INVITED SPEAKERS ABSTRACTS

MONITORING OF LABORATORY PREANALYTICAL PROCESS ERRORS IN NATIONAL SAFETY REPORTING SYSTEM

Dilek Tarhan
General Directorate of Health Services
Department of Health Care Efficiency, Quality and Accreditation, Ankara

Prevention of errors that occurred during health care has become the most important agenda of today's health service providers. As stated in the 1999 report “To Er is Human” published by the Institute of Medicine (IoM), millions of life-threatening errors happen every year. In addition, medical errors have also shown significant damage to countries’ economies. After the report, the prevention of medical errors has been on the agenda for more municipalities. The World Health Organization (WHO) stated, “Improving Diagnosis in Health Care” report published by the same institute in 2015, it was stated that most of the mistakes were experienced during the diagnosis process.

The joint solution proposal, which is carried out by local and WHO in patient safety trials, is the development of a malpractice learning practice. In our country, attention has been paid to report of medical errors and culture of learning from mistakes within the scope of Turkey Quality System in Health since 2005. “Safety Reporting System” was created at the level of the health facility. Also in 2014, the “National Safety Reporting System (GRS)” has been established. The “National Safety Reporting System” is a system developed specifically for Turkey, which aims to determine the adverse events and to make the wettest. It is a system aimed at continuously controlling the services offered to the patient. Clinical errors are errors that are performed to check the conformity of the laboratory service to the standards or requirements. In this study, the safety reporting system will be discussed. To improve patient and employees' safety, quality indicators should be organized. In indicator management, targets must be sustainable and clear. The number of rejected samples and the number of lost samples must be determined. Quality indicators for medical laboratories are also defined in the Health Quality Improvement Program (HQP) of the Ministry of Health. Preanalytical indicators are quality indicators. Quality indicators are system improvement tools that are used in quality assurance. These determinations (evaluation of performance, comparison of performance with standards, etc.) are carried out through the controls performed during the laboratory processes. In the quality control, the target is determining the error, sorting and classifying it according to predetermined standards. The majority of the methods applied during these procedures are statistical methods.

At quality assurance, work performed with quality control is being carried to the next level. The main objective of quality assurance is to secure the continuity of control. There is a matter of taking precautions to prevent large losses in quality assurance. These precautions include early warning systems. The results obtained with quality assurance are gain not only for the laboratory but also for patient and the hospital. The results obtained with quality assurance are gain not only for the laboratory but also for patients and the hospital. The number of rejected samples and the number of lost samples must be determined. Preanalytical errors are errors related to laboratory preanalytical process. This study aimed to detect these errors from GRS data in laboratory setting. Further analyzes of GRS reports have not yet been undertaken. Detailed analyzes should be carried out in the academic frame by using the data of the Ministry and the results of the national GRS should be compared with the evidence based studies carried out at the institutional level. There is also need for studies to compare GRS data with national and international academic literature results. It should also be used to improve the healthcare system of our country and to improve patient and employees safety, as well as the use of the results of the current outcomes and detailed analyzes to provide scientific contributions to the national and international literature.

QUALITY CONTROL AND QUALITY ASSURANCE AT PREANALYTICAL PHASE

Canan Yılmaz
Gazi University Medical Faculty, Department of Medical Biochemistry, Ankara

Quality control is the whole of the verification activities, methods and instruments that are performed to check the conformity of the laboratory service to the standards. The quality control system is an application that is carried out to check if the service meets the expectations and it aims to prevent possible mistakes and deficiencies by examining and testing with appropriate methods before presenting the service to the patient. Quality control aims to keep the quality under continuous control. Service provided in laboratories should have certain standards. The point we reached today is “quality assurance” which is a patient-focused concept. Securing the quality is a legal and ethical obligation in laboratories. Quality control, especially for clinical laboratories mean that the reliability of laboratory tests, productivity and clinical use are continuously improving, measurable and traceable. It is the whole of planned and systematic activities that are performed to ensure confidence that a product or service fulfills the requirements stated in the quality. On the basis, it aims to protect the quality through which the product or service passes at the planned level by using minimum resources at all stages such as instructions, duties, responsibility definitions, authentication, training and raising awareness (besides quality assurance). It is also implemented for other quality assurance systems. It is important to focus on the target, not the fault in the process. Even if preventing faults before occurring is ideal, it is not always possible. It is aimed correcting the fault and prevent repeating, not ignoring. Quality assurance applications are used in laboratory service to determine the causes of deviations from standards and to provide process standardization; it includes quality planning and error prevention approaches. In this way, all of the laboratory processes are handled as a whole, and the continuity and improvement of the quality is ensured. Therefore quality assurance is an indication of reliability of the presented service. It simplifies the scope of quality control by securing the quality. It saves time and money, minimizes labor and material losses, and ensures the highest efficiency at the lowest cost. It increases motivation of the employees. It encourages to improve product and service quality. It protects the foundation’s reputation. It increases the satisfaction of the customer and gives confidence the customer. It provides competition advantages.

There are some fundamental differences between quality control and quality assurance. The main difference is that quality control is based on examination, whereas quality assurance is based on prevention. The main goal of quality control is to provide the benefits that will help to correct the current processes in the laboratory. In other words, quality control is focused on the detection of faults. These deductions are important in order to prevent recurrence. At this stage, indicator management is important. As a result of performance (with standards, etc.) are carried out through the controls performed during the laboratory processes. In the quality control, the target is determining the error, sorting and classifying it according to predetermined standards. The majority of the methods applied during these procedures are statistical methods. At quality assurance, work performed with quality control is being carried to the next level. The main objective of quality assurance is to secure the continuity of control. There is a matter of taking precautions to prevent large losses in quality assurance. These precautions include early warning systems. The results obtained with quality assurance are gain not only for the laboratory but also for patient and the hospital. The number of rejected samples and the number of lost samples must be determined. Preanalytical errors are errors related to laboratory preanalytical process. This study aimed to detect these errors from GRS data in laboratory setting. Further analyzes of GRS reports have not yet been undertaken. Detailed analyzes should be carried out in the academic frame by using the data of the Ministry and the results of the national GRS should be compared with the evidence based studies carried out at the institutional level. There is also need for studies to compare GRS data with national and international academic literature results. It should also be used to improve the healthcare system of our country and to improve patient and employees safety, as well as the use of the results of the current outcomes and detailed analyzes to provide scientific contributions to the national and international literature.

QUALITY CONTROL AND QUALITY ASSURANCE AT PREANALYTICAL PHASE

Canan Yılmaz
Gazi University Medical Faculty, Department of Medical Biochemistry, Ankara

Quality control is the whole of the verification activities, methods and instruments that are performed to check the conformity of the laboratory service to the standards. The quality control system is an application that is carried out to check if the service meets the expectations and it aims to prevent possible mistakes and deficiencies by examining and testing with appropriate methods before presenting the service to the patient. Quality control aims to keep the quality under continuous control. Service provided in laboratories should have certain standards. The point we reached today is “quality assurance” which is a patient-focused concept. Securing the quality is a legal and ethical obligation in laboratories. Quality control, especially for clinical laboratories mean that the reliability of laboratory tests, productivity and clinical use are continuously improving, measurable and traceable. It is the whole of planned and systematic activities that are performed to ensure confidence that a product or service fulfills the requirements stated in the quality. On the basis, it aims to protect the quality through which the product or service passes at the planned level by using minimum resources at all stages such as instructions, duties, responsibility definitions, authentication, training and raising awareness (besides quality assurance). It is also implemented for other quality assurance systems. It is important to focus on the target, not the fault in the process. Even if preventing faults before occurring is ideal, it is not always possible. It is aimed correcting the fault and prevent repeating, not ignoring. Quality assurance applications are used in laboratory service to determine the causes of deviations from standards and to provide process standardization; it includes quality planning and error prevention approaches. In this way, all of the laboratory processes are handled as a whole, and the continuity and improvement of the quality is ensured. Therefore quality assurance is an indication of reliability of the presented service. It simplifies the scope of quality control by securing the quality. It saves time and money, minimizes labor and material losses, and ensures the highest efficiency at the lowest cost. It increases motivation of the employees. It encourages to improve product and service quality. It protects the foundation’s reputation. It increases the satisfaction of the customer and gives confidence the customer. It provides competition advantages.

There are some fundamental differences between quality control and quality assurance. The main difference is that quality control is based on examination, whereas quality assurance is based on prevention. The main goal of quality control is to provide the benefits that will help to correct the current processes in the laboratory. In other words, quality control is focused on the detection of faults. These deductions are important in order to prevent recurrence. At this stage, indicator management is important. As a result of performance (with standards, etc.) are carried out through the controls performed during the laboratory processes. In the quality control, the target is determining the error, sorting and classifying it according to predetermined standards. The majority of the methods applied during these procedures are statistical methods. At quality assurance, work performed with quality control is being carried to the next level. The main objective of quality assurance is to secure the continuity of control. There is a matter of taking precautions to prevent large losses in quality assurance. These precautions include early warning systems. The results obtained with quality assurance are gain not only for the laboratory but also for patient and the hospital. The target in quality assurance systems is complying to the specifications of products/services through the use of methods such as assessing compliance with procedures and statistical process control. In quality assurance, institutions aim to establish a system that will control if the work is adequate for both design and conformity aspects.

PREANALYTICAL PHASE QUALITY INDICATORS AND REPORTING

Funda Güçlü
Ankara Etilik Zübeyde Hanım Gynecology Education and Research Hospital Biochemistry Laboratory, Ankara

The importance of laboratory data is great in the medical decision-making phase. Since the presence of laboratory errors will cause medical errors, avoiding laboratory errors will reduce medical errors. Medical laboratory errors come into play in many analytical and clinical aspects. Medical laboratory errors make the patient die or suffer from medical errors every year. In addition, medical errors cause preventable death and preventable disability. There are studies that show that hospital patients die or suffer from preventable medical errors. In the “Improving Diagnosis in Health Care” guideline, it is emphasized that every 5 or 10 people die or suffer from medical errors every year. In addition, medical errors are present in every country and every hospital. In the “National Safety Reporting System (GRS)” has been established. At this stage, indicator management is important. As a result of performance (with standards, etc.) are carried out through the controls performed during the laboratory processes. In the quality control, the target is determining the error, sorting and classifying it according to predetermined standards. The majority of the methods applied during these procedures are statistical methods. At quality assurance, work performed with quality control is being carried to the next level. The main objective of quality assurance is to secure the continuity of control. There is a matter of taking precautions to prevent large losses in quality assurance. These precautions include early warning systems. The results obtained with quality assurance are gain not only for the laboratory but also for patient and the hospital. The target in quality assurance systems is complying to the specifications of products/services through the use of methods such as assessing compliance with procedures and statistical process control. In quality assurance, institutions aim to establish a system that will control if the work is adequate for both design and conformity aspects.

Key Words: Quality indicator, preanalytic phase.
RISK MANAGEMENT IN THE PREANALYTICAL PHASE

Güzin Akyal
University of Health Sciences, Antalya Training and Research Hospital, Clinical Chemistry Laboratory, Antalya

Risk: Combination of the probability of occurrence and the severity of harm. Risk analysis: Systematic use of available information to identify hazards and to estimate the risk. Risk evaluation: Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk. Risk management: Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk.

1. Risk identification is the first and the most important step in the risk management. Every preanalytical step carries varied risks and may require varied control measures.
   1.1. Process mapping: This tool is used to analyze a particular preanalytical process by breaking it down into small steps from start to finish.
   1.2. Fishbone diagram: A fishbone diagram outlines the cause and effect of a testing process.
   1.3. Risk identification table is a simple table that lists all the errors identified in the different testing phases for a specific test.

2. The risk assessment matrix is constructed and interpreted according to the acceptability of the risk.

3. Risk mitigation: For any risk that is deemed unacceptable, the lab should identify ways to reduce the probability of harm, using prevention and detection methods, in order to bring the risk down to an acceptable level.

3.1. Determine a monitoring plan.

3.2. The risk assessment will be used to develop an laboratory QC Plan.

The implementation of the preanalytical risk management may seem daunting and certainly time consuming, but the process, if performed diligently, will increase laboratory quality and patient safety.

LBYS AND HBYS IN MONITORING OF THE PREANALYTICAL PROCESS

Cihan Coskun
Istanbul Haseki Training and Research Hospital, Istanbul

Information system is an arrangement of data, processes, human and information technologies and these elements are in constant mutual interaction in order to collect, process, store and provide information required for supporting an organization. Health Information Systems (HIS) basically comprise of two main factors: administrative and clinical information systems. The first applications of HIS come across in developed countries such as the United States of America. Developments in this area have gained a momentum by means of some organizations such as “Healthcare Information and Management Systems Society” that was aimed at improving healthcare quality, safety, cost-effectiveness, and access, through the best use of information technology and management systems. However, early HIS applications were generally administrative-oriented due to health policies applicable in the United States in the 1960s. With the introduction of healthcare reforms based on patient safety and quality in healthcare services and the accelerated development in information technology in subsequent years, practices for clinical HIS have also become widespread. While the use of computers in healthcare institutions started in the mid-1990s in our country, especially in the beginning of the 2000s, the number of software for HIS increased with the incentives from the Ministry of Health. “Health-Net Project” launched in 2009 by the Ministry of Health in order to collect data from healthcare institutions has been accelerated the use of HIS across the country and the integration efforts among HIS. In addition, the Ministry of Health has made mandatory to use Hospital Information Management Systems (HIMS) and Laboratory Information Management Systems (LIMS) in certain preanalytical processes conducted by laboratories in accordance with “Health Quality Standards”. Conducting of preanalytical processes performed outside or in the laboratories such as patient record, test request, and collecting, barcoding, aliquoting, sorting of samples with supporting of HIMS and LIMS reduced the errors in the preanalytical phase, which is responsible for a major part of errors in the total testing process. In addition, the use of preanalytical automation systems integrated with HIS has contributed to reducing the errors in the preanalytical phase. Conclusionally, the HIS used in the preanalytical phase helps to shorten the turnaround time and improvement of the quality of the health service offered. On the other hand, not fully standardized HIS applications, existing integration of turnaround time and improvement of the quality of the health service offered.

THE IMPORTANCE OF EDUCATION IN THE PREANALYTICAL PHASE

Bagın Örhan
Istanbul Training and Research Hospital, Istanbul

Laboratory test result is necessary and effective in many medical decisions such as detection, classification, treatment and follow-up of the disease. It is important for patient safety to report accurate and timely test results. Laboratory test process comprises of preanalytical, analytical and postanalytical phases. It is also possible to add pre-preanalytical phase to the preanalytical phase before the analysis and covers the process from requesting the test appropriate for the patient to taking sample, its transport and preparation for analysis. The majority of laboratory errors (40-70%) occur in the preanalytical phase. Most of these errors originate from humans. Although automated systems and the developments in information management systems are effective in reducing errors in the preanalytical phase, many errors still occur.

In the preanalytical phase, procedures such as test request, patient identification, preparation of the patient, taking samples and transport, centrifugation and storage of samples are carried out. Errors based on these procedures may result in failure to request the appropriate test, errors in preparing the patient, errors in patient description, errors in taking the samples, holding the tourniquet for periods that are more than necessary, errors in taking samples, failure to observe the order of taking blood tubes and transfer-related problems etc.

In the preanalytical phase, the current condition must be determined; then the process should be improved. One of the most important components of process improvement is training. In addition to providing training to new beginners, other employees should also refresh their training. There are a high number of studies showing that continuous training is effective in preventing errors. A good communication and cooperation between laboratory and other medical departments will reduce the errors in the total test process and especially, in the pre-analytical phase. Healthcare professionals such as physicians, nurses and others, transportation personnel and laboratory technicians from various training levels and professions play a key role in the preanalytical phase. When training is given, it is necessary to organize the training according to the professions and roles of such people, to refresh their knowledge at regular intervals and to measure the effectiveness of such training. Consequently training has a great importance in reducing the preanalytical errors that constitute a large part of laboratory errors during the total test process.
PEDIATRIC BLOOD DRAWING AND BLOOD DRAWING FROM IV LINES

Ipek Cinaroglu
Becon Dickinson, Istanbul

Pediatric patients in difficult vascular access group, and blood collection procedures differ from adults. Different equipment for venous and capillary blood collection have been manufactured by Becton Dickinson, Istanbul. Therefore, before drawing blood; technique, site, proper equipment selection and the amount of blood to be drawn should be determined.

While the equipment differs depending on the site preference, age and weight for the venous collection, in capillary collection the depth and width of the incision device and determining the maximum amount of blood to be used in accordance with the patient weight is also important. It may be necessary to draw blood from patients who are interfering with the catheter. It is a source of anxiety for both the child and parents as it is routine in addition. Therefore, the appropriateness of the procedure is very important to control the risk of infection, preventing catheter occlusion and providing sample quality.

There are many articles, guidelines on different aspects of catheter disinfection, appropriate washing solutions, syringe sizes, lumen choice, duration of infusions, amount of waste blood, equipment, and transferring sample to the tubes. Defining the most appropriate to create the most suitable, standard institutional procedures from these views is important.

Key words: Safe blood drawing, pediatric blood drawing, capillary blood drawing, difficult vein access, catheter blood drawing

References:
11. BD White Paper VS9100

PLASMA OR SERUM? EFFECTS ON ANALYTES AND TURNAROUND TIME

Z. Gunnur Dikmen
Hacettepe University, Faculty of Medicine, Department of Medical Biochemistry, Ankara

Turnaround time (TAT) is the time interval which begins when a clinician orders a test and ends in the clinician obtaining the result of that particular test and is crucially important for emergency laboratories. To give glucose test results on a test and ends in the clinician obtaining the result of that particular test and is crucially important for emergency laboratories. To give glucose test results within one hour was the goal of our emergency laboratory. To improve the accuracy of results and evaluation tube. This can be achieved using specimens from a minimum of 20 subjects or by performing duplicate testing in the accuracy study. Results can be evaluated by EP Evaluator. Determine the clinical acceptance limit (CAL) for the selected measurands. CALs can be generated based on: Evaluation of data using the formula for imprecision of replicates, biological variation for a measurand and published data. Perform linear regression analysis, Bland-Altman plots and a two-sided confidence interval paired t-test. Laboratories should demonstrate that blood collection tubes do not interfere with measurement or that they have no effects on analysis.

The Clinical and Laboratory Standards Institute (CLSI) published guideline, GP7-A2: Standardization and Stabilization of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline is a guideline for manufacturers of venous and capillary blood collection tubes and users of blood collection tubes for serum, plasma, and whole blood testing. Verification is confirmation, through the provision of objective evidence, that specified requirements have been fulfilled (ISO 9000).

Validation is confirmation, through the provision of objective evidence, that requirements for a specific intended use or application have been fulfilled (ISO 9000).

Validation is initially a manufacturer’s responsibility to ensure that design goals are met in performance and accuracy statements. Verification is an end-user (clinical laboratory) responsibility to confirm that manufacturer’s claims are met on the specific device in its hands, and also that medical needs are met.

Laboratory tests can be affected by numerous preanalytical variables, including the material used to manufacture the blood collection tube. Blood collection tubes are not inert containers for blood but have several constituents, including anticoagulants, surfactants, and lubricants for rubber stoppers, clot activators, and separator gels that can potentially interfere with assays.

Steps for verification:
Select groups of subjects to test (Samples from particular patient populations; such as dialysis patients, healthy subjects, emergency testing etc., or mixed group). The subjects must be adults (> 18 years old, one half of the participants should be women and one half should be men).

Select measurements of interest for testing. “Spiking” of samples may be necessary to achieve the needed analytical measurement range of each measurand. The subjects are chosen to cover a clinically meaningful range for the analyte.

Consider whether any visual observation of the sample is recorded such as serum yield, gel barrier formation, fibrin, and hemolysis.

Select the instrument(s) and method(s) for use in testing.

You can use single or duplicate tubes, with single tube, one can determine whether the mean difference between the control and evaluation is acceptable and ideally within predefined criteria.

Randomization is an important scientific primary that applies to all aspects of evaluations.

Preanalytical variables must be standardized for all tubes collected and blood samples analyzed.

Determine the number of subjects required. For statistical significant, about 20 to 30 subjects are sufficient for most measurands. Some institutions provide guidance on this, such as the US Food and Drug Administration (FDA) and the World Health Organization (WHO), where 40 subjects are the norm.

Ethics committee approval must be received at the institution.

For within-tube precision, perform duplicate analyses on each type of comparative and evaluation tube. This can be achieved using specimens from a minimum of 20 subjects or by performing duplicate testing in the accuracy study. Results can be evaluated by EP Evaluator.
USE OF PLASMA TUBES IN URGENT SAMPLES

Ebayekir Bakar, Nurcan Kiliq Baygutalp1 2
1 Department of Medical Biochemistry, School of Medicine, Ataturk University, Erzurum
2 Department of Biochemistry, School of Pharmacy, Ataturk University, Erzurum

Objectives: In this study, comparative analyses of serum and plasma specimens of some routine analytes in our laboratory, processing the plasma tubes in pre-analytical systems, recommendations and practices about the usage of plasma tubes in specific patient groups are studied.

Materials and Methods: BD Vacutainer® Barricor™ Plasma Blood Collection Tube (BD Barricor™) and BD Vacutainer® SST™ serum Tubes (BD SST™) were selected simultaneously for the selected analytes in routine clinical chemistry and immunoassays using Beckman Coulter AU 5800 and Beckman Coulter DXI 800.

Results: Statistical comparisons of the analytical performances of BD Barricor™ tubes and BD SST™ serum tubes showed that the results were acceptable and the test tubes can be used interchangeably. TAT was improved about 30-40 minutes by using BD Barricor™ tubes. Thanks to the different cap color of BD Barricor™ tubes, they can be automatically recognized by the inspector as “urgent” and thus BD Barricor™ tubes can be used in samples requiring priority, which can be send from emergency department, intensive care and daily chemotherapy clinics.

Additionally, when we analyzed a number of Barricor™ tubes samples/day for about 6 months, it was observed for the tubes processed in pre-analytical system that the centrifugation process in pre-analytical system was sufficient for getting down the mechanical separator by centrifugation, and no problem was observed in decapping and recapping processes in pre-analytical system.

Conclusions: It was concluded that BD Barricor™ plasma tubes can easily be used in on-line pre-analytical and post-analytical systems for emergency patients as well as using in manual centrifugation and in stand-alone analytical systems for urgent sample analyses.

Keywords: BD Barricor™ plasma tubes, pre-analytical, stat samples

PREANALYTIC PHASE IN IMMUNOCHEMISTRY

Didem Barlak Keti
Department of Biochemistry, Faculty of Medicine, Erciyes University, Kayseri

In spite of the improvements in laboratory medicine, the pre-analytical phase is still the main responsible for laboratory errors. Immunoassay is an important part of the diagnostic process. Because of the relatively low concentrations of analyte being measured and the complexities of the antigen-antibody interaction, the method is relatively susceptible to interferences. There are many possible reasons for false results to be obtained during an immunoassay procedure. Interferences in immunology fall into two broad categories: analyte-independent and analyte-dependent interferences.

Analyte-dependent interferences
- Cross reacting substances (lack of specificity)
- Endogenous antibodies
- Antireagent antibodies (heterophile, HAAA, RF)

Analyte-independent interferences:
- Inadequate centrifugation with microcrystal formation
- Hemolysis, lipemia, icterus
- Specimen collection tubes, transport, stability and storage
- Disease states

The ways of becoming aware of possible interferences and the investigation them:

Discordant results
Clinical correlation
High index of suspicion
Exclude pre-analytical problems
Repeat analysis on another instrument from a different manufacturer
Treatment with heterophile blocking reagents
PEG precipitation
Serial dilutions
Check using a different matrix e.g. urine for hCG
Selective removal of immunoglobulins
Chromatography
Tandem-mass spectrometry

Falsely high or falsely low results due to interferences endogenous to the specimen present a particular risk to patient care because they (a) are not detectable by normal laboratory quality control procedures, (b) are reproducible within the test system, (c) are often clinically plausible and (d) are relatively rare.

The mechanism of interference and its severity depend both on assay design (two-site; one step) and on the nature of the interfering antibodies.

It is important to recognize that interfering antibodies may be present only transiently in a patient’s serum, and that their characteristics and reactivity may vary, such that no immunoassay can be considered to be completely robust to all possible interferences. Therefore it is important to inform clinicians and activate the consultation process between the departments.

References:
3. Ellen Anckaert and Johan Smits. Interferences in Immunoassays: Johan Schelte, Laboratory Accreditation and Clinical Immunology, Belgium

PREANALYTIC PHASE IN ADVANCED SYSTEMS

Fehime Benli Aksungur
Acibadem University, School of Medicine, Department of Biochemistry, Acibadem Labmed Clinical Laboratories, Advanced Tests and Metabolism Section, Istanbul

Diagnostic medical branches such as clinical biochemistry, clinical microbiology, pathology and radiology, keep pace with technology in a faster way than other medical areas. In the last 15 years, with the emergence of electrospray ionisation (ESI) method especially for the ionization of molecules, mass spectrometry finds place in routine laboratories. All analyse methods have three common stages: Isolating the particular analyte from a complex matrix, determining the concentration and reporting the result in proper units. Mass spectrometers (MS) determine analyte concentrations more accurately than the other systems. Especially therapeutic drug concentrations, biologic anions and steroid hormone measurements are more sensitive in MS measurements. Today, in routine laboratories, small molecule (metabolite) analyzes are shifting towards mass spectrometers. High-precision measurement of modern MS systems means that chemical contamination is also measured. Hence, preanalytical errors can lead to serious misinterpreters in these systems. In the clinical laboratories, in addition to the pre-analytical phase of routine biochemistry and hormone systems, preanalytical phase of MS systems must be evaluated and unfortunately the process has to be re-examined from the very beginning. Sample collecting time, sex, age, fasting state, sample types, tubes and sample containers should be re-examined for MS systems. The preferred sample type for blood analysis in MS systems is plasma. In addition, dried blood spot (DBS) is accepted to be an alternative sample for MS measurements. Plasma and serum metabolite profiles are different. Metabolomics of the cells in serum continues until conglutination has occurred. In particular, platelets are active from the moment they are removed out from the body, and secrete many metabolites during coagulation eg. lipids and proteins. It is important that the plasma or whole blood can be placed directly in ice. Preanalytic stage standardization in MS systems:

1. Before validating the method, evaluation should be done for any contamination from water, equipment used: tubes, pipette tips
2. Hemolytic specimens must be handled carefully and clarify the interaction with the analyte
3. As soon as samples are collected, precautions must be taken to quickly start the cooling process
4. Cells from plasma/serum should be separated as quickly as possible and samples should be transported in liquid nitrogen. Then they are stored in -70 °C
5. Samples to be stored for analysis should be stored at -20 °C and then at -80 °C
6. Repeated thawing-freezing is not acceptable
7. A standardized / validated SOP should be prepared for sample pretreatment prior to analysis
8. An SOP is also required for each new method, containing sample collection, separation, transport, storage and sample preparation steps. Metal analytes have been identified by Atomic Absorption Spectrometry (AAS) or Atomic Emission Spectrometry (AES) methods from the early 1900’s. In the last 20 years, Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) has been developed to measure simultaneous and highly precise measurement of multiple heavy metals in a single run Whole blood, serum, urine and CSF heavy metals can be analyzed by these systems. Contamination may be a problem during sample collection and analysis. Hence special equipment and training are required for the sample collection.

THE IMPORTANCE OF PREANALYTICAL PHASE IN THERAPEUTIC DRUG MONITORING AND DRUG ABUSE TESTS

Cigdem Karakucuk
Saglik Bilimleri University, Kayseri Education and Research Hospital, Department of Biochemistry, Kayseri

Therapeutic drug monitoring (TDM) is defined as measuring serum concentrations of a drug in a single or multiple time points in a biological matrix after a dosage. The purpose of therapeutic drug monitoring is to individualize the dosage to achieve maximum efficacy of a drug and at the same time minimize adverse reactions and toxicity risk. Drug abuse tests (DAU) are usually categorized as a part of drug tests and defined as the excessive and persistent use, usually by self-administration, of any drug, licit or illicit, which may lead to adverse physical or psychological consequences. Examples of drugs of abuse include depressants (opioids, barbiturates, benzodiazepines, alcohol), stimulants (amphetamines, cocaine), hallucinogens (LSD, mescaline, phencyclidine), and cannabinoids (marijuana). The laboratory plays a central role in the detection of DAU and quantitating therapeutic drug concentrations in different human specimens. Preanalytical phase is as critical as the analytical phase for accurate results during TDM and analysis of DAU tests. Identification of sources of error can take under
control. One of the most important aspects to this phase is the knowledge of the time at which the sample was collected and its relationship to the time of drug ingestion. These pieces of information are absolutely necessary for interpretation of the results. In addition, samples must be collected using the proper devices and maintained under conditions that prevent or minimize degradation that may affect the accuracy of the analytical results. Sample collection and transport is the first and one of the most important pre-analytical factors that influence the correct interpretation of the analytical results. Patient related factors such as pharmacogenomics and pharmacokinetics, those change the metabolism of drugs individually must be taken into consideration in TDM to calculate the accurate dosage of drug or when toxicity is suspected.

In addition to TDM, DAU tests can include some more pre-analytical error sources for urine specimens which are the most preferred sample type. For the assurance of no substitution, adulteration or dilution made, specimen integrity tests including urine temperature, specific gravity, creatinine, pH and oxidants must be applied before the analytical procedures. Also direct observation of sample collection and storage conditions. Continuous efforts to optimize workflow, improve safety for the staff and avoid preanalytical mistakes are important and should reflect quality management standards. It is necessary to begin to describe the concept of “preanalytical error” in the first class and as soon as possible. Because preanalytical error is a cultural issue. It takes a lot of time to place it.

PNEUMATIC SYSTEMS: FEATURES AND IMPORTANCE ON STAGE PREANALYTICAL

Çevat Yazıcı
Erciyes University Faculty of Medicine Department of Medical Biochemistry, Kayseri

The term “blood gas analysis” (BGA) is used for all laboratory tests related to the patient’s acid-base balance and oxygenation status. BGA is an important factor for intensive care medicine. Current analyzers measure not just blood gas parameters but electrolytes (sodium, potassium, chloride, bicarbonate, calcium, magnesium) and metabolites (glucose, lactate, bilirubin, creatinine) which are reflective of the patient's condition. BGA is exposed to risks of errors caused by improper sampling, transport and storage conditions. Therefore, laboratories and clinicians should have appropriate procedures for the collection of arterial blood specimens. In addition, calibration of equipment is very significant to provide accurate measurement. Continuous efforts to optimize workflow, improve safety for the staff and avoid preanalytical mistakes are important and should reflect quality management standards. It is necessary to begin to describe the concept of “preanalytical error” in the first class and as soon as possible. Because preanalytical error is a cultural issue. It takes a lot of time to place it.

PREANALYTICAL PHASE RELATED TO BLOOD GAS AND PH TEST

Cevel Yazıcı
Erciyes University Faculty of Medicine Department of Medical Biochemistry, Kayseri

The total laboratory error rate of this period, including collecting and transfer of samples and blood components can cause changes in the laboratory results. For this reason, there are systems established with plastic pipes, stations, and directors. Pneumatic systems are the most common error seen in pneumatic systems is hemolysis. The most important pre-analytical factors that influence the interpretation of the analytical results. Patient related factors such as pharmacogenomics and pharmacokinetics, those change the metabolism of drugs individually must be taken into consideration in TDM to calculate the accurate dosage of drug or when toxicity is suspected.

In addition to TDM, DAU tests can include some more pre-analytical error sources for urine specimens which are the most preferred sample type. For the assurance of no substitution, adulteration or dilution made, specimen integrity tests including urine temperature, specific gravity, creatinine, pH and oxidants must be applied before the analytical procedures. Also direct observation of sample collection and storage conditions. Continuous efforts to optimize workflow, improve safety for the staff and avoid preanalytical mistakes are important and should reflect quality management standards. It is necessary to begin to describe the concept of “preanalytical error” in the first class and as soon as possible. Because preanalytical error is a cultural issue. It takes a lot of time to place it.

PNEUMATIC SYSTEMS: FEATURES AND IMPORTANCE ON STAGE PREANALYTICAL

Çiğdem Sönmez
Director-Central Laboratory-Ankara Provincial Health Directorate, Ankara

“Modern Laboratories now provide transfer of samples with pneumatic systems.”

In clinical laboratories, there are three phases in the total test process: pre-analytical, analytical and post-analytical. Pre-analytical phases consist of intra-laboratory and extra-laboratory processes. The total laboratory error rate of this period, including collecting and transfer of the sample, is up to 70% of the total sample. Sample transport has great prominence in the management of clinical laboratories.

Pre-analytical phase affects the analysis results in a significant way, thus it is being investigated in the scope of laboratory process within the preanalytical phase. Nowadays, sample preparation is required and some tests analyzed in chromatograph laboratories and autoanalyzers. This preparation is an important step in the analysis, sometimes it can go up to 60% of the analysis time. For this reason, a careful sample preparation stage is very important for the correct result and time and hold in perpendicular position. Tubes should be always capped and paced in the centrifuge in balanced. Daily cleaning and periodical maintenance of centrifuges should be scheduled. Training should be given about how to deal with inappropriate situations that may arise.

Pneumatic systems are very powerful and useful resource and has been presented to the use of laboratory staff and researchers.

The sample preparation stage affects the analysis results in a significant way, thus it is being investigated in the scope of laboratory process within the preanalytical phase. Nowadays, sample preparation is required and some tests analyzed in chromatograph laboratories and autoanalyzers. This preparation is an important step in the analysis, sometimes it can go up to 60% of the analysis time. For this reason, a careful sample preparation stage is very important for the correct result and time and hold in perpendicular position. Tubes should be always capped and paced in the centrifuge in balanced. Daily cleaning and periodical maintenance of centrifuges should be scheduled. Training should be given about how to deal with inappropriate situations that may arise.

Pneumatic systems are very powerful and useful resource and has been presented to the use of laboratory staff and researchers.

The sample preparation stage affects the analysis results in a significant way, thus it is being investigated in the scope of laboratory process within the preanalytical phase. Nowadays, sample preparation is required and some tests analyzed in chromatograph laboratories and autoanalyzers. This preparation is an important step in the analysis, sometimes it can go up to 60% of the analysis time. For this reason, a careful sample preparation stage is very important for the correct result and time and hold in perpendicular position. Tubes should be always capped and paced in the centrifuge in balanced. Daily cleaning and periodical maintenance of centrifuges should be scheduled. Training should be given about how to deal with inappropriate situations that may arise.

Pneumatic systems are very powerful and useful resource and has been presented to the use of laboratory staff and researchers.

The sample preparation stage affects the analysis results in a significant way, thus it is being investigated in the scope of laboratory process within the preanalytical phase. Nowadays, sample preparation is required and some tests analyzed in chromatograph laboratories and autoanalyzers. This preparation is an important step in the analysis, sometimes it can go up to 60% of the analysis time. For this reason, a careful sample preparation stage is very important for the correct result and time and hold in perpendicular position. Tubes should be always capped and paced in the centrifuge in balanced. Daily cleaning and periodical maintenance of centrifuges should be scheduled. Training should be given about how to deal with inappropriate situations that may arise.

Pneumatic systems are very powerful and useful resource and has been presented to the use of laboratory staff and researchers.

The sample preparation stage affects the analysis results in a significant way, thus it is being investigated in the scope of laboratory process within the preanalytical phase. Nowadays, sample preparation is required and some tests analyzed in chromatograph laboratories and autoanalyzers. This preparation is an important step in the analysis, sometimes it can go up to 60% of the analysis time. For this reason, a careful sample preparation stage is very important for the correct result and time and hold in perpendicular position. Tubes should be always capped and paced in the centrifuge in balanced. Daily cleaning and periodical maintenance of centrifuges should be scheduled. Training should be given about how to deal with inappropriate situations that may arise.

Pneumatic systems are very powerful and useful resource and has been presented to the use of laboratory staff and researchers.

The sample preparation stage affects the analysis results in a significant way, thus it is being investigated in the scope of laboratory process within the preanalytical phase. Nowadays, sample preparation is required and some tests analyzed in chromatograph laboratories and autoanalyzers. This preparation is an important step in the analysis, sometimes it can go up to 60% of the analysis time. For this reason, a careful sample preparation stage is very important for the correct result and time and hold in perpendicular position. Tubes should be always capped and paced in the centrifuge in balanced. Daily cleaning and periodical maintenance of centrifuges should be scheduled. Training should be given about how to deal with inappropriate situations that may arise.

Pneumatic systems are very powerful and useful resource and has been presented to the use of laboratory staff and researchers.

The sample preparation stage affects the analysis results in a significant way, thus it is being investigated in the scope of laboratory process within the preanalytical phase. Nowadays, sample preparation is required and some tests analyzed in chromatograph laboratories and autoanalyzers. This preparation is an important step in the analysis, sometimes it can go up to 60% of the analysis time. For this reason, a careful sample preparation stage is very important for the correct result and time and hold in perpendicular position. Tubes should be always capped and paced in the centrifuge in balanced. Daily cleaning and periodical maintenance of centrifuges should be scheduled. Training should be given about how to deal with inappropriate situations that may arise.

Pneumatic systems are very powerful and useful resource and has been presented to the use of laboratory staff and researchers.

The sample preparation stage affects the analysis results in a significant way, thus it is being investigated in the scope of laboratory process within the preanalytical phase. Nowadays, sample preparation is required and some tests analyzed in chromatograph laboratories and autoanalyzers. This preparation is an important step in the analysis, sometimes it can go up to 60% of the analysis time. For this reason, a careful sample preparation stage is very important for the correct result and time and hold in perpendicular position. Tubes should be always capped and paced in the centrifuge in balanced. Daily cleaning and periodical maintenance of centrifuges should be scheduled. Training should be given about how to deal with inappropriate situations that may arise.

Pneumatic systems are very powerful and useful resource and has been presented to the use of laboratory staff and researchers.

The sample preparation stage affects the analysis results in a significant way, thus it is being investigated in the scope of laboratory process within the preanalytical phase. Nowadays, sample preparation is required and some tests analyzed in chromatograph laboratories and autoanalyzers. This preparation is an important step in the analysis, sometimes it can go up to 60% of the analysis time. For this reason, a careful sample preparation stage is very important for the correct result and time and hold in perpendicular position. Tubes should be always capped and paced in the centrifuge in balanced. Daily cleaning and periodical maintenance of centrifuges should be scheduled. Training should be given about how to deal with inappropriate situations that may arise.

Pneumatic systems are very powerful and useful resource and has been presented to the use of laboratory staff and researchers.
Preanalytical phase is the most important phase of laboratory work flow process. It has been demonstrated that errors especially in the sample collection, identification, transportation to the laboratory steps result in misdiagnosis of the patients. Poor quality of samples such as hemolysed, lipemic or icterus is approximately 5-10-fold higher than the other preanalytical conditions that lead to the suppression of the test results. Breakdown of the erythrocytes and the release of hemoglobin and other intracellular components to serum results in chemical and spectrophotometric interferences and laboratory errors. Visual inspection of the sample should not be used for making a diagnosis or to exclude interfering substances in plasma. Other factors including the level of interfering substance in plasma, the assay principle and the assay system should be carefully examined. The main causes of unsuitable samples is the presence of interfering substances.

In former times, checking sample quality by visual inspection was the most common method for technical errors. Today, a number of coagulation analysers allow a systematic assessment of interference by optical measurement using different wavelengths. Understanding the potential impact of these variables on laboratory results is of great importance. Results affected by pre-analytical errors can have a significant impact on patient outcomes, such as diagnosis or treatment.

The clinical and Laboratory Standards Institute (CLSI) guidelines (Document H21-A5) state that whole blood samples or plasma samples stored at room temperature (RT), for routine haemostasis tests or determination of coagulation factors should be analysed within 4 hours after sample collection, with exception of prothrombin time (PT) tests with a reagent lot up to 24 hours. However, for many coagulation parameters, acceptance of a longer storage time at RT is described. This information can be interesting, for example, when additional coagulation tests are requested or when laboratories have to outsource coagulation tests to a laboratory at distance from the place of sample collection.

The preanalytical process is the most important phase of laboratory work flow process. It has been demonstrated that errors especially in the sample collection, identification, transportation to the laboratory steps result in misdiagnosis of the patients. Poor quality of samples such as hemolysed, lipemic or icterus is approximately 5-10-fold higher than the other preanalytical conditions that lead to the suppression of the test results. Breakdown of the erythrocytes and the release of hemoglobin and other intracellular components to serum results in chemical and spectrophotometric interferences and laboratory errors. Visual inspection of the sample should not be used for making a diagnosis or to exclude interfering substances in plasma. Other factors including the level of interfering substance in plasma, the assay principle and the assay system should be carefully examined. The main causes of unsuitable samples is the presence of interfering substances.

In former times, checking sample quality by visual inspection was the most common method for technical errors. Today, a number of coagulation analysers allow a systematic assessment of interference by optical measurement using different wavelengths. Understanding the potential impact of these variables on laboratory results is of great importance. Results affected by pre-analytical errors can have a significant impact on patient outcomes, such as diagnosis or treatment.

The clinical and Laboratory Standards Institute (CLSI) guidelines (Document H21-A5) state that whole blood samples or plasma samples stored at room temperature (RT), for routine haemostasis tests or determination of coagulation factors should be analysed within 4 hours after sample collection, with exception of prothrombin time (PT) tests with a reagent lot up to 24 hours. However, for many coagulation parameters, acceptance of a longer storage time at RT is described. This information can be interesting, for example, when additional coagulation tests are requested or when laboratories have to outsource coagulation tests to a laboratory at distance from the place of sample collection.

The preanalytical process is the most important phase of laboratory work flow process. It has been demonstrated that errors especially in the sample collection, identification, transportation to the laboratory steps result in misdiagnosis of the patients. Poor quality of samples such as hemolysed, lipemic or icterus is approximately 5-10-fold higher than the other preanalytical conditions that lead to the suppression of the test results. Breakdown of the erythrocytes and the release of hemoglobin and other intracellular components to serum results in chemical and spectrophotometric interferences and laboratory errors. Visual inspection of the sample should not be used for making a diagnosis or to exclude interfering substances in plasma. Other factors including the level of interfering substance in plasma, the assay principle and the assay system should be carefully examined. The main causes of unsuitable samples is the presence of interfering substances.

In former times, checking sample quality by visual inspection was the most common method for technical errors. Today, a number of coagulation analysers allow a systematic assessment of interference by optical measurement using different wavelengths. Understanding the potential impact of these variables on laboratory results is of great importance. Results affected by pre-analytical errors can have a significant impact on patient outcomes, such as diagnosis or treatment.

The clinical and Laboratory Standards Institute (CLSI) guidelines (Document H21-A5) state that whole blood samples or plasma samples stored at room temperature (RT), for routine haemostasis tests or determination of coagulation factors should be analysed within 4 hours after sample collection, with exception of prothrombin time (PT) tests with a reagent lot up to 24 hours. However, for many coagulation parameters, acceptance of a longer storage time at RT is described. This information can be interesting, for example, when additional coagulation tests are requested or when laboratories have to outsource coagulation tests to a laboratory at distance from the place of sample collection.
PREANALYTICAL PROCESSES AND ERROR RESOURCES IN PUBLIC HEALTH CARE LABORATORIES

Fazila Erkal
Antalya Public Health Care Laboratory, Antalya

Preanalytical errors are one of the most important problems in Public Health Care Laboratories (PHCL) as other laboratories. Antalya PHCL is one of the most important laboratories in Turkey, has of two main units which are medical laboratory and water analysis laboratory. In the medical laboratories family physicians are served, in some cities patient application are accepted. In APHCL routine biochemistry, hemogram, sedimentation, Hb A1c, blood group and thalassemia analyses are performed. Antalya provides services to 780 family physicians in 240 family health centers. The samples of easternarea are studied in the Alanya Laboratory and the samples of the central and western district are studied in the Central Laboratory. Test requests are made by family physicians, and samples are centrifuged after taken by family members. Collected samples are sent to laboratories and taken to the relevant units for analysis. Preanalytical phase consists of preanalytical and “real” preanalytical phase. Pre-preanalytical test selection, sample collection and transportation phases and preanalytical phase involves sample acceptance, centrifugation, aliquoting, dilution steps. Especially in PHCL which serves to family physicians cause preanalytical and some preanalytical processes are not under the control of the laboratory and intervened only after samples reach to the laboratory makes it difficult to follow up and results in higher error rates. In addition, the excess number of centers and the change of staff over time make process management difficult. Pre-preanalytical errors observed in APHCL are sample collection of blood in addition to what doesn’t have record in Laboratory Information Management System (LIMS) and recorded to LIMS but samples does not arrive to laboratory. Preanalytical errors in PHCL are, Hemolysis / Icterus / Lipemic Samples, Clotted Samples, Incorrect Recordings (Identification Error), Erroneous Test Requests, Inadequate Samples and Inappropriate Results.

In order to manage the preanalytical processes more controllably barcoding, sample transport arrangements and education programs to family physicians, family health workers and carer are planned in the near future.

Key words: Public Health Laboratory, Pre-preanalytical error, Preanalytical error.

EFFECTS OF POSTURE AND EXERCISE ON LABORATORY TESTS

Ayfer Colak
University of Health Sciences, Tepecik Training and Research Hospital, Medical Biochemistry Department, Izmir

Postural change during venous blood collection is a major source of bias in clinical chemistry testing. Blood volume in an adult decrease about 10% with changing position from supine to standing upright. For this reason concentration of many large molecular weight analytes (proteins and protein-bound analytes) increases remarkably. Postural change increase catecholamine, aldosterone, angiotensin II, renin and antidiuretic hormone secretion. Serum epinephrine and norepinephrine may increase twofold in 10 minutes but their urinary excretions do not change. Thirty minutes after standing upright a significant rise in potassium level occurs. Prothrombin time is not altered. In laboratory tests changes depending on exercise type, intensity and duration. Moderate intensity regular exercise shows opposite effects compared to vigorous exercise. Previous studies revealed that vigorous exercise increase free radical formation and regular exercises strengthen antioxidant defense. Exercise decreases plasma volume and results in hemoconcentration. Hemoglobin rises because of reduced fluid volume which leads to increased oxygen carrying capacity. Leukocytes rapidly increases. Serum glucagon, cortisol and growth hormone rises during acute exercise. Transient proteinuria is common after exercise.

Regualr exercise has beneficial effects on lipid levels. Decrease in total cholesterol and increase in HDL is observed. Regular exercise leads to augmentation of macrophage functions, it enhances neutrophil functions slightly and natural killer cell functions markedly. Additionally, as activated partial thromboplastin time, platelet aggregation, tissue plasminogen activator antigen, anti-hemophilic factor A levels decrease tissue plasminogen activator activity increase, prothrombin time is not altered. Exercise reduces cellular adenosine triphosphate leading to increased cellular permeability. Increased cellular permeability causes to a slight increase in serum levels of skeletal muscle originated enzymes including CK, LDH, AST and aldolase. Serum CK increases may be permanent in regular exercise. As a result considering all biochemical parameters, experimental researches shows that regular exercise has beneficial effects whereas acute exercise shows opposite effects. Patients with increased or decreased laboratory test results and unclear effects. Patients with increased or decreased laboratory test results and unclear results are study the effect of formalin contamination in urine protein estimation resulting in markedly protein estimation.

PREANALYTICAL CASE REPORTS-II

Esin Avci
Pamukkale University, Faculty of Medicine, Department of Medical Biochemistry, Denizli

Medical Biochemistry Laboratories should inform the clinician in a timely and reliable period with the most accurate form of patient results. Before reporting patient results in post analytical phase, to be sure the results are accurate, preanalytical and analytical phases should be complete with minimal error. Studies about laboratory quality show that laboratory errors originate from the preanalytical phase. It is about 560-75.

It is effective to determine errors under quality indicators for evaluating preanalytical errors frequency all around the world. Some quality indicators can be classified as:

- samples lost-not received
- samples collected in inappropriate container
- hemolyzed samples
- clotted samples
- insufficient sample volume
- inadequate sample-anticoagulant ratio
- samples damaged in transport
- samples improperly labelled
- samples improperly stored

Although classification of errors under quality indicators is effective in terms of standardization and classification, patient-centered evaluations are at the forefront. For example:

A 45-year -male with kidney transplant from an outside hospital came to a laboratory for 24 h urine protein estimation. On testing, the 24 h urine protein estimation came out to be 18,000 mg/dl. A repeat test was done, and the value remains unaltered. On close examination of the sample received, it was found that the urine sample was sent in a formalin container which was reused after washing. Strong formalin odor was present in the sample. The literature search was done to study the effect of formalin contamination in urine protein estimation resulting in markedly protein estimation.

Turk J Biochem, 2018; 48 (S2) http://www.TurkJBiochem.com