

1st EFCC-BD European Conference on Preanalytical Phase

Preanalytical quality improvement – from dream to reality

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BD Diagnostics, Preanalytical Systems

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P1

Prevalence hemolytic specimens for arterial blood gas analysis in a large Academic Hospital

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Background: In vitro hemolysis is the leading source of unsuitable specimens in clinical laboratories. Although several studies have documented the prevalence of hemolytic specimens, most of them have focused on errors related to clinical chemistry, immunochemistry, coagulation and hematological testing, while no reliable information has been provided so far on arterial blood gas (ABG) analysis.

Materials and methods: This study was undertaken at the Clinical Laboratory of the Academic Hospital of Parma (Italy). All the specimens received in our core laboratory for ABG analysis in August 2010 were systematically inspected for hemolysis immediately after ABG analysis has been completed, by transferring the blood into secondary tubes, and further centrifugation at 3500 x g per 10 min. In vitro hemolysis has then been assessed by visual inspection of the plasma by a skilled technician and a supervisor.

Results: Out of a total of 1228 ABG specimens received in our laboratory throughout the 1-month study period, we identified 15 samples (1.2%) with various degree of hemolysis. The vast majority of these samples were referred by the Nephrology Dialysis Transplantation unit (12 out of 15, 80%).

Conclusions: The results of our investigation attest however that the prevalence of hemolytic specimens referred for ABG is still meaningful (1.2%), so that there is a real chance that the clinical decision making undertaken on these might produce adverse analytical and clinical outcomes, especially for those tests of the ABG panel which are more hemolysis-dependent (i.e., potassium, pH, pO₂,

pCO₂). As such, we suggest that the systematic centrifugation and scrutiny at least by visual inspection of all ABG samples (the turnaround time of the hemolysis index might be unsuitable for this type of testing) might be a reliable approach to decrease the adverse consequences of unreliable results obtained on unsuitable ABG specimens.

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P2

Automation of the preanalytical phase in a clinical laboratory: personal experience

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Background: The automation of the preanalytical phase is still seen as radically innovative in the context of laboratory diagnostics. Here we describe the automation of the workflow in the preanalytical section of the clinical laboratory of the Academic Hospital of Parma.

Materials and methods: Our laboratory receives an average of ~1,400 and ~1,000 samples (daily) from in- and out-patients, respectively. The mean number of whole blood, plasma, serum and urine specimens received is ~7,200. The preanalytical section is composed of one HCTS 2000 (m-u-t AG) and four Automate 800 instruments (Beckman Coulter). All instruments are directly connected with the LIS. The staff present in this section comprehends 1 PhD specialized in clinical biochemistry, 3 laboratory technicians and 8 additional healthcare operators.

Results: All the samples first undergo rapid scanning (check-in) and sorting in the HCTS. Whole blood and urine samples are then immediately transported to specific sectors of the core lab, whereas serum and plasma specimens are transported and processed (centrifugation, aliquoting and sorting) in the four Automates. Primary centri-

fused tubes and eventual aliquots of serum and plasma are then transported to specific sectors of the core lab.

Discussion: The automation of several repetitive, error-prone and bio-hazardous processes in our reality has granted several advantages, including a highly improved turnaround time, a substantial reduction of the biological risk associated with operator's exposure to hazardous biological material, a reduction in errors and costs associated with sample handling and a more favorable management of workflows. This organization has also allowed freeing up of laboratory personnel, so they can concentrate on other tasks.

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P3

Estimation of the minimal preanalytical uncertainty

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Background: We sought a model to estimate preanalytical uncertainty of blood samples.

Materials and methods: Blood was collected into 2 RST tubes and 2 SST tubes from both arms of 20 individuals. Optimal preanalytical handling of the blood samples included a loosely-fastened tourniquet, wide bore needles, recommended clotting time and centrifugation speed, and minimal storage before analysis. The serum samples were analyzed on Roche Modular. We used linear mixed-effects models to estimate the between-venipuncture SD, the preanalytical SD, the measurement repeatability SD, systematic differences between the tubes and between venipunctures.

Results: For LDH the preanalytical SD (3.2 U/L, 95% CI 2.8–3.7) was significantly higher than the

SD for measurement repeatability (1.9 U/L, 95% CI 1.7–2.1). For potassium both the preanalytical SD (0.092 mmol/L, 95% CI 0.080–0.110) and the between-venipuncture SD (0.075 mmol/L, 95% CI 0.048–0.120) were significantly higher than the SD of measurement repeatability SD (0.031 mmol/L, 95% CI 0.028–0.035). For glucose the between-venipuncture SD (0.20 mmol/L, 95% CI 0.14–0.27) was significantly higher than the preanalytical SD (0.07 mmol/L, 95% CI 0.06–0.08), and the measurement repeatability SD (0.057 mmol/L, 95% CI 0.051–0.064). No significant systematic differences were found between venipunctures. Statistically significant mean differences were seen between SST tubes and RST tubes for 7 of the 15 analytes.

Conclusions: The linear mixed-effects model is useful to determine the minimal preanalytical uncertainty, which is inevitable even when the samples are handled optimally.

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P5

The presentation of recommendation of The Czech society of Clinical Biochemistry for rejection and refusal of samples of biochemical materials of patients by clinical laboratories

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Background: The aim was the conceiving of the document of the Czech Society of Clinical Biochemistry which summarizes the principles of rejection and refusal of samples by clinical laboratories.

Materials and methods: The basis of proposed recommendations was ČSN ISO 15189, current information from the literature dealing with preanalytical phase and the information located at www.specimencare.com. Part of the communication is a pilot study of analysis of the numbers and types of

disagreements in the area of acceptance and refusal of biological samples. The study was made in three Czech University Hospital laboratories (FN Motol, FN Hradec Králové a FN IKEM Praha).

Results: Result of the work was the presentation of recommendation of the Czech Society of Clinical Biochemistry for rejection and refusal of samples of biochemical materials of patients by clinical laboratories. The presentation was published on the website of the society and it was subject to discussion comments of professional public. The typical frequency of rejected samples was about 0.5%. The most frequent were cases of undelivered samples or requirements (almost 60% of all the mistakes). The number of identification errors was about 5%.

Conclusions: In this presented work we indicate basic reasons for refusal of a defective sample by a clinical laboratory. These reasons protect a patient against risk of diagnostic mistake or even against damage to health. The aim is to increase the safety of patient.

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P6

How much preanalytical phase factors can influence the tests results?

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Background: The haemoculture is one of the most important lab tests and also one of the most affected by the interference of preanalytical factors. During the collection of blood sample there are a lot of possibilities of contaminating the blood, which provides false positive test result, affecting the management of the patient.

We made an epidemiological investigation in our hospital, concerning the collection of haemocultures, because in a short period of time, from 255

haemocultures, 33 positive haemocultures were reported, 11 of them being positive with the same germs: aerobic sporulated bacili (nonpathogenic bacteria often found in ambiental aeromicroflora).

Materials and methods: We analyzed the result by ward and by the person who made the collection and concluded that we had positive results in all departments. The results were also analyzed according to persons who made the collection and it was concluded that positive results came from all of them. We also made the control of the haemoculture media and we could not incriminate the media. The control of the aeromicroflora in hospital rooms gave us positive results for aerobic sporulated bacili, so we tried to make the connection with the contamination of the blood culture.

Results: Because the contamination seemed to occur in all hospital departments, it was not dependent on the collecting person and in aeromicroflora grow the same aerobic sporulated bacili, we made the bacteriologic culture of the cotton used for the disinfection of the patient hand before collecting the blood and concluded it was the cause of the contamination.

Conclusions: 4.3% of the haemocultures were false positive, directly related to the contamination of the aeromicroflora and the incorrect preservation of the cotton used for the disinfection. It was a good method of evaluating how much a preanalytical phase factor can influence the test results.

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P8

Preanalytical Quality Control Spanish Program (2001-2010 summary)

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Background: Preanalytical variables, such as sample collection, handling, transport, may affect pa-

tient results. Quality control mechanisms in preanalytical phase should be established in order to minimize laboratory errors and improve patient safety.

Materials and methods: A retrospective study (2001-2010) of results obtained through the Spanish Society of Clinical Chemistry (SEQC) Quality Assessment Program (Preanalytical Phase) has been carried out to summarize data regarding the main factors affecting preanalytical phase quality. In such a program, participants are asked to register rejections and causes for rejection. In our study we have compared data corresponding to 2006-2010 with our previously published data of the period 2001-2005.

Results: In the most recent period, a decrease in the percentage of rejections can be observed in comparison to the first period (0.409 vs. 0.699%). In the first period whole blood EDTA and serum samples accounted for 75.6% of total collected samples and for 55.8% of rejections, whereas in the second period they represented 82.7% of samples collected and 65.3% of rejections. In both periods the most frequent sample is serum. In the period 2001-2005, the most frequent causes of rejections were: specimen not received (37.5%), hemolysis (29.3%) and clotted sample (14.4%); in the period 2006-2010 these causes are: specimen not received (35.7 %), hemolysis (33.4%) and clotted sample (11.5%). In both periods, plasma-citrate-ERS exhibited the highest amount of rejections, whereas the lowest corresponded to whole blood -EDTA. In these samples the rejection rate found was slightly lower than that corresponding to the first period, 1.142 vs. 1.463% and 0.316 vs. 0.381% respectively.

Conclusions: The overall percentage of rejection in 2006-2010 period is lower than the one found in previously published data. Improvements in organization and implementation of standardized procedures in the preanalytical phase in the Spanish laboratories may have contributed to reducing errors in this phase.

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P9

Detecting paraproteins with measurements of serum index on Siemens analysers Dimension

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Background: Automated measurements of serum index are of great importance to prevent spectral interferences on biochemical tests, especially in laboratories using preanalytical systems and with no possibility for visual inspection of samples. HIL (hemolysis, icterus, lipemia) represents the measurement of serum index on Siemens analysers Dimension. Our aim was to evaluate occasionally unusual high values for lipemia on clear serum samples.

Materials and methods: The measurements of serum index were made automatically in serum samples on Dimension Vista and RXL Max analysers. The results are reported as a three figure number in scales from 1-8 for Vista and 1-6 for RXL Max. The impact of interferences grows with each respective class. The serum protein electrophoresis was made on Interlab Microtech analyser and immunofixation on Sebia analyzer.

Results: In the years 2006-2010 we detected 202 different patients with unusual high lipemia signal and a clear serum, HIL 114-118 on Vista or HIL 114-116 on RXL Max. The signals are due to interference of immunoglobulins, mostly paraproteins in the sample. In 87% a monoclonal peak was found with serum electrophoresis and immunofixation method. Contrary, the signal was present only in 25% of all samples with a monoclonal peak, probably due to formation of immunoglobulin complex.

Conclusions: With a rapid and costless automated measurement of serum index on Dimension analysers we can get quick information for a possible presence of paraproteins in the sample. Unusual lipemia index is mostly found in patients with multiple myeloma, leukemia and lymphoma, rarely in

patients with Sjorgen sindrom, liver cirrhosis and others. The laboratory should pay attention to these signals as they can be of high importance in undiagnosed patients. A simple measurement of serum index can shorten the way of the patient to the appropriate treatment.

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P10

Effective strategies of unequivocal identification of the patient and their biological samples

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Background: The errors of patient identification and/or its biological samples present a serious problem, by involving a potential risk for the patient. Our objective was to establish multidisciplinary team for development of a Safety specification for Identification of patient and biological samples. This instruction must be followed by all professionals

Materials and methods: We carried out the analysis of the actual situation of the identification incidences and the critical points of two origins were detected. As indicator-key we used: analytical form without label of patient, erroneous identifications (number of clinical history does not correspond with the patient) and confusing identification. The report/ratio is the base for a decision about the need for working out a Safety specification for Identification of patients and its biological samples.

Results: The average/day of emergency analytical was from 621. The average of results (measured/per day) of incidence was: identification by hand: 81 patients; confusing identification: 46 patients; without any patient identification: 5 patients; with erroneous identification: 7 patients. The report done as the result of this study was approved by the

Management of the Hospital served as a base for development of the Safety specifications containing obligatory fields in the analytical form of request. After this, there was a significant decrease in identification incidences.

Conclusion: We observed an important percentage of requests whose identification of the patient is incorrect, which makes take fast and effective measures for their solution. This is a very important area which laboratory professionals, working in disciplinary teams, can improve patient safety.

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P11

Comparison of the BD Vacutainer® rapid serum tube with a range of commercially available serum separator tubes for clotting time

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Background: For many diagnostic assays, serum is the preferred supernatant. However, in situations where rapid results are needed, its use is precluded because of the required clotting time. If centrifugation is conducted prior to complete clotting, it will result in fibrin formation in the serum sample and potentially lead to rejection of the sample. A study was conducted to evaluate the clotting performance of BD Vacutainer® Rapid Serum Tubes (BD RST), which contain a thrombin clot activator, in comparison with a number of other widely available serum separator tubes.

Materials and methods: Blood from 32 apparently healthy adult donors was collected into BD RST, BD Vacutainer® SST™ II Advance (BD SST™ II), Greiner Serum Separation & Clot Activator Tube (Greiner) and Terumo Gel & Clot Activator Tube (Terumo). The samples were mixed and the clotting time measured using a stopwatch. The tubes were

then centrifuged according to the manufacturers' instructions. Visual observations of sample quality were made (gel barrier formation; presence of fibrin ring; presence of gel globules in the serum).

Results: Mean (SD; minimum-maximum) clotting times in seconds were: BD RST: 152 (46; 54-240; $P = 0.794$), BD SST™ II: 527 (155; 275-935; $P = 0.188$), Greiner: 673 (146; 275-946; $P = 0.210$) and Terumo: 780 (105; 520-962; $P = 0.868$).

Conclusions: All tubes had no gel globules, contained no fibrin and had complete gel barrier formation. The BD Vacutainer® RST tubes had a significantly shorter clotting time than the other tubes, with samples fully clotted and ready for centrifugation within five minutes of collection.

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P12

NSE and ProGRP - serum or plasma, temperature and time of sample storage

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Background: Recently, NSE and ProGRP are considered to be tumor markers of choice in small cell lung cancer. The aim of study was assessment of the stability of serum as well as plasma for NSE and ProGRP, in respect to time and temperature of specimen's storage.

Material and methods: The study was performed on samples obtained from 44 oncological patients. The serum and plasma specimens stored at 2-8 °C were tested within 1, 24, 48 and 168 hours after collection, and 2 or 4 weeks if stored at -20 °C or -80 °C respectively.

Results: NSE levels in serum and plasma decreased when samples were kept at 2-8 °C for 168 hours. Whereas the median values of remaining NSE levels percentage in serum were 93%, 92.3% and

78.8%, in the plasma dropped to 60.6%, 41.1%, and 29.7% of initial concentration after storage at 2-8 °C for 24, 48 and 168 hours, respectively. NSE in serum was stable where samples were frozen and stored at -20 °C or -80 °C, immediately after collection. Significant correlation was found between serum and plasma ProGRP levels. ProGRP serum levels decreased during storage of samples at 2-8 °C. Median values of remaining ProGRP concentration percentages were 83.6%, 74.8% and 49.4% of initial levels after storage at 24, 48 and 168 hours, respectively. Whereas the changes of plasma ProGRP in the same intervals of storage at 2-8 °C were within 3-10% lower than initial level.

Conclusions: Type of material didn't influence the ProGRP and NSE levels when the determinations were performed within 1 hour after collection. Serum samples for determination of ProGRP and NSE ought to be frozen immediately after collection and stored at -80 °C.

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P13

The relevance of the preanalytical phase in urine examination and urine report

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Background: The aim of this study was to evaluate the reliability of outpatient's urine examination in the Academic Hospital of Parma and the pattern we follow (by means of flow cytometry) for identifying unsuitable samples.

Materials and methods: Our laboratory analyzes 800 urine samples *per day*, using Siemens Pro12 Atlas for chemical analysis and citofluorimetric Sysmex- Dasit Uf100 for morphological examination.

Results: In 300 outcome specimens analyzed daily (35% men; 65% women), 60 of them (20%) were considered unsuitable: 25% probably diluted, 20%

contaminated by squamous epithelial cells of vaginal origin, as well as 40% with significant discrepancies between the number of bacteria, leukocytes and leukocyte esterase, 5% concentrated, 3% without biological elements, 2% contaminated by semen, 2% with abnormal precipitations, 2% with insufficient volume, 1% contaminated by fecal material. As a comparison, unsuitable specimens from in-hospital patients were mostly characterized by discrepancies between bacteria and esterase, dilution (especially from pediatric wards) and contamination with fecal material (especially from geriatric wards).

Conclusions: The two populations of out- and inpatient samples widely differ. Outpatients have a high prevalence of inappropriate sample collection (due to the possible lack of information), whereas inpatient samples are mostly plagued by the objective difficulty of collection and an improper storage.

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P14

Phlebotomy - the most critical extra-analytical procedure - multicentric survey study

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Background: Our group recently reported the state of the quality of extra-analytical phase in some European countries and Mexico. Here we present a part of this previously published multicentric study. Our aim was to identify the most critical issues related to the blood sampling practices.

Materials and methods: The survey included 3 clinical laboratories from Croatia and one from each of the following countries: Bosnia and Herzegovina, Czech Republic, Hungary, Mexico, Poland, Portugal, Romania, Serbia and Ukraine. Laboratory personnel completed questionnaire with Likert scaled questions (never=1, rarely=2, often=3, always=4 and sign x for not applicable) that were later scored (from 1-4). This study analyses part of original questionnaire regarding phlebotomy procedures: patient identification prior to sampling, order of draw, deviating from the recommended time for collecting fasting specimens early in the morning and recording the exact time of blood sampling. Subjects' median age was 42 (20-75) years.

Results: Total of 461 questionnaires was collected, 18 were excluded (< 50% filled questionnaire) and the final number of questionnaires which qualified for statistical analysis was 443. We found that 79% of subjects never confirm patient's identity with picture-based document although 93% of them always ask for patient's name. Almost half of the subjects (45%) always accept samples collected after 11 am if patient is coming from distant destinations. Regarding that last question, subjects from accredited laboratories or laboratories in preparation for accreditation had statistically significant ($P < 0.001$) higher score (2.34 ± 1.00) than subjects from non accredited laboratories (1.86 ± 0.99). Also, there was a statistically significant difference in following the order of blood draw ($P = 0.007$) and recording the exact time of blood sampling ($P = 0.001$) between laboratories that have a written procedure for primary sample collection in comparison with laboratories that do not have it.

Conclusions: Inappropriate patient identification and deviation from the recommended time for collecting fasting specimens early in the morning are identified as the most critical activities related to the phlebotomy practices, in our study. Laboratory accreditation and written procedures for primary sample collection are associated with substantial improvement of the quality of phlebotomy practices.

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P15

From patient to laboratory - Croatian educational project for nurses in primary health care

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Background: Clinical decisions based on laboratory test values are correctly made only when blood and other specimens are properly taken and identified under standardized conditions. One of the primary goals within the reform of the healthcare system in Croatia is to increase access to health care for all citizens. Therefore, in 2008 we initiated a project of blood collecting in primary health care clinics, so that patients would be spared another separate visit to the laboratory for blood withdrawal. This project was jointly designed by three health chambers involved and it was funded by Croatian Health Insurance Institute.

Materials and methods: Launching the project entailed a theoretical and practical training of nurses, the task fulfilled by Croatian Chamber of Medical Biochemists (CCMB). For this purpose, CCMB published a manual which covered and explained all recommended preanalytical standards. These were: test selection, tests requesting, patient preparation, blood sampling (both venous and capillary blood), transport patterns, maximum allowable sample transportation times, the most common mistakes and how to avoid them, as well as safety

instructions during phlebotomy. The emphasis was given to the standardized procedures of blood withdrawal. The practical part is provided within the medical laboratory. Theoretical part is organized by CCMB in form of a series of continuing education courses which are being offered to 2462 primary healthcare nurses in 20 Croatian counties.

Results: Since the beginning of training in December 2009, the course was completed by 1100 of 1591 invited nurses (69%). Although as of January 2011, blood sampling should legally be done by nurses in general practitioners' offices, number of offices where phlebotomy is performed increased from 20% to 40%. Preliminary number of preanalytical errors does not show significant deviations from the previous, when blood sampling was done within the laboratory.

Conclusions: The results show that educational programs are accepted and that by teaching nurses how and why to apply the standards of good professional practice, numerous preanalytical errors can be reduced or eliminated.

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P16

Preanalytical elimination of interferences affecting hematology results in oncologic patients

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Background: For the complete blood count (CBC) on hematology analyzers, we get accurate results in most situations. Red blood cell (RBC) count, mean cell volume (MCV), hemoglobin (Hb) and mean corpuscular hemoglobin concentration (MCHC) results can be spurious in case of cold agglutinins, hyperlipidemia, high amount of paraproteins, very high white blood cell count or giant platelets in samples. These influences depend on

hematological analyzers. In oncologic patients tested in our laboratory, we found cold agglutinins and high concentration of paraprotein affecting RBC count and hemoglobin results. We also studied the influence of lipids on hemoglobin determination. All these interferences can be avoided with proper treatment of the sample (incubating at 37 °C, changing the plasma).

Materials and methods: In our laboratory, we performed CBC count on hematology analyzers Beckman Coulter LH 750 and Siemens ADVIA 120. The serum index for lipemia in serum samples was determined on analyzer Roche Modular.

Results: In samples with cold agglutinins, we found decreased RBC count (10-60%), and increased MCV and MCHC. All samples with MCHC greater than 360 g/L were incubated for 20 minutes and then analyzed again. Cold agglutinins interference was more pronounced on LH 750 than on ADVIA 120. The sample from a patient with paraprotein concentration of 41 g/L was analyzed and the following results were obtained on LH 750: RBC $2.81 \times 10^{12} / L$; Hb 100 g/L; MCV 88.3 fL and MCHC 401 g/L. The results on ADVIA 120 were: RBC $3.03 \times 10^{12} / L$; Hb 86 g/L; MCV 86.7 fL and MCHC 325 g/L. After the plasma was replaced with LH diluent, Hb on LH 750 was 86 g/L. In lipemic samples, we found no interference with hemoglobin determination up to the serum index for lipemia of 280.

Conclusions: Awareness of interferences with CBC is important and, with appropriate preanalytical elimination of them, we can avoid erroneous results and unnecessary testing.

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P17

Quality indicators of the preanalytical phase in blood gas analysis

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Background: The preanalytical phase is often overlooked as a major source of errors in whole-blood analysis, especially in blood gasses. Arterial blood samples are very sensitive because of the physiological properties of blood and the changes after the sampling. Quality indicators of the preanalytical phase are tools that can be used to supervise the activity carried out in the laboratory and activities in relation to the clinical laboratory.

Materials and methods: Sampling of the arterial blood for whole blood analysis is performed by nursing staff on the wards, the analysis are performed by laboratory staff in the clinical laboratory. The standard procedure for sampling and the importance of the preanalytical phase with the aim to avoid errors in laboratory reports has been prepared by both, the laboratory and the nursing staff. 6 quality indicators, based on most common preanalytical errors, have been defined. These are sample volume, mixing of samples, air bubbles in samples, transportation time, identification of the sample and electronic request form, transfer of electronic request form from hospital information system to laboratory information system. The data are collected 14 days pro year for all samples, received by the laboratory.

Results: Until the year 2007, the data are collected and corrective actions, such as education of nursing staff on preanalytical issues, have been taken. A big improvement in fulfillment of the quality specifications goals has been detected. By the end of the 2010 99.6% of the samples fulfill the criteria on sample volume, 98.2% on mixing of samples, 97.8% on air bubbles in the samples, 93.8% on transportation time, 98.9% on identification issues, and 98.9% on appropriate electronic request procedure,

Conclusions: The interdisciplinary approach to manage the quality of the preanalytical phase is a good approach to avoid laboratory errors in whole-blood testing. Process has already proved benefits, continuous actions for all involved in the processes, including new staff, are needed to further improve the quality of the preanalytical phase.

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P18

Stability study of 23 hormones in human whole blood, in serum and in plasma: effect of temperature and delay before analysis according to different tubes.

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Background: To answer to the preanalytical requirements of the standard NF EN ISO 15189, we studied the effects of tubes, time and delay of storage on results for 23 hormones in the objective to provide relevant preanalytical information.

Materials and methods: For each analyte, blood specimens from 10 donors were used, collected in plain glass tubes, serum separator tubes (SST II), and EDTAK3 (Becton Dickinson). Analysis were performed after subsequent delays: 6h, 24h, 48h, and 72h, after storage in whole blood and in serum/plasma, at two temperatures: 4 °C and 25 °C (room temperature, RT). The mean from 10 volunteers was obtained for each analyte: (Tx). The initial value (T_0) was obtained after 30 minutes clotting. To detect a significant change, we compared the mean difference (Tx- T_0) with the goal limits according to international recommendations: the Reference Change Value was calculated using analytical CVa obtained from intra-laboratory quality control data ($RCV = 2.77 \times CVa$), and the 0.5 intra-individual CV (CVb) from Ricos. The assays were performed on the Cobas® 6000 e601 (Roche Diagnostics).

Results: Most of hormonal analytes show a good stability up to 72 h at 4 °C and RT. Some analytes have a better tube or temperature dependant stability: PTH (EDTAK3, 4 °C and RT: 72 h, and all tubes at 4 °C: 72h), insulin (EDTAK3, 4 °C and RT: 72h), C-peptid (all tubes 4 °C: 72 h), osteocalcin (EDTAK3, 4 °C: 48 h), C-telopeptid (EDTAK3, 4 °C and RT: 72 h), ACTH (EDTAK3, 4 °C: 24h). Estradiol and progesterone are less stable in SST II tubes (48 h). FSH and prolactin are stable only 24 h in EDTAK3 at 25 °C.

Conclusions: Data from this study show that hormones stored in whole blood containing EDTAK3 at 4 °C are sufficiently stable up to 72h except osteocalcine (48 h) and ACTH (24 h); in plasma EDTAK3 at 4 °C all these analytes are stable 72 h except ACTH (24 h).

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P19

Identification of system errors in the preanalytical phase of the laboratory process

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Background: The department of Outpatients Laboratory Services and Preanalysis at the Karolinska University Laboratory consists of 61 satellite laboratories and two sample handling units. This department is responsible for the preanalytical phase of the laboratory process including sample collection, transport, registration and handling. Approximately one million phlebotomies are conducted yearly, and 20.000 samples are transported and handled daily. The laboratory uses an electronic error report system to trace errors in the laboratory process. Systematic analysis of statistics on error occurrence led to the identification of system problems in the preanalytical phase.

Materials and methods: Errors reported at our department during 2010 were sorted in two steps according to different categories.

Results: 72 % of all reported errors were categorized as errors in "preanalytical routines". Among those there were 28% referral errors, 25% sample handling errors, 22% registration errors.

Four system errors were identified from this data:

1. Reuse of old electronic referrals.

2. Absence of electronic referrals when patient arrives for phlebotomy.
3. Lack of electronic referrals when samples arrive to the laboratory.
4. Errors in manual registration caused by incompletely filled out paper referrals.

Errors 2) and 3) were confirmed by a manual statistics during one day in all working stations. Measures identified and taken to solve these problems will be presented.

Conclusions: Four major causes of preanalytical errors were identified through the systematic analysis of statistics from an electronic error report system. Three of these were related to the wrong use of electronic referrals and all four were on the interface between healthcare and laboratory.

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P20

Performance of BD Vacutainer® glucose tubes centrifuged with higher g force

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Background: Manufacturers recommend different centrifugation conditions for different blood collection tube types. These differing centrifugation requirements can have an adverse impact on laboratory efficiency, particularly where laboratory work flow is automated. This study was conducted to evaluate the performance of BD Vacutainer® Glucose tubes when centrifuged at 2000 x g as per BD Vacutainer® SST™ II Advance rather than the recommended 1300 x g.

Materials and methods: Blood from 30 apparently healthy adult donors was collected into two of each of the following BD Glucose tubes with different glycolytic inhibitors (fluoride/oxalate (F/Ox); fluoride/EDTA (F/EDTA); heparin/iodoacetate (Hep/

lod)). One was centrifuged at 1300x g for 10 minutes, the other at 2000x g for 10 minutes. Glucose was measured for each of the tubes using a Roche Integra 400 at initial time (t_0) and after 24 hours (t_{24}) storage at room temperature.

Results: Mean (SD) for the glucose measurements in mg/dL were F/Ox 1300 x g t_0 : 5.833 (2.733), F/Ox 2000x g t_0 : 5.785 (2.736); F/Ox 1300 x g t_{24} : 5.816 (2.739), F/Ox 2000 x g t_{24} : 5.758 (2.739); F/EDTA 1300 x g t_0 : 5.832 (2.731), F/EDTA 2000 x g t_0 : 5.816 (2.718); F/EDTA 1300 x g t_{24} : 5.803 (2.741), F/EDTA 2000 x g t_{24} : 5.801 (2.701); Hep/lod 1300 x g t_0 : 5.695 (2.756), Hep/lod 2000 x g t_0 : 5.592 (2.673); Hep/lod 1300 x g t_{24} : 5.699 (2.716), Hep/lod 2000 x g t_{24} : 5.605 (2.699).

Conclusions: BD Vacutainer® Glucose tubes with fluoride/oxalate, fluoride/EDTA and heparin/iodoacetate glycolytic inhibitors that been centrifuged at 2000 x g rather than the recommended 1300 x g gave clinically equivalent results for the measurement of glucose using a Roche Integra 400 instrument at initial time and after 24 hours storage at room temperature.

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P21

Venosafe® Glycaemia tube stops glycolysis

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Background: Ex-vivo glycolysis is the main pre-analytic interfering factor for the determination of glycaemia; removing this factor is essential to ensure adequate diabetes mellitus diagnosis. Terumo Medical Corporation guarantees complete and immediate glycolysis inhibition after venipuncture using Venosafe® Glycaemia tube. Our objective was to estimate the %bias for Venosafe® Glycae-

mia tube and usual gel-serum tube versus Heparin-Lithium tube.

Materials and methods: Three venous blood samples were drawn from 78 patients using Heparin-Li (N = 78), Venosafe® Glycaemia (N = 78) and gel-serum (N = 25) tubes. Heparin-Li tubes were centrifuged (4 °C, 15 min, 3500 rpm) just after collection and processed immediately for glucose replicates (Hexokinase method, Advia 2400 SIEMENS); the two other tubes were kept 20 minutes at ambient temperature then centrifuged and processed under the same conditions as the former. NCLSI-protocol EP09-A2 was used to estimate %bias between Heparin-Li versus Terumo and serum tubes at different medical decision levels. An allowed %bias of $\pm 2.2\%$ was chosen to establish equivalence with a significance of $P < 0.05$.

Results: % bias (95%CI) in glycemia at medical decision levels of 105, 126, 140, 145, 165, 190, 200 mg/dL were: Venosafe® Glycaemia tube 2.1 (1.6, 2.5), 1.6 (1.3, 1.9), 1.4 (1.1, 1.6), 1.3 (1.1, 1.6), 1.1 (0.7, 1.4), 0.8 (0.4, 1.3), 0.8 (0.3, 1.2) respectively; gel-serum tube -11.5 (-14.2, -8.8), -8.6 (-9.9, -7.4), -7.2 (-8.7, -5.7), -6.7 (-8.4, -5.0), -5.2(-7.8, -2.6), -3,7 (-7.3, -0.1), -3.2 (-7.2, 0.7) respectively. Venosafe® Glycaemia tube did not exceed the allowed bias at any medical decision level whereas gel-serum tube only fits allowed bias at 190 and 200 mg/dL.

Conclusions: Our results show that, under ideal preanalytical conditions, Venosafe® Glycaemia tube stops glycolysis completely and immediately (positive %bias vs. Heparin-Li) and it is equivalent to Heparin-Li tube, whereas gel-serum tube has a significant negative %bias vs. Heparin-Li and is not equivalent to it even at favorable preanalytical conditions. We believe this last finding could be supported by the suggestion that blood clotting consumes glucose.

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P22

Validation of hemolysis index in Dimension RxL and verification of cut-off points for interference on 16 biochemical assays. An approach based on patients' results.

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Background: Dimension RxL (Siemens) is able to detect hemolysis interference which is reported as "hemolysis index" (HI). A difference greater than 10% on analyte concentration is stated as significant interference by manufacturer, related to different HI for each analyte. Our aim was to validate the accuracy of HI and verify the proposed cut-off points.

Material and methods: Accuracy of HI (range 1 to 6) on the Dimension was validated using serial dilutions of a known concentration of free hemoglobin (4 replicates). Verification of cut-off points for interference on 16 biochemical magnitudes (total protein, phosphorus, magnesium, LDH, AST, potassium, ALT, glucose, sodium, chloride, creatinine, calcium, urea, GGT, amylase) was performed studying the distribution of the results from a large number of patient samples classified by their HI. This approach has been used by several authors to validate biological reference intervals. It could be assumed that in vitro hemolysis is randomly distributed in patients' samples. Therefore, differences observed between averages of results distribution of every HI would be explained by the effect of hemolysis. Data were obtained from all patients attended in the laboratory for a period of 1 year (from N = 12,429 to N = 186,357) and analyzed with ANOVA test.

Results: A total agreement was found between HI categories and measurements of free hemoglobin. Cut-off values indicated by the manufacturer were verified in 6 assays (total protein, phosphorus, magnesium, LDH, AST, potassium). Two assays (ALT and glucose) showed interference effect at a high

her concentration than declared. Analytes with no declared interference, did not show differences greater than 10%, although adequacy of this criteria should be questioned in analytes such as sodium, chloride and creatinine, regarding their straight biological variation.

Conclusions: We found HI measurement on Dimension RxL accurate. Cut-off points declared by manufacturer have been verified by evaluation of a large number of patients' results.

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P23

Implementation of a computerized system at a high-volume Phlebotomy Ward

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Background: The Phlebotomy Ward (PW) at our hospital attends an average of 600 patients *per* day, including 100 children. Analytical requests are currently made using widely spread paper forms related to different laboratories. In 2009, a new PW was inaugurated and equipped with a specific Information System (IS) including several features: 1) Full registration of patient and request data in IS, recording scanned images of application forms, prior to drawing samples. This allows generation of particular instructions and automation of sample selection that encourages normalization of preanalytical conditions and improvement of the procedure. 2) Data transmission to the Laboratory Information System only after the verification of the process by the nurse. 3) Possibility of prior appointment, and management of different queues of attention to the three areas in the PW (adults, children and special tests).

Material and methods: Hardware consists of 21 computerized phlebotomist workstations including touch screens and barcode label printers. Each

workstation manages its access control, according to a predetermined queue. At patient entrance screen shows information related to analytical request, including scanned images, and printer generates labels customized with name of patient, time of draw, appropriate tube/container required, destination and special conditions. Software is supported by Connectall, a partnership of Becton Dickinson.

Results: In 2010 the PW attended 147,034 patients. Waiting time has been reduced to 7.6 minutes in average, thanks to prior appointment with registration in IS. The attention time ranges from 2.8 to 5.3 minutes, depending on complexity of the process. A significant decrease in sample rejections has been observed (0.39% to 0.07%). The number of unnecessary obtained tubes reduces drastically. Automated call of waiting patients by IS (voice synthesis) and customized labels makes nearly impossible attention to patients with demographic registration errors.

Conclusion: Implementation of computerized system to phlebotomy improves process reliability and quality perceived by users.

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P24

Accreditation of the pre-analytical phase with ISO EN NF 15189. Impact of a pre-analytical review through BD Laboratory Consulting ServicesSM methodology.

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Background: In accreditation context the management of the pre-analytical phase is critical to ensure quality samples. The standard ISO 15189 requires that internal review of all elements of the system shall be conducted at variable intervals.

Materials and methods: The pre-analytical review was part of BD Laboratory Consulting ServicesSM (BD LCSSM) methodology and was conducted by observing: Tube storage, Blood collection, Sample transportation, Centrifugation process, Sample quality. We observed 109 blood collection procedures in 3 days on 5 wards. The tubes were labeled with a review number and tracked from the point of collection, through the laboratory where visual assessments of 145 samples were conducted after centrifugation.

Results: In 91.7% of the blood collections observed, the patient ID was correctly confirmed and 80.7% tubes were labeled after blood collection. The disinfection of the vein puncture site was also accurately performed (93.5%). Tourniquet release after the first collected tube was done in 93.5% of the cases. On the other hand, the order of draw recommended was not consistent in 74% of the samples and only 8% of the tubes were correctly mixed. We also noticed that 12% of the hemolyzed samples came mainly from the emergency department. These results and others were compared to other BD LCSSM pre-analytical reviews. It reveals an excellent practice for patient ID confirmation process but a higher global hemolysis index in our lab compared to other reviews.

Conclusion: This pre-analytical review is a good step before engaging the laboratory into the accreditation process in order to identify improvement points, evaluate the staff needs regarding training and develop good practices.

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P25

The key role of the pre-analytical phase in a high throughput automated sub-regional laboratory

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Background: A precise planning of the pre-analytical phase is a key preliminary step for assuring the quality of the results in a large sub-regional laboratory equipped with very high throughput analyzers. The major aims in planning the Hub and Spoke "Laboratorio Unico Area Vasta Romagna" were: 1) univocal identification of the patient and of the collected tubes; 2) definition of the time and methods of tubes transportation suitable for optimal preservation of biological samples; 3) organization of the Blood Drawing Centers and monitoring of their activity.

Materials and methods: A single Laboratory Information System (DNLab, Noemalife, Bologna, Italy) was set up for connecting the Order Entry of inpatients and outpatients to the Hub laboratory and allowing the univocal identification through barcode of the tubes. Proprietary softwares (Log80, Forlì, Italy and Plurima, Perugia, Italy) allow a daily monitoring of the transportation of the tubes and of the temperature (that is checked and recorded 12 times/hour). We mapped the Blood Drawing Centers which had to be equipped with a centrifuge for assuring the centrifugation of the tubes within 120 min after the collection.

Results: The mean reporting time of routine tests for inpatients was two hours and for outpatients four hours. The Hub receives all the samples (17,000) between 9.00 a.m. and 2.30 p.m. and the activity of the laboratory is scheduled accordingly. The nonconformities of the samples are lower than 0.4 %. The entire activity of the laboratory does not require clerical staff.

Conclusions: A proper planning of the pre-analytical phase greatly improved the productivity of a highly automated laboratory confirming that high automation of the analytical phase should be always coupled to an efficient pre-analytical phase.

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P26

Centrifugation of tubes in blood drawing centers (BDCs): a key in the management of a sub-regional laboratory

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Background: One of the major problems encountered in planning the "Laboratorio Unico Area Vasta Romagna" was to satisfy time limits between the blood drawing and the tubes centrifugation required by Reference International Standards for biological samples management. We investigated: 1) maximum time between sample collection and centrifugation; 2) which tests had to be carried out in spoke laboratories since required special pre-analytical conditions; 3) the geographical location of the 87 blood drawing centers (BDCs) and the estimation of the time required for the transportation of samples to the Hub laboratory.

Materials and methods: We adopted the CLSI standards as reference for the definition of time and temperature acceptable for samples storage before centrifugation. We investigated, with the assistance of a specialized firm using the software "Via Michelin", the best route for the samples transportation from all the BDCs.

Results: In most cases the best solution was the centrifugation of the tubes in the BDCs. We carried out a massive effort for training the nurses working in the BDCs of Area Vasta Romagna; nurses were trained in the proper use of the centrifuges placed in 27 of the 87 sampling points. Today the tubes: 1) are directly transported to the hub laboratory; or 2) are directly centrifuged in the BDC where the samples are collected; or 3) are transferred within 30 minutes to a BDC equipped with a centrifuge.

Conclusions: Today, after two years of activity of the AVR Laboratory, we have a complete map of direct or indirect samples transportation of tubes from the 87 BDCs to the hub laboratory according to the CLSI standards.

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P27

Pre-analytical setting in C-terminal osteopontin recognition: an indicator of total osteopontin production

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Background: Osteopontin (OPN) is a pleiotropic molecule expressed in a series of physiological conditions (e.g. tissue remodeling, biomineralization inhibition and chemotaxis). Clinically OPN levels have been associated with inflammatory diseases including osteoarthritis, rheumatic diseases and mesenchymal-derived tumors. In biological fluids OPN is rapidly cleaved determining a reduction of detectable levels of the intact molecule. Immunodetection represents the most used method to measure OPN concentration; however antibodies recognizing different parts or cleavage products of the molecule are used. Our aim was to evaluate the effects of different storage conditions on the serum/plasma levels of the OPN C-terminal portion, resistant to further proteolytic digestions, as a possible indicator of total OPN production.

Materials and methods: Blood samples from 11 healthy volunteers were collected by standard antecubital venipuncture in plain and K₂-EDTA tubes, centrifuged to obtain serum and plasma. Aliquots of serum and plasma were stored at 4 °C or room temperature over different times from drawing (0, 2, 4, 8, 12, 24 and 48 h) and then frozen at -80 °C. OPN concentrations were determined by ELISA using a capture monoclonal antibody directed against the C-terminal portion of the molecule (Asp288-Lys299). Intra- (N = 20 replicates) and inter-assay (N = 8 samples in 4 separate evaluations) variability was also determined for this method.

Results: No differences were found comparing samples stored at 4 °C or room temperature and frozen at different times for both serum and plasma. Plasma concentrations were found to be always significantly higher (3.8 to 4.8 folds) than those measured in serum and these differences were always higher than intra- and inter-assay variations.

Conclusions: C-terminal OPN recognition is an indicator of total OPN production. Our results demonstrated that this evaluation is not affected by sample storage conditions. Moreover, we suggest carrying out the measurements on plasma due higher concentration observed than serum.

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P28

The influence of standardization of sampling procedure to the number of haemolytic and clotted samples

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Background: Hemolysis and clotting are the most frequent problems in blood sampling and both can be reduced by standardization of sampling procedure. In December 2009 we introduced new sampling products and performed training for the whole hospital nursing staff. We aimed to evaluate the influence of these standardization attempts to the number of hemolytic and clotted samples.

Materials and methods: Preanalytical department visually controlled the samples and registered the unfit sample materials. We examined separately the number of hemolysis and clottings in 3 clinics: surgery, internal diseases and women's clinic. We compared the data from years 2009 and 2010.

Results: The number of hemolytic samples was reduced by 29.3% (from 2018 in 2009 to 1427 cases in 2010) and the number of clotted samples by 14.4% (from 460 to 401 cases) for the whole hospital. In surgery clinic the number of hemolysis was reduced by 34.8% and the number of clottings was reduced by 20.6%. As 77-80% of these hemolytic samples came from emergency department, we estimated it to be a good effect. In internal diseases clinic the number of hemolysis was reduced by even 36.8% and the number of clottings was re-

duced by 10.5%. In women's clinic the number of hemolysis was reduced by 17.4% and the number of clottings rose by 1%. The poor result is due to the difficult sample collection procedure of premature newborns.

Conclusions: Standardization of blood sampling procedures helps to reduce the number of hemolytic and clotted blood samples in clinics treating mainly adults. It has less influence in clinics treating newborns. We suggest that individual training of sampling technique would improve the results.

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P29

Erythrocyte pyruvate kinase deficiency: the preanalytical phase.

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Background: The main difficulty for the diagnosis of erythrocytic pyruvate kinase (PK) deficiency is due to presence of PK activity coded by another gene in the other blood cells. Therefore, it is indispensable to remove them, but the usual elimination of the "BuffyCoat" remains unsatisfactory and the filtration on a cellulose column is cumbersome. Being in accreditation process, the discovery of a complete PK deficit in a 1-day Caucasian girl with high free bilirubin, prompted us to make a study to validate our new protocol for erythrocytes purification.

Methods: 100 anonymous EDTA blood samples (haemoglobin 39-194 g/L, platelets 10-1100 G/L, leukocytes 1-86 G/L, albumin 22-47 g/L) have been studied. After centrifugation (5 min at 2500 x g), 200 µL of erythrocytes sediment is pipetted at the bottom of the tube with a long tip, which is then plunged into normal saline and wiped prior to transfer into a 1 mL syringe (pre-filled with 800 µL

of normal saline), whose plunger was removed and whose Luer tip was sealed with a female Luer-obturator (VYGON ref:888.66--). Next, its upper orifice is closed with the rubber gasket (detached from its plunger) and is pierced with a small needle (immediately removed) to eliminate overpressure (source of turbulence). After a gentle mix and centrifugation (10 min at 2500 x g), the Luer-obturator is removed by slowly turning (not to pull).

Results: Inside, always more than 50 µL of purified packed cells were available, in which number of leukocytes and platelets (counted by phase-contrast microscopy on a 1/5 dilution in haemolysing solution) were always smaller than 1 *per* 100000 erythrocytes, and albumin concentration (measured by immuno-turbidimetric method on supernatant of 1/3 dilution in saline) smaller than 20 mg/L (therefore with very little residual plasma).

Conclusions: Reproducible with little blood (< 500 µL), this reliable protocol is simple, fast, cheap and centrifugation doesn't favor young cells.

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P30

Cost estimation and identification of preanalytical errors

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Background: Healthcare institutions are under tremendous cost pressure and are looking for ways to reduce costs and work more efficiently. Erroneous laboratory results can have severe and expensive consequences not only on the efficiency of the hospital but also on the patient treatment and outcomes.

Materials and methods: We have used a cost model developed by Frost and Sullivan that allows investigating the financial impact of repeated blood

collections. With this model opportunity costs are estimated by approaching data collection top-down. To identify specific areas for improvement we applied the preanalytical review developed by BD. By observing the blood collection process multiple times from storage via transport and analysis to archiving of samples information is gained where processes and interfaces show risks for errors.

Results: We were able to address error costs as a percentage of total hospital operating costs (0.08%) and error costs per bed and year (162€) respectively for the University Medicine of Greifswald, Germany and compared it to a heterogeneous group of other hospitals in Europe and US. Furthermore, detailed information on sub-processes that needed improvement was collected and used for training.

Conclusions: This approach of estimating costs and subsequently identifying specific errors has the potential for significant reduction of preanalytical errors. At the University Hospital Greifswald we have utilized both of these tools in order to evaluate, monitor and improve our preanalytical phase.

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P31

Two quality indicators to access the pre-analytical phase

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Introduction: In 2003, the management of the laboratory decided to restructure its entire organization in order to achieve a substantial improvement of the quality of service provided. As described in the literature, the majority of errors occur in the pre-analytical phase. The aim of this work is to propose two indicators to monitor the quality of this phase.

Materials and methods: The restructuring was guided by the ISO standards; in 2006, the laboratory was accredited by ISO 17025 and, in 2008, by ISO 15189. The two quality indicators chosen to assess the pre-analytical phase, which are computed every semester, are: a) "sample collection repetition" and b) "patient satisfaction". The indicator a) evaluates, for all the outpatients' samples collected by laboratory technicians, different sources of errors: rejected samples, patient identification, specimen collection and the quality of the sample. The number of repeated requests is converted into the sigma-metric. The indicator b) is measured by a satisfaction survey and allows evaluation of personnel, installations and waiting time.

Results: The collection repetitions decreased from 1.8% in 2003 to 0.18% in 2010, corresponding to sigma values of 3.6 and 4.5, respectively. The percentage of outpatients who rated satisfaction with very good/good increased from 39% to 87%.

Conclusions: The errors of the pre-analytical phase decreased drastically with the restructuring of the workflow. Some errors have even been totally eliminated, e.g. transcription errors. The introduction of procedures, employee training and traceability of the process were also crucial to obtain the improved results. The quality indicators used adequately reflect the massive improvement in pre-analytical phase.

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P32

Automation and controlled monitoring and management of nonconformities in preanalytical phase

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Background: Department of Laboratory Diagnostics is in the process of preparing for accreditation according to the internationally accepted standard

ISO 15189. In this complex and challenging process, quality indicators and eligibility criteria are defined. Although the number of analyses is growing yearly, our policy is to reduce the number of nonconformities to a minimum by identifying, recording, resolution and analysis of nonconformities in all aspects of testing, with special emphasis on preanalytical phase.

Materials and methods: All nonconformities and turnaround time were registered through Laboratory Information System. Quality indicators and eligibility criteria were defined based on the incidence of hemolysis in the serum/plasma (< 1.0%), incidence of clots in blood samples (< 1.0%), and specified reporting interval (> 90%).

Results: In the last quarter of year 2010, 1712 nonconformities were registered from a total number of 83,018 patients and 159,144 samples, which is 1.07% of total samples. The largest number of nonconformities is related to failure to deliver urine sample (0.58%), failure to deliver samples for hematological tests (0.09%), and to hemolytic samples (0.14%). In the first two quarters of 2010, nonconformities were recorded manually. During the last quarter, electronic recording of nonconformities was introduced and their number increased by 80% in comparison to the first two quarters.

Conclusions: The introduction of electronic recording of nonconformities in the last quarter of 2010 resulted in a significant increase in the number of recorded nonconformities, thus providing a more realistic data on the number of nonconformities which still did not exceed 1.07%. Electronic recording also enabled us to provide requester with timely information about nonconformities on the report.

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P33

Transcriptional errors in urine analysis

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Background: Laboratory errors can occur in each phase of laboratory work and can be divided into preanalytical, analytical and post-analytical errors. The most common errors are in extra-analytical laboratory phase. Transcription of paper laboratory reports into laboratory information system (LIS) can result in errors and influence patient care.

Materials and methods: This study aimed to investigate the frequency of transcriptional errors on urine analysis. Total of 762 laboratory paper reports were collected during 4 weeks period, revised retrospectively and compared to LIS results. Total number and type of error per each report was recorded and represented as absolute value (number) and relative value (%).

Results: Our analysis discovered total of 48 transcriptional errors. The results have shown that 94.4% (719/762) of laboratory reports were without any transcriptional error, 39/762 (5.1%) of reports had 1 error *per* report, 3/762 (0.4%) had 2 errors and 1 report (0.1%) had 3 errors. The most frequent types of errors were urine color (12/48) and macroscopic examination (11/48) of urine specimen.

Conclusion: Transcription of paper laboratory results into LIS can cause errors. This can be avoided by automation of the transfer of laboratory raw data to the LIS.

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