.0 to 18.0).

Conclusion: Comparison of biochemistry parameters in native and inactivated samples showed statistically significant differences. However, in order to protect laboratory personnel, inactivation procedure could be used, but results should be carefully interpreted.

Key words: Ebola virus, inactivation procedure, biochemistry parameters

P095

SMOKING AND THYROID-STIMULATING HORMONE IN MOTHERS OF A PORTUGUESE BIRTH COHORT

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Background: Current smoking is associated with a fall of serum thyroid-stimulating hormone (TSH) in general populations. TSH changes in fertile women can impact on the development of offspring. Our aim was to evaluate the influence of smoking on TSH levels in childbearing women.

Materials and methods: This study comprised 1985 mothers of a birth cohort evaluated 4 years after the delivery of a liveborn in Porto, Portugal. Serum TSH was measured by immunoassay (Abbott Architect® i2000sr). Women with serum TSH <0.02 or ≥10 mUI/mL, currently pregnant or taking any thyroid-directed therapy were excluded. Continuous variables are presented as median (interquartile range) and compared between groups with the Kruskal-Wallis test.

Results: Four years after delivery, 56.1% of women were never smokers, 16.6% former smokers and 27.3% current smokers. Median serum TSH levels were significantly lower in current smokers than in never smokers (1.27 (0.94-1.77) vs. 1.42 (1.06-1.91) mUI/mL [p < 0.001]). Smokers of more than 20 cigarettes/day (1.5% of smokers) had even lower TSH (1.10 (0.82-1.44) mUI/mL), while there was no difference among less heavier smokers. The duration of the smoking habit did not impact on serum TSH. Subjects who stopped smoking in the previous 2 years had serum TSH similar to that of current smokers (1.28 (0.90-1.89) mUI/mL), subjects who stopped smoking more than 5 years before had serum TSH similar to never smokers (1.42 (1.01-1.88) mUI/mL), and subjects who stopped smoking between 2 and 5 years before had intermediate levels (1.33 (0.97-2.02) mUI/mL). The effect of smoking on TSH was independent of age and body mass index.

Conclusions: Current smokers had serum TSH lower than never smokers by 0.15 mUI/mL, which was dose-independent at least until 20 cigarettes/day. This effect disappeared 5 years after cessation of smoking. This factor could help interpret subclinical hypothyroidism in childbearing age women.

Key words: Thyroid-stimulating hormone, smoking, motherhood.

P096

EVALUATION OF PRE-ANALYTICAL PROCESS IN CLINICAL LABORATORIES: SIX SIGMA METHODOLOGY

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Background: In clinical laboratories, pre-analytical process is the duration between the clinical request of the clinician and the beginning of the analysis. The errors that effect pre-analytical process originates from process variables. According to six sigma methodology process sigma level is the indicator of efficiency and cost effectiveness and makes a holistic point of view to the process. Pre-analytical process sigma levels are calculated according to pre-analytical process errors. These errors are waste of time and money which are; improper labeling, hemolyzed

samples, lipemic samples, clotted samples, inappropriate container, insufficient sample and damaged sample. In this study, we aimed to assess the pre-analytical process performance according to six sigma methodology.

Materials and method: Pre-analytical process error data between June 2014 and November 2014 were obtained from the laboratory information system. Monthly process sigma levels were calculated for every type of error by using formula "NORMSINV[1-(total defects/total opportunities)]+1.5" by the Microsoft Excel Spreadsheet. Number of defect opportunities per component was taken as 4 because the defects were categorized as sample, order, transport and container-related defects. We have specified the target quality performance level as 4.6 sigma which has a waste rate of%10 with 1000 DPM.

Results: For each error type, process sigma levels were found above the target for each month (4.6). Pre-analytical process error with the lowest process sigma level was "clotted sample", the highest was "damaged sample".

Conclusion: Our results showed that process sigma levels calculated according to errors may be useful for evaluation of pre-analytical process. Particularly main errors that effects patient safety can be detected immediately. The origin of the errors that have low sigma levels can be determined, corrective and preventive actions can be carried out immediately.

Key words: Quality, six sigma, pre-analytical process, pre-analytical errors

P097

PRE-ANALYTICAL EFFECTS ON ESTABLISHED AND EMERGING BIOMARKERS OF CARDIOVASCULAR DISEASE (CVD)

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Background: plasma renin activity (PRA), an established marker of CVD, is going to be replaced by plasma renin concentration (PRC). HMGB1 and TWEAK are emerging CVD biomarkers. We verified pre-analytical processing (sample type, temperature and duration of storage, centrifugation protocol) on PRA, DRA, HMGB1 and TWEAK. IL8 was positive control.

Materials and methods: Blood from 10 donors was collected in serum (S), heparin, EDTA and citrate (Cit) tubes and kept at room temperature (RT) or refrigerated (COLD). For PRA and DRA a third series of EDTA tubes was chilled on ice (ICE). Samples were centrifuged one (1Centr) or two (2Centr) times after 30 minutes, 3 and 9 hours. Aliquots (-80°C) were analyzed within three months (immunometric assays).

Results: PRA median CV at 3 and 9 hrs were: 8.16% and 7.68% (COLD), 2.18% and 5.23% (ICE), 18.22% and 17.25% (RT), being intra-assay CV 9%. DRA intra-assay CV was 3.2%; median CV at 3 and 9 hrs were: 1.94% and 4.87% (COLD), 3.32% and 6.07% (ICE), 1.94% and 2.96% (RT). S-HMGB1 was 10 fold lower than any other plasma type (F=7.14, p=0.002). Cit-HMGB1 median CVs at 3 and 9 hrs were lower than intra-assay CV (15%): 2.23% and 8.96% (COLD,1Centr), 8.64% and 5.24% (COLD,2Centr), 11.55% and 6.58% (RT,1Centr), 7.51% and 8.56% (RT,2Centr).
At 3 hrs TWEAK median CV was lower than intra-assay CV (5%) for all pre-treatments. The median 9 hrs CV varied from a minimum of 6.36% (RT,2Centr) to a maximum of 11.37 (COLD,1Centr). S-IL8 at RT, not at COLD, progressively increased at 3 (28+8 pg/mL) (p= 0.0194) and 9 hrs (590+206 pg/mL) with respect to basal (7+3 pg/mL) (p= 0.0250).

Conclusion: S-HMGB1 is not measurable, probably because it interacts with thrombomodulin; citrate plasma is recommended. TWEAK can be measured in any matrix. Refrigeration is not required for HMGB1, TWEAK and DRA.

Key words: cardiovascular diseases, renin, cytokines, HMGB1, TWEAK

P098 – SELECTED ORAL COMMUNICATION

MALDI-TOF/MS PROTEOMIC SIGNATURE OF PRE-ANALYTICAL SAMPLE QUALITY

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Background: Pre-analytical issues represent a critical aspect for proteomic biomarker discovery studies. Pre-analytical processing (sample types, centrifugations, temperatures and storage duration) was studied to identify MALDI-TOF/MS signatures of sample quality.

Materials and methods: 400 mL blood was collected in serum, EDTA and citrate tubes from one donor. Tubes were kept at room temperature (RT) or refrigerated (CT). After 30 minutes (baseline), 3 hours (hrs), 6 hrs and 9 hrs, samples were centrifuged once (1200 g, 10 minutes) or

twice (2500 g, 15 minutes). 100 uL of each sample were precipitated by ACN (1:1v/v). Peptides were dried, resuspended in 0.1%TFA, ZipTip desalted and analyzed at MALDI-TOF/MS. Spectra were processed by mMass; relative intensities (RI) were used to normalize signals. For each anticoagulant and storage condition, the most abundant features were evaluated at each time-point. For the most variable features, their baseline RIs were compared to those obtained after 9hrs of storage.

Results: Features in citrate tubes did not significantly varied. At RT, EDTA tubes centrifuged once, the feature at m/z 1896 showed a RI increase over storage time (from 80% to 120%). In serum tubes, RT storage showed a decreasing trend of the m/z 1206 and 1350 features. By comparing the most variable features at baseline with respect to 9 hrs storage, no significant differences were found in EDTA tubes; in serum tubes, the feature at m/z 2021 dramatically increased after 9 hrs of storage at RT (50 and 200 fold-increase, for 1 or 2 centrifugations, respectively). A lower increase was observed at CT conditions (10 and 20 fold-increase, for 1 or 2 centrifugation, respectively).

Conclusions: EDTA and citrate plasma seem to be less influenced by storage conditions. MALDI-TOF/MS features at m/z 1206, 1350 and 2021 could be indicators of serum specimen quality, especially when RT storage is adopted.

Key words: MALDI-TOF/MS, proteomics, biomarkers

P099

INTERFERENCE IN THE ASSESSMENT OF INTERFERENCES

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Background: Several pre-analytic conditions may result in increased concentrations of chromogens that constitute a usual form of interference in photometric assays and has major impact on samples rejection and monetary waste.

The incorporation of the HIL (Hemolysis, Icterus, Lipemia) reagent, a semi-quantitative test for photometric determination of these indexes in automated-analyzers, as became widespread.

Objective was to study the samples that appeared in our laboratory with a HIL result of Abnormal and try to obtain a reason for it.

Materials and methods: We conducted a cross-sectional analysis off samples with Abnormal results in HIL test arriving at the Laboratory of a tertiary hospital during 30 days. Samples were collected and macroscopically evaluated by two separate observers. All pediatric samples were excluded due to the different characteristics of the sampling tubes.

The samples were diluted with LIH reagent and absorbance was measured using a Beckman Coulter analyzer (AU5400). Existence of interfering substances were produced and reported in conjunction with the results of analysis performed. It was then made the characterization of the chromogenic substance and provided the magnitude of interference.

Results: Within the 22394 samples tested, 489(2.1%) presented abnormal results: Blurred sample-50%, Heavy Hemolysis-15%, Light Hemolysis-12%, Miscellaneous (Hemolysis and Lipemia)-3%. Regarding the type of tube, 64% where Lithium heparinized and 33% Dry tube. As for clinical department, 59%-Emergency Room;19%-Ward;11%-Out-patients;8%-Intensive Care Units.

When comparing clinical departments the abnormal results percentage was 6.4%-Emergency Room;1.4%-Ward;1.2%-Intensive Care Units;0.7%-Out-patients.

Conclusions: The main reason for Abnormal HIL result was Blurred sample, followed by heavy and light Hemolysis. We found a high number in the use of Lithium heparinized tube, curiously the same used in Emergency Room.

Although not being able to determine the reason, literature supports that this may be due to stressful working and patients clinical conditions there encountered.

Key words: HIL index, pre-analytical, interferences

P100

IMPROVING PREANALYTICAL PRACTICE BY QUALITY CHECK

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Background: diagnostic testing plays an important role in clinical decisions for patient management. Controlling preanalytical phase at different steps does help in reducing errors and improving reliability of clinical laboratory results because major errors happen in preanalytical

phase. Observing preanalytical practices may lead to identifying gaps and areas for improvement which play an important role in determining specimen quality and results accuracy.

Materials and methods: in this study we evaluated the preanalytical practice some institutions in United Arab Emirates by conducting BD Preanalytical Quality Check Service. 171 venous blood collection procedures conducted by nurses/phlebotomist were observed. The observations done were focused in three areas: **patients' safety** through proper patient confirmation/minimum patient identification obtained, **healthcare workers' safety** through correct safety blood collection device activation to prevent needlestick injuries and **specimens' quality** including venipuncture site disinfection, tourniquet application time, tubes mixing, order of draw.

Results: in three focus areas observation results show: no minimum patient identification obtained in 51%, improper venipuncture site disinfection in 34%, prolonged tourniquet application in 70%, tubes mixing less than 3 times in 74%, errors in order of draw of citrate coagulation tube in 30%, errors in order of draw of EDTA tube in 29%, incorrect safety blood collection device activation in 63%, fibrin strands/mass were observed in 34% of serum chemistry tubes monitored in laboratories.

Conclusions: based on observation; incorrect practices in preanalytical phase can compromise specimen quality, results' accuracy and also impact patients and healthcare workers safety. Identifying these gaps and working on improving preanalytical practices as per international guidelines by raising awareness and conducting training are key factors to decrease sample rejection and improve patient diagnostic testing outcome.

Key words: Preanalytical practice observation, specimen quality, results accuracy.

P101

INFLUENCE OF DIFFERENT CLOTTING TIME ON ROUTINE LABORATORY ANALYSIS

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Background: Recommendations for sera preparation (Croatian Chamber of Medical Biochemists) is to leave the blood sample to clot for minimum of 30 minutes. The aim of this study was to compare two different procedures of sample preparation due to different clotting time.

Materials and methods: Two blood samples from each healthy volunteer (n=31; 5 men, 26 women) were collected in gel tubes without anticoagulant (Greiner Bio-one, Vacuette). The first sample was left for 15 minutes or less, while the second sample was left for more than 35 minutes after venipuncture. Both of them were centrifuged (1500 g for 10 minutes) and measured for aspartate aminotransferase (AST), lactate dehydrogenase (LD), creatinine kinase (CK), potassium (K) on Dimension RxLMax (Siemens, Munich, Germany) and for thyrotropine (TSH) on Advia CentaurXP (Siemens, Munich, Germany). Paired t-test, Passing-Bablok regression and Bland Altman plot were analyzed in MedCalc, version 12.5.0 (Ostend, Belgium).

Results: Paired t-test resulted with significant difference ($P<0.05$) for AST ($P=0.004$), CK ($P<0.001$) and K ($P<0.001$).
Passing-Bablok regression for AST, y= -1.000(95% CI -2.000 to 1.857) + 1.000(95% CI 0.857 to 1.053)x; LD, y= 7.957(95% CI -23.217 to 37.566) + 0.934(95% CI 0.754 to 1.130)x; K, y= 0.270(95% CI -0.100 to 0.900) + 0.900(95% CI 0.750 to 1.000)x and TSH, y= -0.015(95% CI -0.057 to 0.013) + 1.013(95% CI 0.988 to 1.038)x showed there is no constant or proportional difference and for CK, y= -2.000(95% CI -3.791 to -0.474) + 1.000(95% CI 0.979 to 1.015)x showed constant difference. Bland-Altman plot accompanied by mean difference as%, ± 1.96SD showed clinically significant difference for K (-3.797, -5.230 to -2.244).

Conclusion: Only for TSH, the two procedures of sera preparation can be used interchangeably, but in order to minimize and prevent errors in preanalytical phase recommendations should be followed.

Key words: recommendations, clotting time, difference, preanalytical phase

P102

IMPLEMENTING CONCEPT OF QUALITY INDICATORS IN PREANALYTICAL PHASE – THE EXPERIENCE OF PRIMARY HEALTH CARE LABORATORY

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Background: There is no national consensus in Serbia about quality indicators, so each laboratory can choose various number of them. Our laboratory has started with this from April of 2014. by including in IFCC project "Model of Quality Indicators". The aim of this paper is to

describe the process of implementation of preanalytical phase quality indicators, discuss some difficulties experienced during implementation and show preliminary results from first six months.

Materials and methods: 20 quality indicators were chosen for monitoring preanalytical phase. For each of them we've made an procedure form describing the definition, data collection method and responsible person(s). Collected data are processed and results analyzed to identify needed actions.

Results: Some quality indicators results are reported here as example: misidentified requests: 0.43%, requests with missed test: 2.32%, unintelligible requests: 0.59%, hemolyzed samples: 0.92%.

Conclusions: Obtained results show current situation in our laboratory and highlight areas which need improvement. Also some problems have been observed during collecting these data, especially retrospective collecting of test transcription errors, as well as precise definition of some indicators. Corrective actions should be: full implementation of electronic laboratory request, additional training for laboratory and especially non-laboratory staff, distribution of written documents, periodical check of routine procedures, improving management of quality indicators through laboratory information system. During the implementation we've become aware of all everyday problems in preanalytical phase and the importance of measuring them. After first six months, our opinion is that monitoring of quality indicators is valuable in assessing laboratory performance and improving our processes and patients' safety, regardless of size and capacity of laboratory. But it's necessary to carefully choose appropriate indicators which are clear, useful in particular lab and convenient for monitoring. We hope that our experience should be useful in establishing national list of quality indicators in our country.

Key words: preanalytical phase, quality indicators.

P103

SERUM DELIPIDATION BUT NOT HIGH-SPEED CENTRIFUGATION IS EFFECTIVE ENOUGH IN CLEARING LIPEMIA INTERFERENCE IN SERUM LIPASE ACTIVITY MEASUREMENT

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Background: Acute pancreatitis is commonly followed by hypertriglyceridemia. Most current diagnostic guidelines indicate that lipase should be preferred over amylase. However, grossly lipemic samples may interfere with routine laboratory methods for measurement of serum lipase activity. We aimed to evaluate the accuracy of lipase activity measurement by a method with declared lipemia interference in lipemic samples cleared by two different techniques: high speed centrifugation and delipidation using alpha-cyclodextrin (non-ionic natural macrocyclic polymer of glucose).

Materials and methods: Thirty-four lipemic serum samples with triglyceride concentration range of 4.27 to 124.6 mmol/L were used in this study. Lipase activity was measured by two measuring principles:
–   Roche Lipase colorimetric method (elective reference laboratory method accurate for lipemic samples), in native lipemic samples on Roche Cobas Integra 400 plus analyzer.
–   Beckman Coulter colorimetric method (lipemia interference >10% above 700 mg/dL Intralipid) in native lipemic samples, and in two serum aliquots cleared of lipemia on Beckman Coulter AU400 analyzer.

The results were compared using Bland & Altman plot. Interference of triglycerides on bias was checked by linear regression. All results were analyzed using MedCalc 9.4.2.0 statistical software (MedCalc Software bvba, Mariakerke, Belgium).

Results: Bland & Altman plot revealed statistically significant bias between the two compared procedures measured in lipemic samples (differences (%): -36.35, 95% CI = -50.5834 to -22.1214) and aliquots cleared by high speed centrifugation (differences (%): -22.1744, 95% CI = -33.7913 to -10.5575). However, there was no statistically or clinically significant bias between the lipase activity measured in aliquots cleared by serum delipidation (differences (%):-4.1871, 95% CI = -9.7848 to 1.4107) nor it was affected by varying triglyceride levels (R^2 = 0.03692, P=0.276).

Conclusions: Serum lipase activity can be accurately measured using Beckman Coulter colorimetric method in grossly lipemic plasma samples cleared of lipemia by serum delipidation.

Key words: acute pancreatitis, lipase, lipid interference, high-speed centrifugation, delipidation

P104

ENSURING OF SUITABLE CONDITIONS OF BIOLOGICAL SAMPLES DURING SHIPMENT TO LABORATORY

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Background: The stability of biological samples is substantial preanalytical factor and can have an important effect on the quality of test results. The recommended storage temperature is +2...+10°C. For achieving this the ice packs are needed in transport boxes. We studied the behavior of customers and monitored this temperature in cooler boxes during transport from customer to the laboratory.
Materials and methods: The cooler box with internal volume 20L and common ice packs were used for shipping of biological samples. The special automate dataloggers and software LogTag Analyzer (LogTag, LSTechnology, UK) were used for temperature measurement in the boxes. Totally 67 measurements were done during several days and every logger measurement produced separate graph. We have chosen the transport times of different lengths. 19 of boxes arrived to the laboratory at the same day when samples were collected (transport time was <10 hours) and 48 were on the way more than 20 hours. At the same time the outside temperature was followed. The measurements were performed from July to October.
Results: 31% of all followed boxes measured temperature within predetermined limits (+2...+10°C). Higher temperature was caused by insufficient number of ice packs or they were not correctly pre-cooled. A normal amount of freezed ice packs keep the temperature stable more than 12 hours before it starts to rise slowly. One customer did not use the ice packs in cooler box, therefore the temperature fluctuated up and down respectively to outside temperature.
Conclusions: Our customers use the ice packs in shipping boxes but not all customers do not freeze ice packs correctly or use insufficient amount to ensure the stability of biological samples during the transport.
Our next steps are the instruction of customers about samples transport requirements and how to ensure suitable conditions.

Key words: biological samples, transport time, cooler box, ice packs

P107

PROTOCOL FOR STORAGE TEMPERATURE DURING TRANSPORT FOR PATIENT SAMPLES BEFORE ROUTINE HEMATOLOGICAL LABORATORY ANALYSIS

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Background: Our laboratories perform analyses for patients from other cities in our country. The protocol that every sample goes through since the moment of blood-draw to the moment of arrival to the laboratory, is carefully planned. The choice of suitable vacuum tubes for serum samples that contain gel-separator barrier, proper and on-time centrifugation, as well as proper storage of the samples on suitable temperature, provide the needed analytes stability.
The question was which is the proper temperature for transportation of blood samples prepared with EDTA for hematology. Our method of measurement is fluorescence flow-cytometry. According to tested procedures by the manufacturer, both room temperature at 20-25 oC and refrigerated at 4-8 oC are appropriate.
The aim was to determine the proper temperature for storage and transportation of EDTA samples before analysis for our group of patients.
Materials and methods: Two EDTA samples per patient were taken, from 20 patients and prepared according to a routine testing protocol for hematology. The samples were kept in two different ambient temperatures prior to analysis: at 20-25 o C and refrigerated at 4-8o C.
All analytes were measured within one hour after blood collection, and after prolonged time to analysis after collection at strictly defined time periods. Samples that were kept at 4-8 oC were carefully kept and mixed until reaching room temperature before analysis.
Results: WBC, RBC, RET, HB, HCT, PLT, MCV, MCHC, did not show statistically relevant change, with $p < 0.001$ for all parameters in both ambient temperatures.
The results statistically proved that the storage temperature during transport has no influence on the cells and on hematological parameters.
Conclusion: Preparing and following a strict protocol of collection, preparation, and storage during transport is a must in the presence and in the future of the upgrading of the whole quality control processes in the laboratory.

Key words: storage temperature, hematology, flow-cytometry, prolonged analysis time

P108

SAMPLE REJECTION REASONS AND RATES IN ERZURUM REGIONAL TRAINING AND RESEARCH HOSPITAL, TURKEY

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Background: We aimed to investigate the preanalytical errors and rejection rates of biological specimens and to quantify performance in the preanalytical phase using sample rejection rule, one of the quality indicators, in the central laboratory of Erzurum Regional Training and Research Hospital, Turkey.
Materials and methods: A retrospective study was conducted in biological specimens received central laboratory over a 11 months period. The reasons and ratios for rejection were investigated in samples for complete blood counts, biochemical and microbiological analyses between January-November 2014.
Results: A total of 1 656 027 samples received to our laboratory. 4356 of them were rejected, giving a rejection rate of 26.3%. The main causes of sample rejection were hemolysis in case of serum samples (35.5%), and clot formation (35.3%) in anticoagulated samples. Of the hemolyzed samples, 19% were belonged to emergency patients. The other sample rejection reasons were incorrect samples (11.9%), inadequate sample volume (10.3%), various errors in sample transportation (5.2%) identification errors such as unlabeled or mislabeled samples (0.7%).
Conclusions: The evaluation of preanalytical processes in the laboratory regarding to sample rejection rate is important for improvement of test result quality. Also, rejected samples had an impact on patient care. Clinicians should be aware of these factors to prevent such rejections.

Key words: Laboratory tests, preanalytical errors, rejection rates.

P109

SIGNIFICANT REDUCTION IN NEEDLES STICK INJURIES THROUGH THE INTRODUCTION OF THE BD PUSH BUTTON BLOOD COLLECTION SET

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Background: Healthcare workers (HCW) who collect blood are at risk of sustaining needlestick injuries (NSI). The European Union estimates that one million NSI occur in Europe annually. Data from a Studio Italiano Rischio Occupazionale da HIV (SIROH) nationwide surveillance program, January 1994-June 2013, shows that 31% of all phlebotomy related injuries occurred in staff associated with the laboratory. Further the 2011 EPINet Surveillance Project reported that approximately 60% of phlebotomy associated injuries occur after device usage. The number of NSI can be reduced by the use of safety devices that cover the needle after use. The safety feature of the BD Push Button Blood Collection Set (BD PBBCS) in this study is activated while the needle is still in the patient's vein, ensuring that the needle is made safe immediately after collection.
Materials and methods: At 2 institutions (National Institute for Infectious Diseases L. Spallanzani. Rome, Italy & North Bristol Hospital Trust, UK), the number of NSI per 100,000 uses (NSI Rate) of first generation safety device was calculated. The sites were then trained in the use of the BD PBBCS, following a 2 month familiarization period, NSI were monitored for 12 months. After the 12 months HCW were asked to complete a questionnaire about the effectiveness and ease of use of the BD PBBCS.
Results: At the UK institution the NSI rate reduced from 5.3 to 1.5, and at the Italian institution from 2.5 to 0. When questioned 91% (Italy) and 85% (UK) of the HCW in the 2 institutions believed that, "Exposure to a contaminated sharp was minimized".
Conclusions: Overall the NSI rate across the 2 sites was reduced by 71% when the second generation safety device, the BD Vacutainer® Push Button Blood Collection Set was introduced. HCW believed that the devices significantly reduced the exposure to a contaminated sharp.

Key words: Needle Stick Injuries (NSI), Blood Collection Set, BD PBBCS

P110

DATA FROM A PREANALYTICAL QUALITY CHECKING SUPPORTS INVESTMENT IN LABORATORY EQUIPMENT & PRACTICE CHANGES

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Background: The General Hospital Murska Sobota, Slovenia is a 400 bed nationally recognized hospital, and treats 13,500 patient annually. The laboratory tests more than 14,000 blood/month of which 125 are rejected due to hemolysis, fibrin, clotting or incorrect fill volume a further 435 are marked as non-conformities at accessioning (ID errors, wrong order, missing data on the request form, no request form / no sample delivered). There are no hospital resources available to monitor the preanalytical practices or provide regular education.
Materials and methods: A BD Preanalytical Quality Check (PAQC) was implemented. Data collection during the PAQC was through observation by experts. Standardized data collection forms were used. The individual steps of the preanalytical phase were assessed starting at blood specimen collection, through transportation & processing of the samples and finally by assessing the resultant sample quality. Eighty (80) blood collections were observed and the quality of 420 samples was assessed.
Results: Inconsistences and errors in the identification practice were observed, with an incomplete or no identification process conducted in 10% of the observed collections, the minimum required information was obtained only 2% of the time. In the laboratory, 16% of the samples for chemistry testing contained fibrin and elevated centrifugation temperatures (45°C) were noted, potentially leading to gel separation abnormalities. Based on the identified preanalytical errors, a training solution was established and conducted on a regular basis in order to provide a sustained solution. New and detailed SOPs were prepared and implemented in accordance with international guidelines. In the laboratory, the results of the PAQC were used to justify new equipment temperature controlled centrifuges to help improve sample quality.
Conclusion: The BD PAQC systematically identified a number of preanalytical errors & poor practices, enabling the hospital to define new procedures, implement a sustained training programme and support investment in new equipment.

Key words: Quality management, preanalytical phase, preanalytical errors, centrifugation

P111

A PATIENT-CENTRED PHLEBOTOMY UNIT

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Background: Managing patient flow in a high-throughput central phlebotomy unit (CPU) is challenging. We recently established a new CPU in our academic hospital whereby 35 outpatient phlebotomy policlinics were consolidated and put under the responsibility of the laboratory. The CPU allows management of 500-700 outpatients daily, and concomitantly facilitates function-testing and structural phlebotomy training of medical students and nurses. Our goal was to enhance patient service by optimizing the phlebotomy pathway with maximal queue-times of 15 and 2 minutes for regular- and STAT patients at peak hour, respectively. Additionally, we introduced phlebotomy time registration (PTR).
Materials and methods: We realized fourteen phlebotomy cubicles with separate patient entry and exit points and sufficient privacy. One cubicle was specifically designed for physically disabled patients. Each cubicle is equipped with automated sample mixers, label printers and computer terminals connected to the laboratory information system, and a patient flow management system (PFMS).
Patients report at the self-service points of the PFMS. The virtual queuing application allows parallel queuing (phlebotomy, specimen drop-off, function-testing, wheelchair service) and prioritizes STAT patients. Estimated queue-time is displayed on monitors. The patient is audio-visually called to a designated cubicle where tube labels are automatically printed after activation of the computerized physician order-entry (CPOE).
Results: During morning peak hour (10-11h, 80-120 patients/hour), in the first 3 months, the mean (95% CI) queue-time was 7.1 (±1.1) and 0.9 (±0,3) minutes for regular- and STAT patients, respectively. Improved staffing reduced mean queuing-time to 5.3 (±1.2, P<0.05) and 0.4 (±0,2, P<0.05) minutes, respectively, the following month. CPOE activation directly prior to phlebotomy enables accurate electronic PTR.
Conclusions: Redesigning care pathways and implementing a PFMS has reduced patient queue-time, raised patient service level and made electronic PTR with full track-and-trace feasible. Real-time and retrospective queue-time analyses allows staffing-by-demand, optimal human resource (re)allocation for function-testing and educational tasks without jeopardizing patient throughput.

Key words: Patient service level; patient flow management; queue-time; phlebotomy registration

P112

STABILITY STUDY OF GLUCOSE AND VITAMIN D CONCENTRATION IN SERUM

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Background: Sample stability in clinical laboratories may be affected by the time taken for transportation from the extraction point to arrival at laboratory. Our hospital assists a population of 350,000 inhabitants, where the farthest point of extraction exceeds 100 kilometers.
Materials and methods: 74 patients serum samples were used for measured vitamin D. One aliquot measured immediately and the other were measured at 24 hours (Cobas e 411® (Roche Diagnostics)). On the other hand, glucose levels in 50 patients were studied. Two samples of each patient, one was processed immediately and the other without centrifugation reserves 6 hours at room temperature (Cobas 8000® (Roche Diagnostics)). The stability study was performed as follow: From interday imprecision values (expressed in CV), the stability controls limits ($\pm$ 1.65 CV) were determined. The sample stability was determined by calculating the value of the sample percentage deviation (DP, %): DP = 100 * $\sum$ (x / x) / n, where n: data pairs number, x: value magnitude centrifuged immediately, and: value magnitude centrifuged after a few hours. Stability controls limits were: -6.6% to +6.6% for glucose (92mg/dl) and -19.8% to +19.8% for vitamin D (20 ng/ml).
Results: The mean glucose value decreased from 112.69 mg /dl to 104 mg /dl for samples centrifuged with 6 hours delay (8.56% DP, out of limits). Meanwhile, samples where vitamin D was determined, the mean values obtained for measured samples to be extracted and at 24 hours were 16.84 ng/dl and 17.98 ng/dl (12.35% DP), respectively.
Conclusions: Glucose stability is affected by the time elapsed from extraction to determination, especially in samples from points of extra-hospital extraction; for this reason it's recommended centrifugation and transport at temperatures below 8°C. Instead, the vitamin D is more stable magnitude so data obtained for samples transported without centrifugation or not cooled immediately are reliable.

Key words: Stability, centrifugation, temperature

P113

PRIOR TO ANALYSIS, HOLDING TIME OF WHOLE BLOOD SAMPLES AND ITS EFFECTS ON HBA1C TEST RESULTS

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Background: HbA1c is a currently used biomarker to predict long term outcome of diabetes, thus plays a fundamental role in the management of diabetes. HbA1c is one of the most frequently used tests in our laboratory. We use the Arkray HA-8160 which is based on reverse-phase cation exchange 'High Performance Liquid Chromatography' (HPLC) for HbA1c analysis of whole blood samples. In this method, Hemoglobin types create peak areas based on the amount in the blood. The HbA1c content is calculated based on the ratio of HbA1c peak area to the total hemoglobin peak areas. The analyzer can be loaded with 100 samples at a time. It requires 3 hours of holding time before analyzing the last sample. Since the device has no function of mixing the samples, last blood samples must be kept waiting on the device before analyzing. Lack of homogeneity of a blood sample can lead to incorrect results. Precipitation of blood cells caused by the holding time of whole blood samples is a significant preanalytical factor that can lead to changes in the test results. In this study, the effects of preanalytical holding time of the whole blood samples on HbA1c results were evaluated.
Materials and method: HbA1c levels of the whole blood samples were measured with Arkray HA-8160 analyzer of 100 random patients that admitted to our laboratory and these samples were analyzed again 3 hours later without turning them upside-down.
Results: In 18 samples out of 100 that were analyzed every three hour, statistically insignificant changes were observed.
Conclusion: Homogeneity of sample achieved by mixing of the blood sample is the significant factor for the quality of analytical results. In our study, we observed that precipitation in the whole blood samples caused by the holding time does not lead to any change in the HbA1c results. HA-8160 HbA1c analyzer is a reliable HPLC analyzer for the analysis of HbA1c and could be very useful for the diagnosis, treatment, monitoring and risk assessment of diabetes.

Key words: Analysis, Hb A1c, whole blood sample, effect, holding time

P114

HOW WELL ARE THE PATIENTS INFORMED ABOUT ORAL GLUCOSE TOLERANCE TESTING?

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Background: Oral glucose tolerance testing (OGTT) is a very important procedure in diagnosing diabetes mellitus. It is very crucial to perform it according to the rules that must be taken into account in preparation period. Our aim was to determine the level of awareness about do's and don'ts in the days before OGTT.
Materials and methods: The 68 outpatients from endocrinology and internal medicine departments, who were sent for OGTT, were asked questions about demographic data, level of education, purpose of the test, diet before the test, how they were informed and blood collection course.
Results: Thirty six female and 32 male patients were enrolled in the study. The mean age of the group was 51.8±12.3. More than the half of the patients (55.9%) were the graduates of the primary school. The knowledge level of the patients about the test were in accordance with their level of education. All of the patients came fasting for the test but most of them did not eat a balanced diet containing proper amount of carbonhydrates and did not tell the doctor about the medicines they took. Although most of the patients knew the purpose of the test, only 16 (23.5%) knew what to pay attention before the test. The patients got information firstly from the clinicians who ordered OGTT and later from the laboratory staff.
Conclusions: Most of the patients did not obey the rules concerning about the procedure. The reason was the lack of information offered to them by their doctors. Although giving information to patients is the responsibility of the doctors, the laboratory staff should try to understand if they are well informed or not, when they are giving OGTT appointment to the patients in order to complement incomplete information.

Key words: OGTT, diabetes mellitus, preanalytical factors

P115

EFFECTS OF IMPLEMENTING DIFFERENT LABORATORY OPERATION MODELS ON TOTAL TESTING PROCESS

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Background: In November 2012, hospitals in Istanbul were grouped into 6-main sections under the name "Community Hospitals' Union". In this new settlement two different laboratory operation models were applied. Model 1 (Central laboratory): All non-urgent patient samples that belong to the registered hospitals of Community Hospitals' Union, will be carried to and run in a central laboratory that is located out of these hospitals as a unique lab or in one of these hospitals that is registered in the union. Model 2 (Integrated Laboratory): Only some of the specific tests will be carried to and run in one of these hospitals that are registered in the union. Other routine tests will run in every hospital's own lab. Our aim was to see the effects of this remodeling and reconstruction on laboratory operations by use of a survey study which is applied to clinicians, laboratory experts and nurses.
Materials and methods: With this questionnaire pre-analytical, analytical and post-analytical phases were evaluated. Surveys were conducted in 4 districts on 1054 people composed of 627 clinicians, 298 nurses (10 technicians) and 86 laboratory experts.
Results: All of the respondents gave "strongly agree" answer to "reliability of this test" question. In evaluating pre-analytical phase, different steps like computer based sample input screens, sample delivery, sample barcodes, sample transports, and sample loses were questioned. In this detailed evaluation of two different laboratory operation models, results of North Anatolian and South Anatolian Community Union Labs which were defined as Model-1 (Centralization of the labs) came out to be similar with each other. Likewise the results of Beyoglu and Cekmece Community Union Labs (Integrated Labs) which were defined as Model-2 came out to be similar to each other, too (p< 0.05). However, the results of Model-1 and Model-2 were statistically different from each other (p<0.05).
Conclusion: It is clear that differences in lab. operation models effect the pre-analytical phase. It is also prominent that the rate and significance of pre-analytical errors are directly proportional to the volume of the samples being carried. It can be inferred that the integrated lab. model is less problematical and less troublesome than the central lab. model.

Key words: Preanalytical phase, lab. operation, central-lab.

P116

A NOVEL BLOOD COLLECTION TUBE CAN PREVENT PRE-ANALYTICAL ERROR OF PLASMA GLUCOSE DETERMINATION

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Background: Plasma glucose determinations are hall mark of laboratory tests for diagnosis of diabetes mellitus (DM) and monitoring of medical treatment in DM patients. Commercial tubes are manufactured by coating with various types of antiglycolytic agents and anticoagulant for blood sample collection. Inno Tube is a tube contains lithium heparin, glyceraldehyde, and mannose and manufactured for blood collection for plasma glucose determination. The objectives of this study were to determine the decreasing of plasma glucose levels obtained from blood samples collected by a novel blood collection tube, Inno Tube, and NaF containing tubes.
Material and methods: Five commercial tubes (Inno Tube, NaF, NaF plus oxalate, NaF plus EDTA, and lithium heparin) were used to collected venous blood of 107 health checkup volunteers and 21 DM patients. Blood cells were incubated with plasma portion from base line to two hours, and then plasma samples were separated for glucose determination by hexokinase.
Results: The results showed that plasma glucose levels obtained from NaF, NaF plus oxalate, NaF plus EDTA, and Inno Tube were not significantly different (P>0.05) at base line, 0.5, 1 and 2 hours. Inno Tube showed 1% decreasing of plasma glucose at low, medium, and high concentrations of glucose levels at 2 hours after blood collection. There was decreasing in plasma glucose obtained from NaF, NaF plus oxalate, NaF plus EDTA blood for 3-7% from baseline levels.
Conclusions: In conclusions, Inno Tube showed the most efficiency for remaining of plasma glucose when plasma portion was incubated with blood cells for two hours. Inno tube may be the alternative blood collection tube for preventing of pre-analytical error in plasma glucose determination.

Key words: plasma glucose, laboratory error, glycolysis, blood cell metabolism

P117

AUTOMATED IT-BASED INTERVAL POP-UP (POP-UP) HAS LITTLE IMPACT ON VITAMIN D (VITD) APPROPRIATE MINIMUM RETESTING

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Background: Based on the UK National Minimum Retesting Interval Project Recommendations, we verified whether POP-UP allows appropriate VitD retesting (minimum=90 days).
Materials and methods: POP-UP was applied for one year to inpatients. One year VitD free (FREE-YEAR) and one year POP-UP (POPUP-YEAR) VitD requests were collected (LIS), comparing outpatients and inpatients. These were further classified as coming from medical, surgical, or maternal and child area. The number of patients with repeated VitD was identified for each area.
Results: VitD was requested once/year in 11.6% and in 13.1% and at least twice in 3.7% and 4.1% inpatients in FREE-YEAR and POPUP-YEAR respectively. Considering both in- and out-patients, VitD assay was offered to 35564 and 38217 patients in FREE-YEAR and POPUP-YEAR, being repeated at least twice in 15% and 13% (X2=42, p<0.0001). This reduction was confirmed among outpatients (from 11.3% to 9.4%), not among inpatients (24% unchanged). The time interval between repeated testing was shorter in POPUP-YEAR (128±1 days) than in FREE-YEAR (179±2 days, mean±SE) (t=25.5, p<0.0001). Time interval between two repeated VitD measures was dependent on POP-UP (p<0.0001), medical area (p<0.0001), gender (p=0.02) and on VitD result (p=0.0005), not on age (p=0.308) (multivariate ANOVA). VitD retesting was classified as appropriate (<=90 days) or non-appropriate (>90 days). A significant decrease in inappropriate retesting was observed in POPUP-YEAR for inpatients belonging to medical (p<0.0001) or surgical (p=0.003) areas, while it increased in the maternal and child area or remained unchanged among outpatients (p=0.089). For 4 months POP-UP was replaced by an IT-block for inpatients or a clinical comment for outpatients, and this caused a fall in retesting to 2.5%.
Conclusion: although POP-UP might determine a slight reduction in inappropriate VitD retesting, this approach does not render appropriateness a routine. Minimal retesting interval rejection rules appear a cheap and sustainable method toward more appropriate retesting.

Key words: Minimum retesting, laboratory information system, appropriateness

P118

STABILITY STUDY OF pH, pCO_2, pO_2, SO_2 AND LACTATE CONCENTRATION IN BLOOD SAMPLES

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Background: Blood gas analysis provides information on acid-base balance and oxygenation status of patients. The aim of this study was to analyze the influence of time and storage temperature on the stability of pH, pCO_2, pO_2, sO_2 and lactate concentration in blood samples.

Materials and methods: Blood samples were collected in plastic syringes containing lithium heparin and analyzed on ABL 800 (Radiometer). Elapsed time since blood collection until the analysis was less than 10 minutes in all cases. After the first measurement, samples were preserved under different conditions (25°C, 4-8°C or 0-3.9°C, during 15, 30, 45 or 60 minutes). All samples were retested afterwards. The minimum number of samples for each group was 27.

Acceptance stability limits (S) were determined by *Sociedad Española de Bioquímica Clínica* criteria (S=±1.65*CV*). *CV* was calculated from the differences between duplicate results obtained by analyzing at least 60 samples from patients. The percentage deviation (PD) between the first and the second result, for each biological quantities and storage condition, was calculated as follows: PD= 100 ($\sum$(*Yi- Xi*) /*Xi*)/*n*. Significant changes were detected when PD exceeded the goal limit (S).

Results: pH was stable 30 minutes at 25°C and within 60 minutes, at 4-8 and at 0-3.9°C. pCO_2 was stable at all times and temperatures studied. pO_2 and lactate were not stable at 25°C or at 4-8°C for the shortest time of our study (15 min), but both were stable 45 minutes at 0-3.9°C. *S* at O_2 was stable only in the first 15 minutes at 25°C and at 4-8°C; however, it was stable for 60 minutes at 0-3.9°C.

Conclusions: The storage temperature which allowed longer stability was in the range of 0-3.9°C. In those conditions, samples could be analyzed after 45 minutes, because this was the maximum stability time for the whole set of biological quantities studied.

Key words: Blood gas, time, storage temperature and stability

P119

QUALITY INDICATORS IN PRE-ANALYTICAL PHASE IN ACCREDITED SEROLOGY LABORATORY

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Background: Serology laboratory for diagnostic of hepatitis A, B, C and D, and HIV, Syphilis, CMV, Toxo, Borrelia, HTLV-I/II and EBV infections is accredited due to ISO 15189:2008 since March 2014. Institute is also certificated according to ISO 9001:2008 (since 2001). As a part of quality assurance, Quality Indicators (QIs) are established to monitor and evaluate performance of critical aspects in pre-analytical, analytical and post-analytical phases. Patient samples are from inpatients (collected in CITM) and outpatients (collected outside CITM- hospitals, private laboratories, etc.).

Materials and methods: Appropriate QIs in pre-analytical phase were determined: a. outside CITM: a1. request-misidentified, a2. sample-improperly labeled, a3. sample-nonconform (a3.1. lipemia, a3.2. hemolysis and a3.3. icterus-due to color chart with our guidelines or a3.4. viscosity), a4. sample-clotted, a5. sample-insufficient, a6. sample-improper transport, a7. sample-damaged, a8. insufficient patient's data, a9. order-in-correct, a10. container-inappropriate, b. inside CITM but outside laboratory: entry data (e-Delphyn Information System) errors-b1. wrong name, b2. wrong DOB, b3. wrong identification number, b4. missed test. Since January 2014-October 2014 we tested 18605 patient samples and QIs were analyzed.

Results: In mentioned period we identified 2 samples for a1 nonconformity, 2 samples for a2, 2 samples for a3.2, 1 for a3.4, 1 for a4, 2 for b1, 1 for b2, 1 for b3 and 1 for b4. The QIs for and "entry data errors" are the primary nonconformities.

Conclusions: QIs in pre-analytical phase show that the most prevalent errors are in pre-pre-analytical phase (outside CITM) and errors in data entry to e-Delphyn Information System. Due to risk assessment and risk analysis (FMEA-Failure mode and Effects Analysis) of the TTP (Total Testing Processes) in the laboratory, the highest risk levels are also in determined pre-analytical phases. QIs are valuable tools for quantifying the quality comparing against a defined criteria, they are plan and action.

Key words: serology laboratory, quality indicators, pre-analytical phase

P120

PRE-ANALYTICAL OPTIMIZATION OF PLASMA AMMONIA

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Background: The major sources of variation in ammonia measurement are probably to be due to pre-analytical factors. The sample should be transported on ice, separated within 15 minutes of collection and analyzed in a short period of time. In addition to this, other factors such as age, pharmacological treatments, physical exercise or smoke can cause false positive results. The aim is to evaluate the results of ammonia measurements in the Emergency Laboratory according to the pre-analytical recommendations by evidence-based guidelines.

Materials and methods: We studied the ammonia requests received in the Emergency Laboratory during two years. The determination was performed on EDTA tube by the enzyme glutamate dehydrogenase and reduction of the absorbance of NADPH formed. Previously, we informed to the hospital units about the pre-analytical recommendations during collection and transportation of the samples.

Results: We received 415 samples of plasma for analyzing ammonia, 52 (12.5%) not followed the pre-analytical conditions and 81 (19.5%) showed pathological results.

The causes of hyperammonemia were classified as: acquired 60.5% (liver failure, hepatic encephalopathy, sepsis, drugs), defects of the urea cycle 14.8% (citrullinaemia, argininaemia), other metabolic disorders 11.1% (organic acidurias, lysinuric protein intolerance), and others non-classifieds 13.6%.

Conclusions: For reducing the percentage of pre-analytical errors, staff who perform ammonia measurements should be aware of the factors that origin false positive results. It should be necessary to provide guidance with the standard operating procedures on the measurement of ammonia.

To improve the accuracy of the analysis, all elevated ammonia results should be confirmed with a second sample to exclude false positives 4 hours later.

Key words: false positive results, ammonia levels, pre-analytical recommendations.

P121

THE IMPORTANCE OF THE THIRD SAMPLE IN MYCOBACTERIAL RECOVERY

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Background: A definitive tuberculosis diagnosis requires the isolation of the etiologic agent from clinical samples. Sputum is the specimen most commonly sent to the laboratory when pulmonary TB is suspected, as well as, other lung disease caused by other mycobacteria species, called non tuberculous mycobacteria (NTM). For cultural mycobacteriological study, three sputum samples after deep productive cough with a minimum volume of 5 ml are recommended. Samples must be taken at early morning on three consecutive days. However, some studies have questioned the third sample value.

Materials and methods: We estimate the number of patients for which the third sputum sample was crucial for a positive result in mycobacterial culture. The study included 19629 samples (10595 patients) analyzed between January 2010 and September 2014.

Results: Of 19629 samples, we found a positive result in 1421 (7,2%), corresponding to 650 (6,1%) patients, 455 (70%) males and 195 (30%) females, with an average age of 53/55, respectively. Among these patients, 254 (39,1%) were attended at the respiratory diseases department and 108 (16,6%), 89 (13,7%), 44 (6,8%) and 155 (23,8%) at the departments of emergency, infectious diseases, medicine and others, respectively. 423 (65,1%) were outpatients and 227 (34,9%) inpatients. In 253 (38,9%) patients, 153 males and 100 females, a NTM strain was isolated. The third sample was necessary in 73 (11,2%) patients, 9% of males and 16,4% of females with an average age of 62/63, respectively. Fifty-five (75,3%) were attended in respiratory diseases department and 69 (94,5%) corresponded to outpatients. In 9 patients a strain of *Mycobacterium tuberculosis* was identified whereas in the remaining 64 was identified a NTM strain, which corresponds to 25,3% of the total number of patients with NTM.

Conclusions: The third sample appears to be more important in the recovery of NTM. Additionally, also seems to be more critical in females, older patients and outpatients, probably due to failures in collecting samples.

Key words: Sputum, Tuberculosis, Non Tuberculous Mycobacteria

P122

TIME AND TEMPERATURE CONTROL AS QUALITY INDICATORS IN THE TRANSPORT OF BLOOD SAMPLES

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Background: The preanalytical phase encompasses all processes taking place since the doctor asks a petition to the laboratory until the sample is analyzed. One of the critical points of this phase is the transport of samples from the center of extraction to the clinical laboratory. The minimum checks to be made to ensure the stability of these are the temperature control, transport time and the control of the packaging requirements. The National Committee for Clinical Laboratory Standards (NCCLS) 1994-H3 H5 Guide recommends a maximum of two hours for the transport of blood samples at a temperature of 10-22°C.

Materials and methods: We implanted a new transportation system consisting in refrigerators adequate to P650 packing instruction and a datalogger (BQ tempstick and Mission Started) that record the temperature and the time elapsed since the samples are extracted in health centers until they are received in the clinical laboratory. Records obtained during 12 months were analyzed with the Excel spreadsheet. Our objective was to evaluate the new transport system samples after one year of implementation verifying whether the results are appropriate to the time and temperature indicators described by the NCCLS guide.

Results: A total of 1665 records from the 12 existing transport routes in the health area studied were obtained: At 97.36% of records, transport time the standard condition (<2 hours) is met; however, only 62.16% of which the temperature is maintained between 10-22ºC.

Conclusions: These records let us know our actual working conditions, allowing us to take steps to continuous quality improvement; in our case we found that the routes are correctly designed, but a new educational intervention in health centers for better cooling of the refrigerators is needed. In this way we adapt to the quality standards proposed by the Agency for Health Quality of Andalusia.

Key words: Samples transport conditions, transport time, transport temperature

P124

EVALUATION OF PREANALYTICAL INCIDENTS IN AN EMERGENCIES LABORATORY AFTER THE IMPLEMENTATION OF A COMPUTERIZED SYSTEM OF RECORD

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Background: The preanalytical phase is a crucial part of the analytical process. Mistakes made at this stage constitute 60-80% of total clinical laboratory errors. These involve a high consumption of resources, not only economic, but also from time to resolution, and delay in delivery of results. In short, both can influence analytical results and clinical laboratory productivity. The record of preanalytical incidents allow an agile data exploitation, thus promoting improvement actions to complete the necessary process of continuous improvement in the quality of clinical laboratory. Therefore we implemented in our emergency laboratory a Computerized System to register all preanalytical incidents.

Objective: Evaluate the preanalytical incidents registration system in the emergency laboratory in its first nine months of operation.

Materials and methods: To achieve the computerized recording of preanalytical incidents, we implemented a specific preanalytical comment where the most common incidents were coded, serving as a communication system to relevant services and subsequent working tool for data exploitation. Nine months of system operation were analyzed using the statistical module data of OpenLab SIL.

Results: We obtained 9.15% of incidences in preanalytical phase (1655 incidents in a total of 18086 emergency analytic requests). The incidence that scored a greater number of records was "missing sample" (5.16%), from this, 85,01% are "Foul urine sample". The second more frequent incidence was "hemolyzed sample" (2%).

Conclusions: The results in terms of percentage of incidents are similar to those described in the literature, so we can conclude that we are making good use of the new registration system. Knowing our most frequent failures allow us to improve the preanalytical incident management.

Key Words: Preanalytical incidents record. Computerized register.

P126

DO WE NEED ADDITIONAL INDICATIONS FOR ALPHA-1-ANTITRYPSIN DEFICIENCY TESTING IN PAEDIATRIC PATIENTS?- RESULTS FROM A PILOT STUDY

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Background: Alpha-1-antitrypsin deficiency represents one of the most important inherited causes of liver disease in children. Considering the unsatisfactory detective effectiveness for this condition, the aim was to evaluate whether testing indications other than liver disease might be relevant in pediatric patients.
Materials and methods: Study included 25 subjects (14 girls/11 boys, median age 8 (0-19) years). Liver disease was indication in 10 cases, while among the remaining patients 10 developed lung disorders (recurring bronchitis, asthma and pneumothorax) and 5 were tested due to the family history of deficiency. Molecular analysis of the Z and S deficiency alleles was performed with PCR followed by hybridization with allele specific oligonucleotides. Statistical analysis included Fisher exact P test.
Results: In general, deficiency was confirmed in two participants, while 7 of them were heterozygous carriers. Two cases of deficiency were detected among patients with liver disease, both being homozygous for Z allele. Four heterozygous carriers of Z allele were identified in a group referred to testing due to hepatic disorder, while among those with extra-hepatic indications three heterozygous carriers (two of Z and one of S allele) were present. Significant differences between two types of indication were not observed regarding genotypes' distribution (P=0.062), as well as in number of patients with deficiency (P=0.150) or heterozygous carriers (P=0.378).
Conclusions: Presented results indicate that family history and specific lung disorders might be relevant indications for alpha-1-antitrypsin deficiency testing in pediatric patients. However, these pilot results need to be confirmed in larger studies.

Key words: Alpha-1-antitrypsin deficiency, pediatrics, molecular diagnostics

P128

RETROSPECTIVE ANALYSIS OF TROPONIN I REJECTED SOLICITUDES BY HEMOLYZED SAMPLE

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Background: The cardiac troponin I (TnI) assay is used for the diagnosis of acute myocardial infarction (AMI). 20% change in the value of troponin is considered suggestive of a heart attack happening. For our test, a hemolytic index (HI) superior to 150 causes more than 20% of change in the value of cTnI. In our laboratory a visual inspection of the sample is performed, and if it shows hemolysis, troponin results are not informed, new tests are requested to correctly determine the value.
Materials and methods: Conduct a retrospective analysis of Troponin I solicitudes rejected by hemolyzed sample in our laboratory between 01/01/2014-30/06/2014, analyzing the hemolytic index with which the sample was rejected. Check how many requests were rejected by hemolysis compared to the total requests of troponin. Determine how many were rejected with a lower hemolytic index of 150 when visual inspection was made.
Samples were analyzed on Vitros 5600.

For this, OPENLAB Laboratory computer system statistical tool was used. HI result obtained for each sample in the SI rejected Vitros sought.

Results: In the period studied a total of 4255 troponin requests were received in the laboratory. 139 were rejected by visual detection of hemolysis in the sample, index of rejection of 3.2%. Of the 139 rejected samples, the analyzer was unable to determine the hemolytic index in 12 of them. Of the 127 samples in which it was correctly determined, 38 (30%) had IH<150.

Conclusions: 30% of troponins which were rejected by showing visual hemolysis did not have an IH>150, and therefore could have been conducted and reported without considering it an analytical interference. Troponin rejection depending on the hemolytic index must replace traditional visual inspection.

Key words: Hemolyzed sample, Troponin, Preanalytical interference.

P129

PREANALYTICAL VARIABLES IN LIPID PROFILE MEASUREMENT

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Background: Cardiovascular disease is the most common cause of death worldwide.
Abnormalities in plasma lipoproteins and derangement in lipid metabolism remain the best explained and the leading risk factors for atherosclerosis.
The value of an accurate lipid measurement as a tool for cardiovascular risk assessment and prediction is well established.
The lipid profile involves mainly testing for total cholesterol and his fractions and triglycerides. A number of studies described physiological variations in cholesterol, triglycerides and lipoproteins that add to analytical variations. As opposed to analytical variations that are small, physiological variations are much larger and contribute to the majority of the variation in lipid and lipoprotein levels.

Materials and methods: A review of the literature was made in books and electronic databases without restriction on type of the article or publication year.

Results: Several biological factors can affect lipid and lipoprotein levels such as gender, age, posture, diet and alcohol, fasting, physical activity and medications. Those levels also have diurnal and seasonal variation. Pregnancy and other hormonal states, alterations of glucose metabolism, trauma, infection and other diseases states are also involved.
Other factors occurring during blood collection, storage and transport to the laboratory can also be mentioned, including time of tourniquet application, the choice of anticoagulant and the type of sample.

Conclusions: Considering that the diagnosis and the management of lipid metabolism alterations are based on laboratory measures, the standardization of lipid measurements should be implemented in order to avoid cost to society, avoid harm to the patient and to provide him the best care.

Key words: preanalytical, variable, lipid profile, cardiovascular risk, measurement

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BD PAQC ENABLES CLOSE PARTNERSHIP BETWEEN THE LABORATORY & NURSING TEAMS AT HALMSTAD REGIONAL HOSPITAL, SWEDEN

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Background: The Regional Hospital is located in the city of Halmstad and conducts around 2 million analysis per year. The Laboratory is responsible for providing high quality, fast and accurate result to help the physicians in the treatment of patients. The laboratory has implement a fully automated instrumentation system including preanalytical workstations to reduce Turnaround Time (TAT). However some of the improvements are being offset by inefficiencies resulting from poor preanalytical practices.

Materials and methods: An audit of the blood collection processes and their subsequent impact on sample quality was implemented using the BD Preanalytical Quality Check (PAQC). This implementation required the laboratory and nursing teams to work together to ensure its successful implementation.

Result: Results of the PAQC were presented to the nursing and laboratory management teams. The management team agreed to support an education program led by the laboratory instructor for all staff. A tailored training programme focused on the areas highlighted by the PAQC was delivered to all staff at Halmstad regional hospital. More than 500 persons of the hospital staff have attended these training session during 2014.

Conclusion: The use of the BD PAQC ensured closer alignment between the nursing and laboratory management team and the delivery of a sustained and high quality training programme. These improvements ensure that laboratory maximizes its gains in TAT.

Key words: Education, TAT, Preanalytical quality check

P131

STUDY OF THE PREANALYTICAL PHASE IN THE BIOCHEMISTRY LABORATORY OF ST LUC HOSPITAL MBALMAYO-CAMEROON

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Background: The preanalytical phase is an important part in achieving the medical biology examinations. Multiple sources of errors are due to the absence of procedures. Indeed, 85% of non-conformities during biological analyzes are in this phase. The aim of this work was to study the pre-analytical phase of the biochemistry laboratory, St Luc Hospital Mbalmayo – Cameroon.

Materials and methods: This was a descriptive study for a month at biochemistry laboratory, St. Luc Hospital Mbalmayo in Cameroon. The study was conducted through an audit record comprising the steps of pre-analytical phase: prescription, blood sampling, and transport of sample. For each patient with biochemical analyzes to do, a form was filled from the sample room and sample drawn to the laboratory.

Results: We observed a lack of information: no clinical information (100%), no sex (0.5%), no age (0.5%) no requested tests (0, 5%). Patients were not fasting in 29% of cases. Concerning the sampling phase, we observed 8% of non-conformities concerning the filling tube order and in 78% of cases, the tolerance zone was not respected.

The exposure time of tourniquet was less than 1 minute in 46% of cases and more than 2 minutes in 37.5% of cases. The delivery time of samples to the laboratory was 30 minutes in 85% of cases, and less than 30 minutes in 15% of cases. 78.5% of samples were transported by hands.

Conclusion: Non conformities management of the pre-analytical phase requires adequate training of laboratory personnel.

Key words: preanalytical phase, non-conformities, St. Luc Hospital, Mbalmayo

P132

THE PARTICIPATION OF SERBIAN MEDICAL LABORATORIES IN MQI

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Background: Quality indicators (QIs) are an objective quantified measure of quality in each of the segments of health care in comparison with selected criteria. Model of Quality Indicator (MQI) is a platform undertaken by the Working Group "Laboratory Errors and Patient Safety" instituted by the division of Education and Management of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).

Materials and methods: This list of QIs in MQI contains a series of QIs, covering all steps of the total testing process (TTP), that have been considered to be applicable to all laboratories no matter their organization, complexity, technological level and according to the priority score. Serbian laboratories that are included in MQI have a goal to test QIs and collect data during a 6-month period. Periodically collected QIs are sent monthly to the IFCC website.

Results: Policlinic laboratory of Clinical Centre of Serbia, in Belgrade, has been included in MQI from 2011. In 2014. seventeen more Serbian laboratories from various cities were involved in this project. IQs are monitored by ten laboratories from University Clinical Center (UCC) of Serbia in Belgrade, one laboratory from UCC of Nis, five laboratories of General Hospitals and two laboratories from Primary Health Care level. Laboratories are monitoring QIs applicable to the health care level: laboratories of UCCs (tertiary health care level) are following 15-53 QIs, laboratories of General Hospitals (secondary health care level) are following 28-40 QIs, laboratories from Primary Health Care level are following 15-32 QIs.

Conclusion: Data on QIs followed in medical laboratories in Serbia will be used for harmonization of QIs on international level as well as for definition of national QIs, which will improve the quality of work and avoid potential errors in all the steps of the TTP.

Key words: Quality indicators, Model of Quality Indicators, medical laboratories, patient safety

P133

ULSM (MATOSINHOS LOCAL HEALTH CARE): PRE-ANALYTICAL PHASE

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Background: A key issue in our Medical Lab Organization is definitely the Pre-Analytical Phase. The huge investment in this area, both in the Processes and People commitment results in very thoughtful laboratorial quality standard procedures in the initial steps of the laboratory testing.

Materials and methods: Most of our BS (biological samples), about six hundred a day, arrive from the four primary care units. Our vans carry them each hour, from 8 am until 11 am, to our Clinical Pathology Service/Core Lab. All this method is carried out by qualified lab technicians and the sample collecting, handling, preparing, transporting and storage conditions obey a severe rule set. The transportation times, the sample temperatures, the qualified collectors and the core lab technician receivers, causes for sample rejection or other issues are all registered, continually monitored and evaluated by our Quality Management System.

Results: The outcome of these attentive procedures is the improvement of ULSM organization. Reliable test results are one of the main consequences of this effort, resulting from the improvement and the implementation processes corrections after the decreasing of the Pre-Analytical errors.

The significance of an efficient organization consequently improves the work of all health care technicians. And the effective patient care is better, his clinical diagnostic, the subsequent treatment and an eventual follow up is truly reliable.

Conclusions: The results of a thoughtful Pre-Analytical Phase play a key role ensuring the continuous improvement activities aiming to reduce the risk of errors in clinical practice.

Key words: Pre-Analytical Phase; Quality Management System; Laboratory Testing.

P134

THE EFFECT OF USING BD LUER-LOK™ ADAPTER ON HEMOLYSIS IN BLOOD SAMPLES DRAWN FROM INTRAVENOUS CATHETERS

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Background: Preanalytical phase is important for laboratory errors in clinical laboratories that affect the results. Preanalytical phase errors constitute 46-68.2%, postanalytical phase errors constitute the 18.5-47%'s of the total errors.

Hemolysis is the most frequent laboratory problem in the analytical term. Hemolyzed samples constitute approximately 40% to 70% of the samples within the definition of unsuitable sample and observed 5 times more than other reasons. In particular, the rate of hemolyzed samples is comprehensively higher, up to 8%, in samples collected in the emergency department.

BD Luer-Lok™ Access Device, a sterile device that screwing to intravenous catheter provides collection of blood to the tube by negative pressure without need for syringes in intravenous catheter inserted patients. In this study; we aimed to study, the effect of using luer-lok adapter and syringe to hemolysis.

Material and method: Blood was drawn both with luer-lok adapter and syringe to different collecting tubes from fifty patients who inserted intravenous catheter at emergency department. The hemolysis index (HI), aspartate aminotransferase (AST), potassium (K), lactate dehydrogenase (LDH) levels were measured by the auto analyzer (Architect C 16000, Abbott Diagnostic Systems, Illinois, USA).

Result: The mean hemolysis index of samples drawn by syringe (131.69 ± 125.1) was significantly higher (p=0.016) than the samples drawn by luer-lok (23.15 ± 38.8). Also, the mean K (p=0.011), AST (p=0.016) and LDH (p=0.019) levels were significantly higher in samples drawn by syringe than the samples drawn by luer-lok. The mean ± SD values of the samples drawn by syringe and luer-lock were respectively 5.05 ± 0.70 and 4.47 ±0.61 for K, 52.77 ± 53.44 and 42.46 ± 51.34 for AST, 424.85 ±357.39 and 312.23 ± 431.67 for LDH.

Conclusions: According to our data using Luer-Lok™ Access Device for drawing blood from intravenous catheters may be effective for reducing hemolysis.

Key words: Preanalytical phase, Luer-Lok Access Device, Hemolysis

P135

STABILITY STUDY OF pH, pCO_2, pO_2, SO_2 AND LACTATE CONCENTRATION IN BLOOD SAMPLES REGARDING THEIR CONCENTRATION

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Background: The aim of this study was to analyze the influence of time and storage temperature on the stability of blood gas quantities and lactate concentration, according to its initial value.

Materials and methods: Blood samples were collected in plastic syringes, containing anticoagulant, and analyzed on ABL 800 (Radiometer) in less than 10 minutes upon arrival at the laboratory. After storage at 25°C, 4-8°C or 0-3.9°C, during 15, 30, 45 or 60 minutes, were retested afterwards. Results were classified according to the value obtained in the first measurement (within reference range, below the lower limit and above the upper limit of the reference range) for pH, pCO_2 and pO_2; and below and above the upper limit of the reference range, for SO_2 and lactate. Minimum sample size was 26 for each group.

Acceptance stability limits (S) were determined by *SEQC* criteria (S=±1.65*CV*). *CV* was obtained using duplicate measurements. Percentage deviation (PD) was calculated: PD=100($\sum$(*Yi-Xi*)/*Xi*)/*n*. Significant changes were detected when PD exceeded the goal limit (S).

Results: pH and pCO_2 were stable in all groups at 4-8°C and 0-3.9°C. At 25°C were stable for 30 minutes in the group below the lower limit, and 15 minutes and 45 minutes, respectively, within the reference range. pO_2 is not stable at 15 minutes in any group, except for the group below the lower limit at 0-3.9°C, which was stable at all times studied. SO_2 was stable under all conditions in the group above the upper limit, and for more than 60 minutes at 0-3.9°C in the group bellow upper limit. Lactate, in both groups, was stable at all times at 0-3.9°C.

Conclusions: The value of the quantity has influence in its stability. As it is unpredictable before processing the sample, the tightest criteria for samples conservation should be adopted.

Key words: blood gas, lactate, stability, temperature, storage.

P136

SAMPLES HBA1C STORAGE: ROOM TEMPERATURE OR NOT?

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Background: Hemoglobin A1c (HbA1c) measurement is now considered the gold standard for long term (2-3 months), glycemic control in diabetic patients, as well as an index of developing diabetic complications; and HbA1c measurements have been proposed for diagnosing diabetes mellitus (limit 6,5%, 48 mmol/mol). So it's important to influence the preanalytical phase of this magnitude.

Materials and methods: Whole blood EDTA samples with three concentration levels (low (5,5%), intermediate (7,4%) and high (12%)) were kept at room temperature, and HbA1c concentration was measured daily by the 3 analytical platforms during 11 days. These platforms were: HPLC-ADAMS® HA-8180v (Menarini), capillary electrophoresis Capillarys2® Flex Piercing (Sebia) and immunoturbidimetry Cobas® Integra 800 (Roche Diagnostics). Before the start of the study, the 3 platforms were calibrated with the appropriate materials for each one provided by manufacturers. Calculation of standard deviations (SD) were made with the program MedCalc® software package.

Results: Samples selected at the three concentrations remain constant and equal to the baseline until day 7. From day 8, a gradual decrease was observed which last until day 11. After 11 days, the decrease ranges from 0.7% to 0.9%.

Conclusions: In clinical laboratories with high sample volumes, it is frequent to delay the assay. Likewise, these laboratories have a further problem of space availability for storage of samples refrigerated. According to this, stability of samples maintained without refrigeration was evaluated for a long term (two weeks). Stability of HbA1c was maintained during 7 days in these conditions. This represents an important advantage, since these samples can be kept at room temperature booking stays chilled for more temperature sensitive samples.

Key words: HbA1c, stability, concentration

P137

ERRORS OF PREANALYTIC PHASE IN A CENTRAL LABORATORY

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Background: Over the last decade, in clinical laboratories, the preanalytical conditions of the testing cycle are still more error prone than the analytical and postanalytical phase. The aim of our study is to monitor the preanalytical phase from the sampling accessioning to the handling prior to testing in our hospital.

Methods: During two days we observed 73 nurses blood drawing from 337 patient and blood collected to the 1347 tubes in selected 11 different departments. We monitor strictly the workflow analysis of sample accessioning tube labeling, transport time and healthcare worker safety) and sample quality (tube fill volume, clotting and fibrin and hemolysis)

Results: In all departments 337 blood drawing and sample collection are performed by the nurses (100%). Blood drawing was done from antecubital fossa in 288patient, from hand in 92 patient. In 263 patient nurses used safety needles where as in 25 used catheter and in 38 used needle and syringe. After blood drawing 98% of the tubes didn't mixed with inversion by nurses. 92% of the nurses worn gloves during collection. The specimen labelling was prior to the sampling (80%). Specimens were transported manually by ward staff, and turnaround time was approximately 50 minutes. The sample acceptation was done with the barcode and centrifugation began within 10 minutes. From 971 chemistry tube, 40% had fill volume error while the hemolysis was seen in 17% and the clotting and fibrin were seen in 6%. Tubes with EDTA and Citrate had fill volume error 12% and 20% respectively. Clotting and platelet clumps were seen in 1% of EDTA tubes. Hemolysis was seen in 10% of the citrate tubes.

Conclusion: The findings made in the present study to confirm the relative frequency of error from preanalytical phase so the need for more effective procedures for quality assessment requirements.

Key words: Preanalytical Errors, Turn Around Time (TAT), Fill Volume Error

P138

INFLUENCE OF DIALYSIS PROCEDURE ON BONE MARKERS

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Background: Bone markers are deeply influenced by the bone disease in end-stage renal failure and also by the type of dialysis procedure. Contrary to classic hemodialysis on-line haemodiafiltration significantly decreases serum levels of CTx, with marginal decrease of serum P1NP. Influence of the type of dialysis solution on bone markers during haemodiafiltration wasn't studied yet.

Materials and methods: Thirty men with end-stage renal failure on maintenance dialysis by haemodiafiltration (more permeable membrane, combining diffusive and convective transport in comparison with classic hemodialysis) were investigated. Two different dialysis solutions were used: bicarbonate with 3 mmol/l of acetate (BIC, 8 men) and bicarbonate with 0.8 mmol/l of acetate (BIK, 22 men). Both procedures:

4 hours, dialysate Ca concentration 1.5 mmol/l, polysulphone membrane $1.8m^2$. Groups were comparable by age (median 59 years) and by the duration of disease. CTx (μg/l), and P1NP (μg/l) were determined by immunoassay, Roche; PTH (PTH 1-84, pmol/l) by immunoanalysis, DiaSorin, Italy. All test were performed just before the dialysis procedure and immediately after haemodiafiltration.

Results: Higher concentration of acetate in dialysis solution (BIK vs BIC) leads to deeper decrease of CTx (from 2.08 to 0.37 vs 2.15 to 0.78 μg/l) p = 0.005, and PTH (from 17.75 to 6.05 pmol/l in BIK vs non-significant increase from 21.90 to 23.00 pmol/l in BIC), p = 0.007. Decrease of concentrations of P1NP was comparable in both groups.

Conclusions: Bone markers change during dialysis elimination procedures, the type of dialysis solution influences these changes significantly. Type of elimination procedure and type of dialysis solution are important preanalytical factors.

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Key words: preanalytics, bone markers, dialysis

P139

EVALUATION OF THE EFFECT OF THREE PREANALYTICAL VARIABLES ON HAEMOLYSIS OF BLOOD COLLECTION TUBES

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Background: In vitro hemolysis remains a leading cause of unsuitable specimens (40-70%) and is thus a major concern for clinical laboratories worldwide. It is caused primarily by inappropriate specimen collection and handling, and is suggested to be a suitable indicator of preanalytical quality. Three preanalytical variables (fill volume, mixing and the residual vacuum left when a tube is not completely full) were investigated as possible causes of the increased incidence of hemolysis.

Materials and methods: Eleven blood specimens were collected from each of the 28 volunteers: 1 discard tube to prime the collection device and 10 BD Vacutainer® Lithium Heparin Tubes, pre-labelled with a randomized schedule for half the draw volume, mixing and/or venting. Tubes designated for mixing were inverted by the GME Labsystems T-Swing Mixer, and samples designated for venting were decapped and recapped immediately post collection.

Specimens were centrifuged at 1300g for 10min at 25°C, followed by visual inspection of sample quality, hemolysis index (HI) and analysis within 4hr of blood collection. Potassium (K), lactate dehydrogenase (LDH), phosphate and HI were measured on the Roche Integra 400 Plus, whilst folate was tested on Roche Elecsys 2010. The data were compared by ANOVA.

Results: Fully-filled tubes irrespective of mixing/venting showed no increase in hemolysis and no statistical difference in K, LDH, phosphate/folate results. Underfilled tubes lead to higher levels of hemolysis (p<0.001) especially if in combination with mixing (p<0.05) and venting (p<0.001). Venting alone had little impact on the HI and analyte results, unless in combination with half draw/mixing (p<0.001) where further hemolysis occurred. Underfilled, mixed and vented tubes in combination lead to higher K, LDH and folate results (p<0.05).

Conclusions: The data demonstrate that the incidence of hemolysis is higher when tubes are underfilled. It is thus important that tubes are filled to the correct volume and mixed as per manufacturer's recommendations.

Key words: Hemolysis, Underfilling, BD Vacutainer®, Mixing, Venting, Vacuum.

P140

APPROPRIATENESS OF CLINICAL REQUEST: IS IT POSSIBLE TO MEASURE IT?

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Background: Evaluation of the requested tests appropriateness (AT) is a domain of the pre-analytical phase where laboratory is strongly involved, but its measurement is very difficult for laboratory professionals because it requires a deep knowledge of the patient's health care status. The Aim of this work is to report the results of two quality indicators (QIs) to measure the percentage of requests reporting the clinical question (CQ) and the appropriateness of requested tests.

Materials and methods: 797 outpatient requests, collected in November 2013, were counted and the AT analyzed (by a group of laboratory professionals on the basis of clinical recommendations about the use of tests) with respect to CQ (776) and data stored in our repository.

Results: 2013 requests with CQ (97%) compared to 2007 ones (26,5%) resulted: congruent, 71.1% and 80.4%; partially congruent, 12.2% (17% missed, 83% added tests) and 8.2%; incongruent (not responding to CQ), 11.2% and 3.1%; with unspecific CQ, 5% and 2.3%; with incorrect CQ, 0% and 0.8%; difficult to assess, 0.5% and 5.2%. In many cases, requests with added tests concern patients with diseases (51.6%) that are not linked to reported CQ or patients free of costs (48.4%, i.e. disabled, low-income).

Conclusions: The requests with CQ increased over time while the appropriateness slightly decreased. This could be due to the issue of a national regulation that imposes the introduction of CQ in the requests and a raising awareness of laboratory but, also, it highlights the need to better educate physicians on the appropriate use of the test. Even if it has been not assigned the higher priority for the difficulty of measurement to the two QIs introduced in the list proposed in the Consensus Conference held in Padova on 2013, their use is very important to identify the aspects that negatively impact on appropriateness.

Key words: appropriateness, test requests, quality indicators

P141

CRITICAL ASPECTS IN THE MANAGEMENT OF THE PRE-ANALYTICAL PHASE FOR CRYOGLOBULIN DETECTION

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Background: Cryoglobulins are serum immunoglobulins that undergo reversible precipitation below 37°C and may be re-dissolved upon rewarming of the sample at 37°C. For this reason, cryoglobulin detection is susceptible to temperature variations, and require strict pre-analytical conditions already at blood withdrawal and immediately during sample transportation and handling.

Pre-analytic cryoglobulin test protocols are poorly standardized, leading to the possibility of underdetection and missed diagnosis, this test is often neglected by clinicians For this reason, it is of great importance to reduce inappropriate sample handling.

Moreover, as cryoglobulinemia is often associated to HCV positivity, a disposable and cost-efficient system would ensure optimal safety conditions.

Aim: The aim of this study was to evaluate the diagnostic performance of two different devices employed for sample transportation within hospital premises, and to propose standard pre-analytical guidelines for the harmonization of cryoglobulin sample collection and handling in patients with and without HCV infection.

Materials and methods: blood samples from 30 age-matched patients (20 HCV-positive subjects and 10 subjects affected by plasma cell dyscrasias) were collected into pre-warmed, anticoagulant-free tubes, and immediately split into two aliquots by means of pre-warmed equipment. Each aliquot was then placed in either warm water (37°C) or in a disposable device composed of a filter paper-lined thermos filled with warm water (37°C). Samples were left standing for 1hr at room temperature and subsequently processed. Temperatures were recorded and cryocrits were assessed.

Results: A significant difference in temperatures was recorded between the two methods (P<0.0001) as higher temperatures were retrieved by the disposable device.

Conclusion: Constant temperatures observed by using the filter paper lined thermos enables low cryocrit detection, otherwise unobserved by using warm water only, all to the detriment of the patient. Moreover, the disposable device is also cost efficient and preserves from eventual contamination.

Key words: Cryoglobulins, HCV, Pre-analytics, Plasma cell dyscrasias

P142

PRE ANALYTICAL PHASE IN A TERTIARY HOSPITAL IN SUBSAHARA AFRICA. EXPERIENCE AND CHALLENGES

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Background: Preanalytical phase in laboratory medicine is critical in patients' management as it may be a deciding factor on accuracy and precision of laboratory results. Quality systems are the mainstay of clinical laboratory management. However, the major source of errors

in laboratory diagnostics, arise during patient preparation, sample collection, sample transportation, sample preparation and sample storage.

Aim: To evaluate factors supporting preanalytical phase errors in Chemical Pathology laboratory of Usmanu Danfodiyo University Teaching Hospital Sokoto, Nigeria.

Materials and method: This was a description of 2 years' experience in a tertiary hospital through interaction with clinicians, nurses, laboratory attendants, and examination of laboratory request forms. The study was narrative. Most responses were centered on wrong sample collection, inadequate patient preparation, delayed in sample processing in the laboratory and improper storage of sample before analysis in the laboratory.

Result: The study revealed that patient variables which include diet, body mass, age, medications and gender constituted a source of error. Also specimen collection variables like posture, diurnal variation, time of collection, fasting status and tourniquet were also recognized as a source of serious error. In addition, specimen handling variables like hemolysis, lipemia, centrifugation, processing time and temperature also formed significant source of error in the preanalytical phase of analysis.

Conclusion: To reduce errors in the laboratory medicine practice in the Subsaharan Africa will require excellent communication and cooperation among all members of the health care team, from the phlebotomist to the courier who transport samples to the testing laboratory and the personnel receiving the specimens. With more emphasis on established guidelines and procedures, preanalytical errors will be greatly minimized.

Conclusion: To reduce errors in laboratory medicine in sub-Saharan Africa, attention to sample collection, handling, transportation and processing would be given adequate attention.

Key words: Errors, laboratory, pre analytical, phase, sub Saharan Africa.

P143

THE COMPARISON OF THE EFFECTS OF PNEUMATIC TUBE TRANSPORT SYSTEM AND MANUAL TRANSPORT ON COAGULATION TESTS

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Background: The aim of our study was to investigate the effects of pneumatic tube sample transport on coagulation assays.

Materials and methods: Paired blood samples obtained from each of 30 patients were transported to the laboratory with PTS and manually. Coagulation tests, including Prothrombin time (PT) and activated partial thromboplastin time (aPTT) were measured from each samples.

Results: The results of PT and aPTT transported by PTS were 15.67 ± 3.62, 33.07 ± 9.67; and by manual were 15.63 ± 4.09, 33.38 ± 10.21 respectively. No statistically significant differences were observed ($p= 0.36$, 0.56 respectively).

Conclusion: The PTS yielded no preanalytical effects on PT and aPTT test results. We concluded that the use of PTS is proper for rapid and reliable PT and aPTT test results.

Key words: activated partial thromboplastin time; prothrombin time; pneumatic tube system.

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THE EFFECTS OF TRANSPORT BY PNEUMATIC TUBE SYSTEM ON BLOOD CELL COUNT

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Background: Today the pneumatic tube transport system (PTTS) is used frequently because of its advantages such as timing and speed. In this study we aimed to examine the effects of PTTS on the quality of blood cell counts.

Materials and methods: Blood samples were collected from 30 patients during 1 day period. For each patient blood samples were collected into 2 pairs of tubes. The blood was collected into 2.0 ml K2 EDTA vacuum tubes. Collected samples were divided into 2 groups. Group 1 samples were immediately transported to the laboratory by staff and Group 2 samples were transported to laboratory from emergency service (farthest distance) by PTTS. Blood cell count performed using Beckman Coulter LH 780 Hematology Analyzer.

Results: Group 1 values; wbc 8.09±1.93, rbc 4.44±0.41, hgb 12.71±1.46, htc 37.5±3.82, mcv 84.66±5.66, mch 28.66±2.38, mchc 33.83±0.64, plt 265.4±98.24, mpv 8.8±1.17.Group 2 values; wbc 8.01±2.08, rbc 4.46±0.41, hgb 12.79±1.46, htc 37.8±3.92, mcv 84.78±5.5, mch 28.68±2.26, mchc 33.8±0.56, plt 262.8±93.5, mpv 9.25±1.24.Mpv values were statistically significant ($p=0.002$). Wbc, rbc, hgb, htc, mcv, mch, mchc and plt values were not statistically significant ($p=0.58, 0.44, 0.43, 0.25, 0.30, 0.80, 0.72, 0.24$).

Conclusions: The PTTS is becoming a common method for transporting samples in hospitals. However this type of transport method has been cited as potentially affecting certain laboratory measurements (hemolysis etc.). In this study we observed that the PTTS used in our hospital imparted significant effects on mpv and no significant effects on wbc, rbc, hgb, htc, mcv, mch, mchc, plt values. We recommend that all laboratories investigate the effects of their PTTS on test results.

Key words: Pneumatic tube transport system; mpv; wbc; rbc

P145

THE EFFECTS OF TRANSPORT BY PNEUMATIC TUBE SYSTEM ON ROUTINE BIOCHEMISTRY PARAMETERS

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Background: Today the pneumatic tube transport system (PTTS) is used frequently because of its advantages such as timing and speed. In this study we aimed to examine the effects of PTTS on the quality of routine biochemistry parameters.

Materials and methods: Blood samples were collected from 30 patients during 2 days period. For each patient blood samples were collected into 2 pairs of tubes. The blood was collected into 5.0 vacuum tubes. The PTTS used in our hospital (Swisslog Pneumatic System) has 330 mmX120 mm diameter which made by crystal quality polycarbonate. It has protection cover which prevents the leakage and 3-6 m/sec. speed. Collected samples were divided into 2 groups. Group 1 samples were immediately transported to the laboratory by staff and Group 2 samples were transported to laboratory from emergency service (farthest distance) by PTTS. Routine biochemistry parameters performed using Beckman AU 5800 autoanalyzer.

Results: Group 1 values; AST 21.9±8.03, LDH 201.16±62.29, UIBC 298.63±67.40, K 4.55±0.46, Fe 76.93±38.02, Mg 1.95±0.17, Group 2 values; AST 22.46 ±7.8, LDH 222.36±59.89, UIBC 299.93±67.07, K 4.58±0.45, Fe 77.03±37.98, Mg 1.98±0.16.AST, LDH and Mg values were statistically significant ($p<0.02$). UIBC, K and Fe values were not statistically significant ($p=0.16, 0.30, 0.73$).

Conclusions: The PTTS is becoming a common method for transporting samples in hospitals. However this type of transport method has been cited as potentially affecting certain laboratory measurements (hemolysis etc.). In this study we observed that the PTTS used in our hospital imparted significant effects on AST, LDH, Mg and no significant effects on UIBC, K, Fe values. We recommend that all laboratories investigate the effects of their PTTS on test results.

Key words: Pneumatic tube transport system; AST; LDH.

P146

COMPARISON OF HEMOLYSIS LEVELS DETERMINED WITH TRADITIONAL (VISUAL) METHODS AND AUTOMATED SYSTEMS

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Background: Hemolysis is one of the most common mistake that can lead to the wrong interpretation that affecting many medical tests in clinical laboratories. In the present study, we aimed to evaluate the levels of hemolysis that cause significant interference in biochemical test result by comparing with traditional (visual) methods and automated systems. Hemolysis levels of the samples were measured using serum index Gen 2 kits in Cobas 8000 (Roche diagnostic). Measuring range for hemolysis index was 5 – 1200 mg/dL.

Materials and methods: In the present study, we compared the hemolysis we determine through observation and hemolysis index of the sample (mg/dl) (daily 100 samples randomly selected in 5 different days, to a total of 500 samples). We recorded hemolyzed samples that determined through observation as "less hemolysis," "hemolysis" and "excessive hemolysis" according to the color.

Results: The number of hemolysed samples that determined by observation was 96 (46 "less hemolysis", 46 "hemolysis", 4 "excessive hemolysis"). Hemolysis index values were between 50- 100 mg/dl in "less hemolysis" group except for 4 samples, between 100-400 mg/dl in "hemolysis" group and above 400 mg/dL in "excessive hemolysis" group.

Conclusion: In the present study the traditional (visual) methods and automated assessed levels of hemolysis was found to be compatible. The detection of hemolysis with automated systems is favorable for its reproducibility, quantitativity, cost-effectiveness, to provide test-based rejection and to reduce workload.

Key words: Hemolysis, Interference, Traditional, Automated Systems.

P147

EQA FOR THE PREANALYTICAL PHASE

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Background: External quality assessment (EQA) schemes have traditionally surveyed the quality of the analytical testing phase. Managing all phases of the total examination process is however equally important to ensure patient safety. This study presents the design of preanalytical EQA schemes organized by Labquality and summarizes the first results.

Materials and methods: Labquality released its first 4 preanalytical EQA schemes in 2014. These schemes are run by using real life scenarios as case studies. In addition to written case descriptions, images and videos are provided if necessary. The participants review the materials and select the appropriate flaw(s) from a list of about 30 possible preanalytical errors.
This study assesses the results of a case focusing on the phlebotomy process. The results given by groups of different laboratory professionals are compared as anyone involved in phlebotomy could participate. The results were obtained both as part of EQA and running a free online trial survey.

Results: The selected survey case included at least 12 preanalytical errors, e.g. poor hand hygiene, incorrect use of tourniquet, insufficient sample volume and improper mixing of sample. In the EQA round, about 70 unique responses were received and 100 through the trial survey. In general, most respondents identified several errors regardless of their professions. Altogether 22 different errors were reported with the actual errors being those most commonly detected. Most of the biomedical laboratory scientists or technician reported that the phlebotomy was not successful while half of the nursing staff regarded the event successful.

Conclusions: Our results show differences in preanalytical procedures between laboratories. The differences may be due to varying conventions between countries and organizations yet also varying level control of the preanalytical phase. While sharing best practices, EQA provides an important tool in ensuring preanalytical competence.

Key words: External quality assessment, scheme design, quality, preanalytics

P148

EFFECT OF PREANALYTICAL SAMPLE HANDLING ON FLOW CYTOMETRIC EVALUATION OF CEREBROSPINAL FLUID SAMPLES

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Background: Flow cytometry (FCM) is a sensitive diagnostic tool to evaluate cell composition of cerebrospinal fluid (CSF) samples. As CSF cells are extremely vulnerable appropriate fixation of the specimens is essential.

Materials and methods: Altogether 67 CSF samples were investigated by multicolor FCM, 23 of them were evaluated by morphological examination on cytospin preparations as well. White (WBC) and red blood cell numbers (RBC) were counted in Fuchs-Rosenthal chamber. In order to find the most appropriate fixative (Transfix, Cytomark) ratio we added different amounts of fixative to 1 ml CSF (WBC <100/microliter) and performed a Syto/CD45 labeling at 0, 24 and 48 hours. Samples were acquired by a FACSCanto II flow cytometer and analyzed by FACSDiva software.

Results: Retrospective analysis of 42 CSF samples showed that in 3 out of 8 cases cells were destroyed and flow cytometric analysis was impossible when Transfix was added to the CSF in the recommended ratio (1:5) and kept overnight. When fresh CSF was stained within 4 hours after drawing (n=37) only one sample was not evaluable due to cell destruction. While Syto+ viable cell ratio decreased to 59±37% and 37±23% (24 and 48 hours, respectively) compared to the fresh sample (n=3) when Transfix was added in the recommended 1:5 ratio, 69±9% (24 hours) and 59±5% (48 hrs) cells were evaluable when 1:10 ratio of fixative was applied. Dramatic decrease of lymphocyte ratio was observed with 1:5 Transfix ratio while 1:10 ratio conserved the original lymphoid-myeloid ratio. CSF samples drawn into tubes containing 10 microliters Transfix (n=22) were all evaluable for FCM analysis.

Conclusion: Proportional decrease of Transfix volume added to CSF samples resulted in better sample quality for FCM analysis and may provide a standardized sample handling for reliable and appropriate interpretation of FCM results especially in childhood acute leukemia patients where low WBC in CSF is usual.

Key words: flow cytometry, cerebrospinal fluid, fixation

P149

EXTERNAL QUALITY CONTROL IN ENDOCRINOLOGY – IMPACT ON PREANALYTICS

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Background: Our immunoanalytical laboratory has participated for 10 years in a national EQC scheme SEKK, organized by a member of European Committee for External Quality Assurance Programmes in Laboratory Medicine. The Endocrinology programme is realized in cooperation with Referenzinstitut für Bioanalytik (Bonn, Germany).

Materials and methods: Quaternally, two serum samples are distributed and a participating laboratory has to perform quantitative tests of thyroidal and other hormones and proteins. The results are evaluated in groups of similar analyses principles (e.g. chemiluminiscence, luminescence,...) and the laboratory obtains an evaluation report and, in case of "successful" results, a certificate of quality.

Results: The performance of the analysis of thyroidal hormones has been very good all over the 10-year period. On the other hand, the performance of the measurement of renin and aldosterone has been complicated. It has urged us to revise our preanalytical phase with respect to these analytes. The results will be discussed in details in the presentation.

Conclusions: The participation in an EQC scheme is an important tool for assessing the performance quality of a clinical laboratory. It helps to reveal and improve many preanalytical errors.

Key words: EQC, immunoanalysis, thyroidal hormones, renin, aldosterone, serum

P150

TIME AND TEMPERATURE CONTROL IN THE TRANSPORTATION OF BLOOD SPECIMENS FROM REMOTE BLOOD-DRAWING STATIONS TO THE LABORATORY

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Background: According to the Clinical and Laboratory Standards Institute (CLSI) guideline H5-A3 of 1994 a maximum of 2 hours is recommended for the transportation of blood specimens at a temperature of 10-22°C between specimen collection and delivery to the laboratory. At ULSM specimens reach the laboratory from offsite blood-drawing stations in appropriate refrigerated containers, with a data logger (Ebro®) that measures time and temperature between specimen collection and testing. Our goal was to evaluate if our transportation conditions are in conformity with the guidelines preconized by CLSI.

Materials and methods: ULSM has two transportation routes: rout A includes peripheral health centers where blood specimens are centrifuged *in loco,* and rout B, for central health centers.

We analyzed 697 time and temperature registers, between February and November of 2014 using IBM SPSS Statistics 20®.

Results: Medium temperature was between 10-22°C for 545 (78,2%), and bellow 10°C for 151 (21,7%) of a total of 697 registers. Transportation time was greater than 2 hours in 606 (86,9%) registers. Rout A was the major contributor with 444 (94%) of a total 472 registers for this rout, and rout B, 162 (72%) of a total of 225 registers for this rout.

Conclusions: In 78,2% of registers the standardized guideline for temperature was followed. The transportation time four rout A surpassed 2 hours in 94% of registers, which validates the necessity to centrifuge blood specimens before transportation. This results allow us to know our real working conditions, and therefore improve laboratory services. Namely, the design of faster routs and continuous educational action regarding thermal accommodation of samples.

Key words: Data Logger; Time; Temperature.

P151

IMPACT OF PLASMA BILIRUBIN ON HEMOLYSIS INDEX VALUE

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Background: Hemolysis is the most common pre-analytical interference and it often causes blood sample rejection. A new generation of laboratory analyzers can report cell-free hemoglobin qualitatively or semi-quantitatively as hemolysis index (HI). Every manufacturer of reagents specifies the HI at which analysis is permitted. As bilirubin can affect free-hemoglobin measurement and consequently HI, impact of plasma bilirubin on HI value was evaluated in emergency laboratory as part of laboratory method verification.

Materials and methods: 49 samples were prepared by mixing hemoglobin-free low-bilirubin plasma pool (blank pool), hemolysate and bilirubin enriched pool to get different degrees of HI (0 – 115) and bilirubin concentrations (5.4 – 436.7 μmol/L). The HI and bilirubin concentrations were measured in triplicate on Roche Cobas ce6000 analyzer. Results of HI measurements were evaluated and presented as absolute differences from blank pool. Statistical analysis was performed using Wilcoxon rank-sum test.

Results: For samples with bilirubin concentrations 37.2, 55.1, 82.2 and 188.6 μmol/L, absolute difference in measured HI was ≤ 2 and no statistically significant difference in HI value was observed (P>0.05). There was statistically significant difference in HI value for samples with bilirubin concentrations of 276.8 μmol/L (P=0.0312) and 436.7 μmol/L (P=0.0156). The absolute differences in measured HI were 0 – 11 leading to decrease of HI values and were greater as bilirubin concentration was higher.

Conclusions: The use of new technology for detection and measurement of common interferences can aid in detecting improper samples received in laboratory and furthermore, in minimizing erroneous clinical decisions based on laboratory test results.

This study shows that high bilirubin can cause false decrease in HI values and thus the samples, that are usually rejected, can be wrongly accepted. To avoid errors and promote continuous quality improvement of laboratory service, further examination of pre-analytical interferences should be of high interest.

Key words: hemolysis, hemolysis index, bilirubin, interference

P152

CLOTTING TIME AFFECTS MEASUREMENT OF THE SERUM LEVEL OF THYROID HORMONE FREE THYROXINE

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Background: Clinically reliable determinations of analytes in serum or plasma can be achieved by the attention to the preanalytical phase. In this respect, processing of the sample is one of the critical points. Among others, also an inadequate clotting of serum has to be considered during the preanalytical phase. According to clinical evaluations in the year 2011unexpectedly low levels of free thyroxine (fT_4) were observed in some of our patients. The aim of our work was to determine the effect of clotting time on the serum concentration of fT_4.

Materials and methods: In October 2011 we designed a comparison using 40 randomly selected samples from patients with various thyroid disorders visiting thyroid specialists. For each patient, blood was collected in two serum vacuum tubes. Serum samples were separated from the clot by centrifugation after either 20 min (group 1) or 45 min (group 2) of clotting time at the room temperature. Analysis of fT_4 was performed on automated analyzer (Advia Centaur, Siemens). Finally, the two-tailed paired t-test was performed to compare the results of two groups.

Results: Levels of fT_4 between the two groups were significantly different (p=0.019). In the group 2, 24 samples had significantly higher and 9 samples significantly lower value of fT_4 than the corresponding samples from the group 1 (p<0.001 and p=0.006, respectively). A positive deviation of fT_4 values was on average 1.6-times higher than the negative deviation. Remaining 7 samples minimally differed between the two groups (difference in values was less than 1%; p=0.047).

Conclusion: Our results showed that longer clotting time positively affects determination of fT_4 on our automated analyzer in patients with various thyroid disorders. Consequently, a clotting time of 45 min was introduced into our daily practice.

Key words: clotting time, free thyroxine (fT4)

P153

THE COMBINATION OF BOTH LUER-LOK CATHETER ADAPTOR AND PARTIAL DRAW TUBES ARE SUCCESSFUL IN REDUCING HEMOLYSIS RATES IN A&E DEPARTMENTS

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Background: Hemolysis is the main cause of rejection in the preanalytical phase and in A&E laboratories it is responsible of not being able to determine certain parameters, sample re-drawing and delaying result delivery. In our laboratory, we indicate the possibility of interference if Hemoglobin concentration exceeds 0.84g/L. We state the impossibility of delivering results for K, AST, ALT, LDH, CK, CKMB if hemoglobin concentration is over 1,22g/L.
We have 25,9% of samples with hemolysis rates over 0,5g/L that have been drawn in the A&E department.

Materials and methods: Full drawn tubes in use were from Terumo Venosafe 3,5mL, 13x75mm. Partial draw tubes and the catheter adaptor were from BD (BD SST II Advance 4mL, 13x100mm, BD Luer-Lok Access Device). During 2 months, 3 different nurses did the following blood collections: 158 collections with the current tube and the adaptor and 163 collections with the partial draw tube and the adaptor. Centrifugation was performed as recommended by the manufacturers. The hemolysis index was retrieved with a Roche Cobas c501 analyzer.

Results: The usage of the current tube with the adaptor caused 27,8% (9,5% to 36,7%) of samples with IH >0,5g/L. The use of partial draw tubes with the Luer-Lok adaptor gave a result of only 0,6% (0% to 1,4%) of hemolyzed samples

Conclusions: The combined use of partial draw tubes with a luer-lok catheter adaptor in the A&E department has been proved effective in reducing hemolysis incidence from 27,8% to 0,6%.
The use of a luer-lok catheter adaptor with full draw tubes has shown a partial reduction in hemolysis indexes in 2 of the 3 phlebotomist observed. This result states the influence of phlebotomist practice in the overall results.

Key words: partial draw, hemolysis, adaptor.

P154

JOAQUIM CHAVES ANALISES CLINICAS USES BD PREANALYTICAL QUALITY CHECK TO IMPLEMENT AND MONITOR EFFECTIVE HEALTHCARE WORKER SAFETY

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Background: Grupo Joaquim Chaves is an important private laboratory group in Portugal that is focused on delivering the highest quality results to their customers and providing the safest working environment for their staff. The distributed nature of the laboratory group, with more than 150 collection sites throughout the Algarve and Lisbon regions, is a challenge to ensure maintained high quality standards in all locations. They wanted to implement the tools, products and training for their staff to ensure implementation of safe phlebotomy practices.

Materials and methods: The laboratory implemented the BD Preanalytical Quality Check (PAQC), a quality control tool that provides a comprehensive analysis of the preanalytical phase, including HCW & patient safety. The PAQC was implemented in 6 collection sites to establish

a baseline to determine the best safety products to use and develop a specific training programme which was performed individually with all the staff. Subsequently, a second PAQC was conducted in the same sites, to show whether the changes in best practice alignment, implementation of HCW safety had been maintained.

Results: The first PAQC highlighted a limitation with their initial safety product which required a hard surface for activation and as a result only 50% of the safety devices were made safe, therefore the laboratory group were not complying with the latest legislation. After changing the devices used and training, the activation rate increased to 100% during the second PAQC.

Additionally improvements were made in the collection practices and sample quality, with hemolysis rates reducing from 9% to 0% in coagulation samples and by 2% in chemistry samples.

Conclusions: The PAQC, appropriate selection of safety devices and training has been the key to ensure effective implementation of HCW safety throughout the group.

Key words: Preanalytical Quality Check, safety, phlebotomy, best practice.

P155

PREANALYTICAL ERRORS IN PUBLIC HEALTH LABORATORY

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Background: Pre-analytical steps, the major source of errors in laboratory diagnostics, arise during patient preparation, sample collection, sample transportation, sample preparation, and sample storage. Family physicians and family health officials were trained in January 2014 on pre-analytical errors, and our aim was to determine if this training was effective in decreasing pre-analytical errors.

Materials and methods: All causes of tube rejections in 2013 were retrospectively retrieved from ALIS laboratory data system, after which all causes in the period between January – December 2014 were retrieved. These two periods were compared, in order to determine a decrease or increase in rejections.

Results: The total number of rejections due to hemolysis of the sample between January 1st and December 31st, 2013 was 265, while it was 144 in 2014. Also, rejections due to clot in samples was 599 in 2013, while it was 442 in 2014. Rejections due to insufficient sample was 668 in 2013, which decreased to 173 in 2014.

Conclusions: The statistical analysis of the comparison of all causes of rejections between these two periods show that training was effective. We could not clearly determine if the training was effective on only the Family Physicians, or both healthcare groups. We hope to make a better differentiation with feedback forms which will be used for both groups.

Key words: preanalytical errors, family physicians, training

P156

BD PREANALYTICAL QUALITY CHECK SUPPORTS JOINT COMMISSION INTERNATIONAL ACCREDITATION ACTIVITIES IN THE LABORATORY OF COSTA DEL SOL HOSPITAL (SPAIN)

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Background: Costa del Sol Hospital is a regional hospital, where the population served varies from 400.000 to 800.000 people due to seasonal changes. It is accredited by Joint Commission International (JCI) and consequently it applies strict quality standards. In order to comply with this, the hospital needed a way of demonstrating compliance with international recommendations.

Materials and methods: The hospital implemented the BD Preanalytical Quality Check (PAQC), a quality control tool that provides a comprehensive analysis of the preanalytical phase, showing the impact of non-conformities on sample quality, laboratory efficiency &

analytical results and compliance to international guidelines. A risk matrix aligned with PAQC observations was developed to assess where improvements were needed in order to comply with the JCI requirements. A specifically designed training plan was implemented by BD for the healthcare professionals, focusing on areas where improvement was identified through the use of the PAQC and risk matrix. After the training, the PAQC was repeated to determine achieved improvements.

Results: The first PAQC showed an overall 'alignment index' of 51% with best practices. Issues such as inappropriate centrifugation conditions, non-standardized mixing and high hemolysis rates were found. After the training, the second PAQC 'alignment index' increased to 71%. This was driven by improvement in critical parameters, such as hemolysis rates which decreased by more than 10%, correct mixing which improved from 48% to 90% or underfilled tubes citrate tubes which were less than 5% now.

Conclusions: The PAQC with the associated risk matrix enabled the hospital to identify key non-conformities, and focus the BD training. Through the follow up PAQC the hospital was able to demonstrate a reduction in non-conformities and support their JCI accreditation.

Key words: Preanalytical Quality Check, accreditation, risk matrix.

P157

AUDIT OF PRE-ANALYTICAL PHASE IN CLINICAL LABORATORY

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Background: The implementation of health care software solutions with increasingly automated processes, allow logistical management of workflow and sample processing in the laboratory. One of the most important consequences of these technologies is the reduction of analytical errors.

Traditionally, laboratory practices can be divided into three processes: the pre-analytical process; the analytical process and the post analytical process. According to various publications the pre-analytical process is the one that contributes the most to the laboratory errors (46% -68.2%).

Objectives: An audit intended to monitor the main variations found in the pre-analytical process, at the Laboratorial Hematology (including Cellular Immunology) and Clinical Chemistry.

Materials and methods: This prospective audition is restricted to the reception of samples.

Results: At the Clinical Chemistry and Laboratorial Hematology services 390 samples were checked for a population size of 500 samples. The samples were randomly chosen.

As for Cellular Immunology we evaluated 310 samples.

In all services, agreement values greater than 90% were obtained in most audited variables, excepting the following ones: accessible online form, clinical information and requesting physician identification. No serious nor light non-compliances were detected.

Conclusions: Better results would have been obtained with regard to the integration of the o request form in the laboratory software system, as well as the complete filling out of the form, including the placement of the name of the referring physician and patients clinical information. Thus a plan of training sessions for nurses, were recommended. These actions should be focused mainly on the finalizing act, upon harvesting, of the respective request form, mandatory for its integration in the laboratory software application. Among clinicians there is an accentuated need to understand the correct and complete fulfillment of request forms, particularly with regard to clinical information and time of collection.

Key words: Preanalytical phase, sample reception, laboratory hematology, clinical chemistry, cellular immunology.

P158

CASE REPORT: FALSE RESULTS IN COMPLETE BLOOD COUNT DUE TO EFFECT OF COLD AGGLUTININ

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Laboratory gets a few hundreds demands to examine complete blood count (CBC) every day. Hematology analyzers have sophisticated technologies (impendance or flow cytometry), therefore they are exact and confident. Laboratory's staff duty is to be aware of all pre-analytical and analytical factors that cause false CBC results. This includes hemolysis, lipemia, agglutination in the presence of EDTA, platelet aggregates, resistant to lysis RBC, cold agglutinin etc.

Laboratory received a blood sample from 81-year old female patient hospitalized at Department of cardiology. CBC was ordered. Results from Cell-Dyn Ruby were: WBC 18,4x10e9/L, RBC 3,2x10e12/L, HGB 135 g/L, HTC 0,289 L/L, MCV 87,7 fL, MCH 40,9 pg, MCHC 467 g/L, PLT 158x10e9/L. We excluded hemolysis and lipemia, but asked to repeat venipuncture and new blood sample to be immediately delivered to the laboratory. WBC and PLT values were not changed, but repeated RBC was 4,16x10e12/L, HTC 0,356 L/L, MCH 32,0 pg, MCHC 373 g/L. These results were validated.

After two hours we run that sample again. RBC changed, also as HTC and MCHC did. To confirm our suspect on cold agglutinin interference we heated sample in warm water to 37 °C and repeated counting. Results of RBC and RBC-related parameters "recovered".

Cold agglutinins (CA) are auto-antibody which are able to agglutinate RBC at temperatures lower than that of the body. Their production can be related to some acute inflammatory stages. CA interfere with the analysis of RBC and RBC-related parameters, while HGB, WBC and PLT counts are not affected. To prevent this interference blood sample should be immediately delivered to laboratory.

Key words: CBC, interference, cold agglutinin

P159

A SYSTEMATIC APPROACH TO OPTIMIZE THE PREANALYTICAL PHASE OVER THE LAST 6 YEARS

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Background: The preanalytical phase is of great importance for correct laboratory testing results. However, the preanalytical phase is complex and difficult to control. We implemented a project to increase awareness of the importance of the preanalytical phase with the aim to optimize practices.

Materials and methods: In 2008, we analyzed the blood collection and sample processing practices using a BD Preanalytical Review. A communication campaign was launched to create a sense of urgency with the aim to increase willingness to change long standing practices. As next step, we used a cost model to estimate the cost of poor sample quality in the University Hospital, involving all head nurses. During the whole period of time, we offered continuous training and communication on the preanalytical phase. To assess changes in behavior, we then developed a customized preanalytical audit methodology. 126 routine blood collections on 23 wards were observed.

Results: Generally, communication on preanalytical issues and the results of our studies have been perceived with great interest by physicians and nurses and have triggered a discussion on the importance of the blood collection process. The cost model revealed that 0.19% of total hospital cost could have been saved would no preanalytical errors happen. There was an improvement in practices over the period: pumping with the fist decreased from 21% to 10%, prolonged tourniquet time from 88% to 32%, and insufficient mixing of tubes from 76% to 46%. Still, obviously our efforts have not completely eliminated errors. Some deviations from SOP may occur for specific reasons. Additionally, the high turn-over of staff, especially of the physicians in training, create a need for continuous re-training and communication.

Conclusions: Auditing the preanalytical phase combined with continuous training and communication provide a sustainable way to improve blood collection practices and consequently, patient care.

Key words: BD Laboratory Consulting Services, Audit, Continuous learning

P160

A PRE-ANALYTICAL EQA SCHEME FOR SAMPLE INTEGRITY: A WEQAS STUDY TO MONITOR THE EFFECTIVENESS OF SERUM INDICES

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Background: Whilst most EQA schemes focus on the data counting of the number of rejected samples, WEQAS has developed a programme to evaluate the laboratory's ability to detect unsuitable samples and assess their testing protocols for the analytes affected.

Materials and methods: Samples were distributed every 3 months with varying degrees of lipemia, hemolysis and icterus over a 4 year period. Two matched pools were distributed, one containing the interferent and the other containing normal physiological levels. Participants were asked to provide their serum indices value and to report results as they would a patient sample. The data for the two matched samples was also compared with a reference method wherever possible to ascertain the degree of analytical interference.

Results: For the icterus sample, 220 laboratories returned results, 57 provided serum indices and 41 provided additional comments indicating as to whether they would have reported the result on a patient sample. Of these, the majority stated that they would not report total protein, creatinine or GGT.

For the lipemic sample, 111 laboratories provided serum indices and 61 participants provided additional comments. Of these, the majority stated that they would not report ALT and AST with 8 laboratories adding further lipid investigations.

For the hemolyzed sample, 144 laboratories returned results, 109 participants provided additional comments that they would not report Potassium, ALT, AST CK, LDH and ALP. Fifteen stated that they would not have provided any results.

Conclusions: There appears to be little harmonization of reporting for serum indices even within users of the same instrument. It is important that laboratories are aware of potential interferences in their assays, are aware of which analytes could be affected, have the ability to detect the potential interferences and have systems in place to ensure the accuracy of results when these interferences are present.

Key words: Serum indices, EQA, lipemia, icterus, hemolysis.

P161

VALIDATION OF BLOOD COLLECTION TUBES FOR VARIOUS BIOCHEMISTRY TESTS IN THE ASPECTS OF STABILITY AND INFLUENCE OF GEL SEPARATORS

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Background: Blood collection and processing are two major steps in preanalytical laboratory testing. Proper blood collection and timely processing by well-trained staff using appropriate devices are needed to ensure test reliability. In this study, we compared three different tube brands Vacuette serum separator clot activator tube, (group B tube; Greiner Bio-one, Germany), BD Vacutainer SST II Advance tube, (group C tube; Becton, Dickinson and Company, UK) and Improvacuter gel and clot activator tube, (group D tube; Guangzhou Improve Medical Instruments Co. Ltd, China) which are approved by FDA and investigated the effect of gel and the storage time in comparison with each other in routine biochemistry analyses.

Materials and methods: Blood samples were collected from sixty healthy participants into 3 different gel separator tubes and one gel-free glass tube. They were analyzed simultaneously for routine biochemical parameters on an AU5800 (Beckman Coulter Inc, USA). Analyses were repeated at 24, 48 and 72 hours.

Results: The results of the study showed that the difference of analyte concentrations when compared with the reference tube were within the Total Allowable Error Limits at the 0 hour except LDH in C tubes. The stability study showed that clinically significant differences has occurred for LDH, Na and Cl parameters in C and D tubes.

Conclusion: Validation of blood collection tubes are essential for a reliable test performance. Tube manufacturers and well trained laboratorians should all be careful in protecting against the adverse effects of blood collection tube problems on clinical laboratory assays.

Key words: Preanalytical phase, validation, blood collection tubes

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IS THERE A DIFFERENCE IN THE RESULTS OF PLATELET AGGREGATION TESTING BY MULTIPLATE® ASSOCIATED WITH A TYPE OF A NEEDLE USED FOR VENIPUNCTURE?-RESULTS FROM A PILOT STUDY

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Background: Measurement of platelet aggregation is of importance for understanding the mechanisms of ischemic vascular disease and therapeutic monitoring of antiplatelet drugs. Multiple electrode aggregometry (Multiplate®, Roche, Germany) is one of the techniques most

commonly used for this purpose. Among the numerous preanalytical steps, necessary for obtaining reliable results, special attention is focused on blood collection procedure. The aim of the study was to evaluate the difference in the Multiplate analyses results when two different needle types were used for venipuncture.

Materials and methods: Study included 5 patients on clopidogrel therapy. Venipuncture was performed with BD Vacutainer Precision Glide Multiple Sample Needle and BD Vacutainer Eclipse Blood Collection Needle. In each procedure 6 mL of blood were collected into BD Vacutainer with lithium heparin, which were mixed as recommended by the manufacturer. In less than 30 minutes after the collection platelet function was assessed (ASPI®, ADP® and TRAP®) by multiple aggregometry on the same analyzer (Multiplate®, Roche, Germany). Significance of difference was evaluated using Mann Whitney U test.

Results: Results of ASPI®, ADP® and TRAP® test differed for 8.9%, 11.2% and 10.9% respectively. However, the observed differences were insignificant, as evidenced by P values of 0.174 for ASPI®, 0.521 for ADP® and 0.255 for TRAP® test

Conclusions: Presented results indicate that platelet aggregation testing on Multiplate® is not influenced by the type of the needle used for venipuncture. However, these pilot results need to be confirmed in larger studies, including both patients on antiplatelet therapy and healthy volunteers.

Key words: platelet aggregation, venipuncture, needles

P163

EFFECT OF SAMPLE TYPE AND TIME ON VITAMIN B12 AND FOLIC ACID MEASUREMENTS

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Background: Vitamin B12 and folic acid are two coenzymes that have interdependent functions in intermediary metabolism. Knowledge of the stability of the specimens is important to obtain correct results for vitamin B12 and folate. In the present study we aimed to investigate the effect of sample type and duration of storage on folate and vitamin B12 concentrations.

Materials and methods: Blood specimens from 13 healthy volunteers were collected in BD Vacutainer SST II Advance tubes and BD lithium heparin tubes. Duplicate vitamin B12 and folate measurements were performed by DXI 800 immunoassay analyzer in both serum and plasma samples immediately (0 h, initial point), and after 2 h, 4 h, 8 h and 24 h from the initial point. The significance of differences between groups were analyzed by repeated measures ANOVA and paired Student t-test.

Results: According to t-test no difference was obtained between serum and plasma samples of 0 h, 2 h, 4 h, 8 h and 24 h. However, according to repeated measures ANOVA, within subjects effects were significantly different for serum and plasma vitamin B12 and for plasma folic acid concentrations (p <0.001, p <0.001 and p < 0.05, respectively).

Conclusions: As a preanalytical variable, duration of storage before analysis affects serum and plasma vitamin B12 and plasma folic acid concentrations.

Key words: Vitamin B12, folic acid, preanalytical variables, time.

P164

SAMPLE MANUAL – UTILITY AND PROBLEMS

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Background: In July 2007, and for the certification of the Serviço de Patologia Clínica, Centro Hospitalar Lisboa Norte (CHLN), was drawn 1st edition of Sample Manual. The aim was to bring together in one document the procedures for the collection, transport and storage of organic products and information on response times in order to reduce errors of pre analytical phase.

Material and methods: A comprehensive list of laboratory tests was drawn up, alphabetized, indicating sample collection materials and types of biological samples required, predictable response times, as well as the correct forms of transport and conservation of each product to the various types of tests. There are also general information and specific rules wherever justified. The Manual was disseminated in all

drawing sites, in and out of CHLN, initially only on paper and later also in computerized form. There have been regular updates to keep up with the increased supply of analysis and ease of reference.

Results: Its existence has proved highly beneficial, not only to external users but also to the employees of the service. This manual is an essential tool in the Quality Management System, reflected in the small number of pre analytical errors, through analysis of customer satisfaction and noncompliance records.

Conclusions: The existence of a Sample Manual brings together comprehensive information on a service with wide range of tests. The preanalytical errors related to collection, transport or storage, currently, are low.

The greatest difficulties are updating the analytic menu, the standardization of nomenclature and disclosure of the document.

Key words: sample manual; pre-analytical phase; sample collection

P165

THE PROS AND CONS OF USING AN AUTOMATED SAMPLE PROCESSING SYSTEM

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Background: The sample processing systems are the optimal solutions for handling the ever-increasing workloads, labor shortages, and high laboratory labor budgets. In our daytime, most of the laboratories having heavy workload suggest the use of an automated serum processing unit.

Material and methods: In our 900-bed hospital, the number of patients applying to the outpatient clinics is around 5000. The number of tests ordered from outpatients and inpatients and the number of tubes used per month are 360000 and 25000, respectively. Before the installation of sample processing unit, the average time spent for the samples to be prepared to be ready for the analyzers was one hour. The tubes drawn were 40000 tubes per month and there were four technicians doing this sample delivery, serum separation and tube sorting job.

Results: After the installation and the start of the sample processing unit (Beckman Coulter Automate 2500) the time spent has decreased to half an hour, the tube number has decreased to 25000 tubes/month and only one personnel is used to run the instrument.

The pros are decreased labor, faster workflow, tube sorting without any mistakes, separation of the primary tubes up to seven secondary tubes, and placing of the tubes according to test types (tests run on a specific day of the week can be placed on a separate rack to be kept till the runtime) or origin of the request (inpatients placed on the initial racks and outpatients on the terminal racks).

The cons are too much space needed for the instrument and the turbulent hours when the system has broken down or not working for some reason.

Conclusions: In conclusion, we recommend the use of a sample processor unit for labs that handle a heavy workload.

Key words: Sample processor, pre-analytics, tube sorter

P166

PREANALYTICAL SAVING MEASURES IN CHOLESTEROL REQUESTS

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Background: One of the most demanded tests in general laboratories is cholesterol and its fractions. We have launched a rejection protocol of the analytic demand for cholesterol fractions (LDLc and HDLc calculated with the Friedewald formula) to patients whose diagnosis or biochemical parameters permit, since the Evidence-based medicine shows that have no added value. This protocol has been established and agreed between parts. The objective is to assess the impact of the new protocol on the economics.

Materials and methods: The protocol to follow was: LDL and HDL cholesterol are performed when calculated total cholesterol is greater than 220 mg/dl. We consider exempt from this screening patients with cardiovascular disease or cardiovascular risk factors (diabetes, hypertension, dyslipidemia...).

Results: During the first half of May 2013 to October 2013 the number of patients and requests was 54,208, 31,133 cholesterol (57% of requests) and LDLc 26,606 (49% of the requests). In the first half of May 2014 to October 2014 the number of patients was 65,712, 31,794 cholesterol (48%

of requests) and LDLc 25,012 (38% of the requests). Moreover, during this half of 2014, after applying the protocol rejection, from 25,012 LDLc, only 17,368 were made (7,644 rejected 31% of applications).

We observed a gradual increase in the number of patients and, therefore, the number of cholesterol solicitudes relative to period in 2013, but we noticed a 9% decrease of cholesterol requests. With respect to 2014 period, 1,594 LDLc requests were made, less than in the same period in 2013, reducing by 11% the requests with LDLc after protocol rejection application.

Conclusions: Although the savings seems small compared to the total laboratory costs, it is important to maintain a quality public health and avoid as far as possible expenses that have no diagnostic value or clinical justification.

Key Words: Cost evaluation, Cholesterol reject, Preanalytical cost measures.

P167

PREANALYTICAL PHASE HAS A DECISIVE INFLUENCE ON THE PLASMA RENIN ACTIVITY DETERMINATION

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Background: Renin is a part of the renin-angiotensin-aldosterone system and is used for the calculation of ARR (aldosterone to renin ratio) in the screening for primary aldosteronism (PA). Methods for plasma renin determination vary considerably. Determination of the renin's enzyme activity (ng/mL per hour) by RIA (Radioimmunoassay) method requires special handling throughout the process. Sample has to be taken into an ice cold tube, transported to the laboratory in an ice cold bath, and centrifuged in a cold centrifuge. Therefore, preanalytical phase represents a critical point using RIA method. On the other hand, automated method (CLIA-Chemiluminescent Immunoassay) establishes the concentration of renin (mIU/L) and requires no special precaution which makes it very easy to handle and diminishes preanalytical errors. Our aim was to compare the reliability of both methods in the determination of renin, and consequently, of ARR.

Materials and methods: We have compared the above-mentioned two methods for the renin determination in 34 samples using Deming regression. The calculation of ARR was performed. ARR >1.0 nmol/L/ng/mL/h for RIA and ARR >30 pmol/L/mIU/L for CLIA was considered a positive screening test for PA.

Results: Association between the two methods was described by the following regression equation: Y(CLIA) = 31.1 (95% CI:27.8-34.3) x RIA − 1.3 (95% CI:-7.1-4.5)(r^2=0.935). Out of 34 samples, 11 were positive using RIA method and 3 were positive using CLIA method. All CLIA method-positive samples were also RIA method-positive. According to the subsequent results of saline infusion test which was used to confirm PA, remaining 8 RIA-positive samples were false positive.

Conclusions: Our results showed the importance of the preanalytical phase on the plasma renin activity determination. Lower renin activity due to inappropriate handling before using RIA method affects ARR value and might cause false positive results leading to unnecessary further testing.

Key words: sample handling, renin determination, ARR.

P168

IS THERE ANY IMPROVEMENT IN GLYCOLYSIS INHIBITION DUE TO NEW ADDITIVE MIXTURE?

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Background: Reliable stabilization of blood glucose concentration directly after sampling is significant because it can affect the accuracy of measurement. Therefore, it is necessary to set higher quality standards for preanalytical phase by ensuring effective glycolysis inhibition in order to increase the accuracy of the diagnosis. In this study we wanted to investigate whether new Vacuette Glucomedics tubes (additive: sodium EDTA, sodium fluoride, citric acid and sodium citrate, Greiner Bio-One) are more efficient in immediate and complete inhibition of glycolysis than conventional BD Vacutainer tubes (additive: sodium fluoride and potassium oxalate, Becton–Dickinson).

Materials and methods: Venous whole blood was collected from 48 presumably healthy donors by using a Vacuette Glucomedics and BD Vacutainer tubes. The collected sample tubes were centrifuged initially after blood collection and analyzed for glucose (hexokinase method) at the initial time point, 24h and 48h after blood collection on the AU680 analyzer (Beckman Coulter, Tokyo, Japan). Statistical analyses were performed with Mann—Whitney and Kruskal-Wallis tests by using MedCalc 12.2.1.0. statistical software (MedCalc, Mariakerke, Belgium). P<0.05 was considered statistically significant.

Results: Our results showed that glucose concentration was significantly higher at all time points in Vacuette Glucomedics compared to BD Vacutainer tubes (P values were as follows: P(0h)=0.002; P(24h)=0.002; P(48h)=0.001). On the other hand, there was no significant decline at different times of analysis after blood collection either in Vacuette Glucomedics tubes (P=0.67) or in BD Vacutainer tubes (P=0.53).

Conclusions: According to our results the stabilization rate of glucose concentration is more effective for Vacuette Glucomedics tubes. Additionally, the glucose concentration of plasma samples in both types of tubes was constant at room temperature for up to 48 hours. These results indicate that Vacuette Glucomedics tubes are more suitable for reliable determination of glucose concentration after blood collection and if prolonged processing time (including transport and/or storage) occurs.

Key words: Glucomedics tubes, glycolysis inhibition, blood glucose

P169

EFFECT OF PRESERVATIVE CONTAINING TEST TUBE IN URINALYSIS

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Background: Urinalysis is an array of tests performed on urine, and one of the most common methods of medical diagnosis. Collection, transport, sample preparation and analysis should be the basis of an effective urinalysis.
Sampling and analysis after two hours, will lower the quality of urinary test results. Urinalysis should be performed in two hours. Alkaline pH, low relative density and low osmolality can induce a rapid lysis of some urine particles. In a recent study, the value of a preservative containing transport tubes for the assessment of urine cultures especially in cases when the sample transport time is two hours was investigated. Aim of the this study is to investigate effectiveness of the preservative containing urine test tube in urinalysis.

Materials and methods: Urine samples were obtained from 30 patients. The samples were collected into test tubes (BD Diagnostics-preanalytical Systems, USA)) containing sodium propionate, ethyl paraben and chorhexidine preservative. Baseline urine were analyzed chemically and microscopic from the fresh specimens. Second measurements were performed after four hours. Urine sediment and strip analysis were studied by the automated IRIS IQ 200 analyzer (*Iris* Diagnostics, USA).
Statistical analysis was performed using NCSS (Number Cruncher Statistical System) 2007 Statistical Software (USA).

Results: Urinalysis after four hour did not differ from baseline concentrations (p>0.05). Results showed highly significant correlations with those of the urine sediment (erythrocytes, leukocytes, epithelial cells), and urine strips (glucose, albumin, bilirubin, urobilinogen, ketone, color, pH, hemoglobin, leukocytes esterase).

Conclusion: These results indicate that success of urine analysis results after four hours using sodium propionate, ethyl paraben and chorhexidine preservative containing urine tube may play an important role in the measurement of urine specimens.

Key words: Urine, urinalysis, preservative containing tube

P170

USE OF RIGHT SAMPLE COLLECTORS DECREASES THE MOST ENCOUNTERED PREANALYTICAL ERROR IN BLOOD GAS ANALYSIS – CLOTTED SAMPLES!

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Background: In our emergency laboratory the most encountered pre-analytical error in blood gas analysis is clotted samples. Unfortunately, clinicians used liquid heparin washed insulin syringes to send blood gas samples to analysis.

Material and methods: To overcome this problem, blood gas analyzer's company organized trainings, which were carried out by the application specialists. Then another training was done by the tube company's blood gas analysis section. No improvement was observed. We used to deliver almost 100 samples for blood gas analysis daily. From these 100 samples 10 to 15 samples had a clog in the syringe and most of the time it also initiated clogging of the analyzer, which led to the start of the auto clean process and auto calibration. Auto clean process took 5 to 10 minutes and a single point calibration took an extra 8 minutes. This clog cleaning process was so long that this prolonged waiting times caused other samples to clog as a vicious cycle. More samples coming to the lab meant more waiting times and more clots which prolonged the turnaround times of the blood gas analysis to over one hour. We changed the syringes from insulin syringes to blood gas analyzer's original sample collector syringes.

Results: This unique change has decreased the clotted samples from 10-15 to 1-2 per day. Turnaround time has been reduced to 15 minutes, number of calibrations decreased to normal routine counts and the time of the technician spent on the analyzer has fallen down to insignificant minutes.

Conclusions: This is a considerable example of decreasing errors in pre-analytical phase by the use of right equipment in the labs.

Key words: blood gas, pre-analytical errors, clotted samples

P171

QUALITY MANAGEMENT IN PRE ANALYTICAL PHASE OF MEDICAL LABORATORY TESTING PROCESSES

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Background: Medical laboratories should *give a* high quality service to the patients and clinicians during total testing process. Preanalytical phase include test selection, sample collection and transport to the laboratory.
Most of the error source of pre-preanalytical phase in some laboratories is patient/specimen misidentification.
Inappropriate test request, sample collected from infusion, hemolysis, insufficient volume, clotting, handling, storage and transportation errors are the others preanalytical error sources.
It is difficult the solve the misidentification because of variety of groups including patient recording secretaries, computer secretaries, laboratory workers, clinicians, phlebotomists, transport workers.

Materials and methods: Looking for all the samples working in the laboratory for count all wrong tubes, insufficient, hemolyzed, clotted samples. But we can't understand misidentified samples, wrong patient names. For this, we should look all the samples and ask their name to the patient at the same time in blood collection unit.

Conclusion: Accreditation is important tools for solve preanalytical problems. Joint Commission International (JCI) and the College of American Pathologists, 15189 are effective procedures for patient sample identification and true results.
ISO 15189 standard is used by our medical laboratories in developing quality management systems.
In the pre-analytical area, we can use true sample acceptance and rejection criteria which are used to monitoring of the collection and transport processes. May be we can use automatic sample identification systems to avoid misidentification. We should use laboratory quality indicators.

Key words: Quality assurance, Medical laboratory, accreditation, ISO 15189.

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PREANALYTICAL ERRORS IN ARTERIAL BLOOD GASES ANALYSIS AFTER THE IMPLEMENTATION OF A SOLID HEPARIN SYRINGE

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Background: The analytical process is divided into three phases, pre-analytical, analytical and post-analytical; and is in the preanalytical phase where most errors occur. In 2013 the liquid heparin syringes were replaced by solid heparin ones. The aim of the study is to assess the

preanalytical errors in blood gas samples received in the emergencies laboratory after implantation of the new sampling device (solid heparin syringes).

Materials and methods: We compared the different preanalytical errors occurred in two periods, four months before implantation of solid heparin syringes, and four months after the beginning of its use.

Results: Percentages of preanalytical errors in blood gases samples during the first study period (Liquid heparin syringes): 3.1% of all samples were not received, 0.6% of samples had insufficient volume to perform the analysis, and 1.1% were coagulated. The percentages of preanalytical errors in the second study period (Solid heparin syringes) were: 3.4% of all samples were not received, 0.3% had insufficient volume, 0.1% were contaminated with air and 2.6% were coagulated.

Conclusions: After the introduction of the new syringe for measuring blood gases, we detected an increase of 1.5% of coagulated samples while other errors remained equal. Clots in blood gas samples may obstruct the analyzer or give inaccurate measurements of pCO_2, pH and hemoglobin; To overcome these drawbacks, it is necessary to stir adequately syringes so heparin is correctly dissolved and thus prevent coagulation of the sample. The correct recording of preanalytical errors allows us to detect significant variations that may occur in them, and therefore analyze the causes and promoting corrective actions.

Key words: Preanalytical errors, Arterial blood gases, Solid heparin syringe.

P174

REDUCING NEEDLESTICK INJURIES IN HEALTHCARE WORKERS: THE USE OF SAFETY MEDICAL DEVICES AND EDUCATION PROGRAMS

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Background: Healthcare workers are exposed to potentially bloodborne pathogens, primarily through needlestick and sharps injuries. Needlestick injuries can occur during use of the device, after device use prior to disposal and during disposal. Over 80% of needlestick injuries can be prevented with the use of safer needle devices. Worker education and work practice controls, can reduce injuries by over 90%. The aim of this study was to compare the rate of needlestick injuries before and after the use of safety medical devices.

Materials and method: Data was obtained from needlestick and sharp object injury report forms of the hospital's Occupational Health Service. Serological results of patients and healthcare personnel were checked in the laboratory information system.

Results: In 2010, the year before the use of safety devices (blood collection safety needle, sterile closed system with luer adapter and cannulas for blood collection from catheters etc.) 198 needlestick injuries were self-reported. The highest incidence was observed among medical staff in the emergency room, intensive care unit and blood collection unit. Of all occupational groups, phlebotomist and nurses (32.7%) had the highest risk to expose. In 2011, 2012,2013 and 2014 (after use of safety devices) 137, 124, 101 and 97 cases were reported respectively. Thus an overall reducing of 51% for injury was provided when safer medical devices were applied.

Conclusion: The use of safety medical devices has provided a reduction of injury and significantly reduces the risk of bloodborne infections. Prevention is cost-effective. Hundreds of workers have experienced illness and countless more suffer the anxiety and trauma that accompanies every injury as they complete months of testing and treatment.

Key Words: Needlestick injury, safety medical devices

P175

"GREEN LABORATORY": LEAN METHODS IN THE PREANALYTICAL PHASE

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Background: Nowadays, the healthcare service systems are facing a double challenge. First, high-level service and failure reduction are expected; secondly, severe cost reduction is needed. These requirements are met by the application of LEAN principles in healthcare system.

Materials and methods: Our goal is to improve the quality and cost indicators of the preanalytical phase. By the study of the preanalytical process, we reveal the potential reasons of failure, the critical parts of the process and we propose corrections. Kaizen is one of the pillars of the LEAN, this is a development that does not involve a significant investment but improves the process quality and results in cost reduction.

Results: In our study the process reliability is increased and lead-time is decreased by failure reduction. In the process, the potential failure modes are detected and their causes are identified by FMEA (Failure Mode and Effects Analysis) method. The patient is in the focus of all process development activities. The processes contain only value-creating activities: the sample collection and transport are carried out according to a previously determined quality framework, the process cannot be interrupted and by adequate feedback mechanisms a failure-free diagnostic process is realized.

Conclusions: The implementation of LEAN principles into the healthcare system is not possible by automatic takeover of the LEAN tools, therefore special adaptation is needed.

Key words: preanalytical, FMEA, LEAN, process rationalization

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LABORATORY INFORMATION SYSTEM AS A TOOL FOR PREANALYTICAL ERRORS DATA MANAGEMENT

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Background: Systematic identification and recording of preanalytical errors can improve the organization of the key activities of the laboratory process and allows to plan and monitor measures for its improvement.

Preanalytical errors can be recorded manually in specific laboratory datasheets but electronic recording of errors within the laboratory information system or dedicated programs has many advantages.

Materials and methods: In February 2013 we started to use electronic type of recording of preanalytical errors through developed template inside the laboratory information system Kobis. In the preanalytical error list there were 7 test order errors and 22 sample errors. Each error was also associated with appropriate comment on the lab report and sample matrix type.

With a simple function the appropriate preanalytical error is chosen from the list of predefined errors. As such a developed electronic system for recording errors allows us to collect standardized and continuously recording errors from any terminal and includes the compilation of statistics on the percentage of individual errors based on the number of orders or of individual samples.

Results: The overall rate of preanalytical errors in 2013 was 1,4% of all received samples and 2,4% of all laboratory orders. Hemolysed sample was found to be the most common preanalytical error (50,2% of all errors), followed by missing sample (17,8%) and clotted sample with anticoagulant (10,2%). Comparison with previous data was not possible because of different collection criteria.

Conclusion: Preanalytical errors data collection via electronic recording grants major benefits over manual one. Logging is simpler and faster and it is easier to analyze the data collected.

Despite the fact that the recording of preanalytical errors is an obligation for all employees, with the use of electronic recording we provide a more objective and credible information on the number of preanalytical errors and the actions taken.

Key words: preanalytical errors, laboratory information system, laboratory data management

P178

THE USE OF GEL TUBES CAN JEOPARDIZE ADRENAL VEIN SAMPLING: A CASE REPORT

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Background: This case report aimed to demonstrate that primary blood tubes with gel separator should be avoid during adrenal venous sampling(AVS).

Case report: A patient with primary aldosteronism diagnostic-hypothesis was admitted to perform an AVS. The venogram was performed to confirm the catheter position with 2mL of media contrast. Eight samples with 10mL (each) were collected from four sites: super cava vein(SCV), inferior cava vein(ICV), left adrenal vein(LAV), and right adrenal vein(RAV). Blood from each vein were immediately transferred into two tubes: one with lithium-heparin and one with clot activator – both with gel separator. All eight samples were immediately delivered to our laboratory to determinate both cortisol and aldosterone concentration. All tubes were centrifuged together using the same protocol, at the end, both tubes (serum and plasma) with blood from RAV had shown abnormal flotation of gel separator; surprisingly all other tubes (i.e., with blood from SCV, ICV, and LAV), exhibited a standard gel barrier formation. The radiologist was contacted and he informed that was necessary to use more than 2mL of media contrast close to RAV because the patient has anatomic variation. The media contrast used had $1.33g/cm^3$ of density. Since the lead principle of gel barrier formation is the difference density degrees between blood and gel, the excess of media contrast used near RAV increased blood density and itself can explain the abnormal flotation of gel separator only from samples collected there. We tried to access the serum and plasma from RAV under the gel barrier by a pipette but we couldn't, due to the occlusion of pipette tip by gel. Without both cortisol and aldosterone results from RAV, the endocrinologist lacks the best outcomes from AVS procedure.

Conclusion: To avoid gel-tubes then to use plan-tubes during AVS procedure could both prevent this nonconformity and improve patient safety.

Key words: blood specimen collection, laboratory variability, medical errors, patient safety preanalytical phase

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PREANALYTIC PHASE IN ROMAGNA GREATER AREA STANDARDIZATION OF THE ASSESSMENT OF BEST PRACTICE

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Background: The 8 laboratories in Romagna receive samples from 500 different Blood Collection Centres (BCC) dedicated both to inpatients and outpatients, and serve about 1.2 million inhabitants.
Since some severe errors, affecting the quality of clinical outcomes, can be rarely or never detected, it is important to efficiently monitor best practice application within the preanalytical phase.

Materials and methods: By conducting a Preanalytical Quality Check (PAQC), an innovative service, based on an iPad application, developed and offered by BD Diagnostics Preanalytical Systems (BD PAS), a team of BD PAS clinical experts has observed a day routine for the blood collection procedures performed at 5 collection centres of the Cesena AUSL. Blood collections were observed with the aim to disclose and identify each error occurring in the preanalytical process.
The observations referred to the following areas: devices storage, patient identification, biohazard exposure, blood collection procedure, health care worker safety. A score has been assigned to each observation defined as "correct or un-correct" *according to CLSI Standards* and internal approved Standard Operative Procedures (SOPs) in order to allow both a specific evaluation of the given item and a benchmark among observed BCC and other 11 Italian institutions.

Results: 73% o blood collections have been observed during the auditing day. Within the group of BCC the following results are to be reported in terms of compliance to the best practice suggested by the CLSI standards. Storage of blood collection devices: 100%; Patient identification:80%; Prevention of biohazard: 67,5%; Best practice in blood collection procedure:44%; Health care worker safety (correct use of devices and/or proper measures of prevention): 70%.
The global performance of the assessed group was 72.3% (benchmark 68%).

Conclusions: The observation of the blood collection process through the application of the PAQC by BD, conducted by external "observers" allows to gain fact based information on a process very difficult to monitor for a laboratory. The results analysis and the findings sharing with the professionals, involved into the blood collection procedure, have allowed to plan an audit and an educational program, more tailored to the nurse needs. The new tool has been instrumental to document the compliance to the lab SOPs and to plan the required actions for continuous improvement.

Key words: blood collection centres, assessment, procedure, educational program

P180 – SELECTED ORAL COMMUNICATION

THE EFFECT OF AN EXHAUSTION EXERCISE IN ROUTINE CLINICAL CHEMISTRY PARAMETERS

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Background: Physical activity as preanalytical variable has influence on several biomarkers. The level of training, type, intensity and duration of exercise may influence a broad array of laboratory variables.
The aim of this study is therefore to describe the changes of some common chemistries in response to an exhaustion exercise protocol.
Materials and methods: Thirteen male athletes (21.6 ± 3.2 yrs, 72.4 ± 6.5 kg; 177 ± 5 cm) participated in this study. One blood sample was collected with the athletes fasting and before exercise (**M1**). Then the participants completed a concentric/eccentric knee extension/flexion exercise protocol until exhaustion. At this moment, a second blood sample was collected in the seated position (**M2**). Protocol was repeated 2 weeks later and the mean of the two measurements (M1 or M2) considered for comparisons. We analyzed routine clinical chemistry parameters in automated Olympus AU5400® Beckman-Coulter equipment. Descriptive data was reported as mean and standard deviation. Paired-sample t-test was used to compare mean differences between M1 and M2 moments. The % change was compared with expected acceptable Bias. All data were analyzed using SPSS 20 software. The level of significance was set at $p<0.05$, 95% Cls.
Results: In addition to the increase in muscle markers, which was expected (data not shown) and of Triglycerides and Chloride, all analyzed parameters decreased from M1 to M2. Considering these changes the ones that were statistically significant were Total Proteins, Glucose, Total Cholesterol, HDL-cholesterol, LDL-cholesterol, Albumin and Uric Acid. The % change (M1 to M2) was compared to the acceptable biological variation bias. For this comparison the parameters that were outside the acceptable biological variation bias were Total Protein, Glucose, Albumin and Uric Acid.
Conclusion: When comparing the effect of an intense exhaustion physical exercise on different common chemistries only a small group of parameters showed changes that challenged the acceptable biological variation bias.

Key words: Clinical chemistry parameters, Exercise, biological variation.

P181

POSTURE DURING DIAGNOSTIC BLOOD COLLECTION CAN CHANGE ROUTINE HEMATOLOGICAL TESTING RESULTS

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Background: Several preanalytical variables exert a strong influence on laboratory testing, but no data have been published about the effect of posture on routine hematological testing.
Materials and methods: Three K_2EDTA vacuum tubes were collected by venipuncture from 19 volunteers. The first was drawn after 25min resting in supine position, the second after 20min in sitting position, and the last after 20min in upright position. The complete blood count was performed with the hematological analyzer Advia2120®. The plasma volume change was calculated with the reference formula of Dill and Costill. Results were finally expressed as median and interquartile range. The significance of differences was evaluated using Wilcoxon's signed rank-test, and statistical significance was set at P<0.05.
Results: The plasma volume change was -3.4% from supine to sitting, -14.1% from supine to standing and -9.3% from sitting to standing, respectively. The change from supine to sitting position caused a significant increase of erythrocytes [4.7(4.4-5.2) vs. 4.8(4.5-5.3), P<0.001], hemoglobin [131(127-145) vs. 134(129-150), P<0.001] and hematocrit [0.41(0.40-0.44) vs. 0.42(0.41-0.44), P=0.009]; the change from supine to standing caused a significant increase of erythrocytes [4.7(4.4-5.2) vs. 5.0(4.7-5.4), P<0.001], hemoglobin [131(127-145) vs. 141(134-154), P<0.001], hematocrit [0.41(0.40-0.44) vs. 0.44(0.43-0.47), P<0.001], leukocytes [5.4(4.6-6.7) vs. 6.2(5.3-6.7), P<0.001], neutrophils [3.2(2.4-3.5) vs. 3.7(3.0-4.1), P<0.001], lymphocytes [1.7(1.2-2.0) vs. 1.9(1.5-2.5), P<0.001], basophils [0.02(0.01-0.03) vs. 0.03(0.02-0.04), P<0.001], platelets

[194(181-233) vs. 210(198-248), P<0.001], and mean platelet volume [8.9(8.5-9.3) vs. 8.8(8.1-9.1), P=0.018]; and that from sitting to standing caused a significant increase of erythrocytes [4.8(4.5-5.3) vs. 5.0(4.7-5.4), P<0.001], hemoglobin [134(129-150) vs. 141(134-154), P<0.001], hematocrit [0.42(0.41-0.44) vs. 0.44(0.43-0.47), P<0.001], leukocytes [5.7(4.9-6.1) vs. 6.2(5.3-6.7), P<0.001], neutrophils [3.3(2.5-3.7) vs. 3.7(3.0-4.1), P<0.001], and lymphocytes [1.8(1.2-2.1) vs. 1.9(1.5-2.5), P<0.001].

Conclusion: The results of this investigation shown that patient posture can significantly impact on routine hematological testing, consequently is necessary to standardize patient posture during blood collection to guarantee patient safety.

Key words: blood specimen collection, laboratory variability, medical errors, patient safety preanalytical phase

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FAILING LABORATORY DIAGNOSTICS: A POSSIBLY UNDERSTATED PROBLEM IN DIABETES DIAGNOSIS

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Background: Recently, clinical guidelines for pregnancy diabetes have been updated and cut-off values have been drastically lowered. This has sparked an on-going debate.
Even though clinical laboratories play a central role in determining glucose concentrations, little to no changes have been made to update their state-of-art. This can be of impact, since glucose levels may be may be reported incorrectly when one does not adhere to strict analytical protocols.
For example, PG may drop by 1 mmol/l/h due to *in vitro* glycolysis. Immediate centrifugation and cooling of phlebotomy material is impractical, so most laboratories rely on glycolysis inhibitors (sodium-fluoride, NaF). However, it is not widely known that NaF does not prevent glycolysis in the first 2 to 4 hours.
Materials and methods: We describe a survey on the state-of-art in Dutch clinical chemistry laboratories and an in depth study to what extend a deviation from the recommended procedure affects glucose concentration.
Results: Survey response was received from 25 laboratories. In 90% of laboratories, TAT exceeded 1 hour. Most laboratories relied on NaF to prevent glycolysis, while additional steps were taken only in a few laboratories (<5%). Common TAT-phlebotomy material combinations (60-120 minutes, NaF only) result in a significant drop in PG, which may exceed 1 mmol/L. Importantly, NaF has no effect during the first 2 hours. Interestingly, though recommended, cooling of blood is only partially effective and large variation between subjects exists, ranging from complete stabilization to a drop of 0.3 mmol/L within 15 minutes. The glycolysis inhibitor citrate was the only method to consistently prevent in vitro glycolysis.
Conclusion: Only a small percentage of laboratories takes precautions to prevent glycolysis other than ineffective addition of NaF. Therefore, the state-of-art in glucose measurement results in a false low outcome due to in vitro glycolysis and may result in incorrect diagnosis.

Key words: Diabetes, citrate, glycolysis, sodium fluoride

P183

CAN K2EDTA AND K$_3$EDTA BE USED INTERCHANGEABLY FOR HBA1C MEASUREMENTS?

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Background: Measurements of HbA1c is the "gold standard" for therapy monitoring of diabetic patients. There are many concerns about the suitability of test tubes containing EDTA anticoagulant for the measurement of HbA1c. There is a lot of discussion whether it is appropriate to use K$_2$EDTA or K$_3$EDTA anticoagulant. The aim of this study was to check whether they could be used interchangeably to determine HbA1c.
Materials and methods: Blood was taken out from out- and hospital patients on anticoagulant K$_2$EDTA and K$_3$EDTA in Vacuette tubes (3 mL; Greiner Bio-One GmbH, Kremsmunster, Austria). All patients voluntarily agreed to participate in the study. The total number of patients was 29. After sampling, the blood was immediately mixed 8-10 times according to manufacturer recommendation. All measurements were made at the analyzer i2000SR Architect (Abbott, Wiesbaden, Germany) using original manufacturer reagent kit. Every day, before measuring the

samples Lyphochek Diabetes control was made. Data are presented with median and interquartile range. Wilcoxon test and Passing-Bablok regression were used for tube comparison. P < 0.05 was considered statistically significant.

Results: HbA1c concentrations were as follows: K_2EDTA-56 (47-85) mmol/mol, 7.3 (6.5 to 9.9)% and K_3EDTA-59 (50-80) mmol/mol, 7.5 (6.7 to 9.5)%. Wilcoxon test showed no statistically significant differences between the two anticoagulants (P = 0.116. Passing and Bablok regression showed that there is no constant and proportional error: y = -2.07 (-6.57 to 0.91) + 1.03 (0.98-1.10).

Conclusions: The results show that there is no difference between the two anticoagulants and both tubes can be used interchangeably.

Key words: HbA1c, diabetes, K_2EDTA, K_3EDTA

P184

VALIDITY OF STANDARD REFERENCE VALUES IRRESPECTIVE OF REST AND TIME OF DAY PRIOR TO BLOOD SAMPLING – RESULTS FROM ALBUMIN AND THYROTROPIN

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Background: Preanalytical factors affects different biochemical parameters. Therefore reference intervals are recommended to apply to rules of standardization that state that blood samples should be taken in the morning after 15 min rest. However, both hospital and patients have a wish to minimize waiting time prior to blood sampling. Moreover, some parameters have diurnal variation and since there is a growing desire to expand opening hours in the clinics this variation is worth investigating further. Therefore our aim is to test whether the reference intervals of albumin and thyrotropin are valid throughout the opening hours and investigate the impact of resting time.

Materials and method: All patients referred to an outpatient clinic for blood sampling were included during Nov. 2011-Jun. 2014 (opening hours: 7am–3pm). For each patient arrival time and time of blood sampling were registered electronically using Q-MATIC Suite. Impact of resting time and time of day on thyreotropin and albumin values was analyzed using a simple linear regression. The "maximum allowable bias" was used as quality indicator for the reference interval.

Results: Using linear regression we found significant diurnal variation and influence by resting time for albumin (n=15,544) and thyrotropin (n=20,019) with p-values: 0.004 (rest) and $<2x10^{-16}$ (diurnal) for thyrotropin, $2.6x10^{-4}$ (rest) and $<2x10^{-16}$ (diurnal) for albumin. For albumin the maximum allowable bias never exceeded limits for accepting reference values for any resting time or time of day (but was on limit at 3pm). Thyrotropin concentration decreased from 7-9am. After 9am the change exceeded maximum allowable bias. For the resting no pattern was observed.

Conclusion: It is not necessary to wait 15 min prior to blood sampling. Albumin may need a change of reference interval if opening hours is expanded. Thyrotropin diurnal variation is very important and change of procedure or reference interval is necessary.

Key words: Reference interval, thyrotropin, albumin, resting time, diurnal variation

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THE LYOPHILIZED FORM OF CONTROL MATERIALS AND THE INFLUENZE OF "MATRIX EFFECT"

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Background: Quality control of laboratory tests determines the statistical system which, by analysis of control materials permits the evaluation of the results obtained in the laboratory in terms of systematic errors and random errors, quality control, external quality control and complementary system). The most important thing is the quality of control material that should be determined by some characteristics like stability, similarity to routinely investigated samples etc.

The aim of the study was to examine the stability of lyophilized control material of independent manufacturer using dry chemistry techniques. Additionally, attention was paid to the possibility of the "Matrix effect" and the differences between the numerical results during the change of slide generation / series.

Materials and methods: In February and March 2013 in the Quality Control Research Laboratory at Medical Center of Laboratory Diagnostic (Institute of Polish Mother's Health Centre in Lodz), in the procedure of internal quality control determination of parameters from the section of clinical chemistry with the use of *RANDOX Laboratories* control materials were done.

Multiparametres lyophilized control sera in the field of clinical chemistry, at two levels of analyte concentrations in the four production series (*ASSAYED HUMAN SERUM*) Biochemical analyzer Vitros 5.1 FS Ortho Clinical Diagnostics.

Analyzed parameters: ALP, ALT, AMYL, AST, total CHOL, CL$^-$,GGT, GLU, K$^+$, Na$^+$, TBIL, TP, TG, ALB, HDL, LAC, UREA, CREA, Mg, CK, P, LDH.

Results: The lyophilized form of control materials did not affect the generation of "matrix effect".

Independent control materials of *RANDOX company* are characterized by a high degree of stability.

The obtained results were characterized by good precision and correctness.

Conclusion: In the evaluated control materials no signs of fluctuations in the values of controls in case of change slide generation / series for majority investigated parameters were showed**.**

Key words: The lyophilized form of control materials, dry chemistry, matrix effect, stability