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Harmonization of total process:
Influence of the extra-laboratory phases

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EXTRA-ANALYTICAL PHASES QUALITY MANAGEMENT – NEW ACHIEVEMENT

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In the last two decades, the dramatic decrease of the frequency of analytical errors was due not only to technological developments (e.g. higher level of automation and utilization of information technology), standardization and optimization of methods, and better training of the laboratory staff but also thanks to the utilization of reliable indicators. The measurement of analytical quality through internal quality control and external quality assessment programmes has led to a significant improvement in accuracy in terms of both precision and trueness. However, in the last few years, a large body of evidence has demonstrated the high vulnerability of the pre- and post-analytical phases. This finding depends on numerous factors, including the complexity of the processes entailed, limited automation and standardization, and the involvement of different health care operators at the interface between laboratories and clinical practices. Errors and non conformities in the pre-analytical phase strongly affect the analytical quality and lead to waste of technological and human resources. Errors in the post-analytical phase, in turn, may lead to late acknowledgment and wrong interpretation/utilization of laboratory information, thus compromising the contribution of laboratory data to the improvement of clinical outcomes. All together, errors and non conformities in extra-analytical phases decrease the value of laboratory information, increase unjustified laboratory costs and affect patient safety. While there is a large consensus on the vulnerability of the extra-analytical phases and on the need to improve extra-analytical procedures and processes, the current debate is about the strategies to be adopted to establish performance specifications and tools for reducing extra-analytical errors. In theory, the performance goals for the pre- and post-analytical phases should follow the same concepts as for analytical performance goals and, when these phases include numerical uncertainty, it should be incorporated into the measurement performance goals. However, up to now, no outcome studies and, obviously, no biological variability data are available to set performance goals in extra-analytical phases. Therefore, at least today, pre- and post-analytical goals will best be reflected by quality indicators based on the state-of-the-art. The Working Group of the IFCC "Laboratory Errors and Patient Safety" has launched a project on a model of quality indicators (MQI), available at the website www.ifcc-mqi.com, and collected data that provide preliminary performance criteria. These criteria should be used, first and foremost, to guide improvement programs in each clinical laboratory and, in addition, represent a benchmark allowing inter-laboratory comparison of performances. Other initiatives, sponsored by the European Federation of Laboratory Medicine (EFLM), aim to provide further data on quality specifications in extra-analytical phases. However, it was recently described the so-called quality indicators paradox. On the one hand, an increasing interest is being expressed by the International Federations of Laboratory Medicine (both IFCC and EFLM), National Scientific Societies and laboratory professionals, with numerous papers on this issue and a specifically developed website to spread the information and collect data (free of charge and treated confidentially). On the other hand, there is the evidence that only a few clinical laboratories are making a regular collection of comprehensive data on indicators for the extra-analytical phases. Based on this evidence, some corrective actions and projects have been planned to close the gap, but the main goal is to raise awareness in laboratory professionals of the importance of QIs and related performance specifications, which are the key to allowing the identification of priorities in improvement programmes and to developing appropriate guidelines at a national and international level to set performance criteria and improve the quality of extra-analytical phases of laboratory testing.

RATIONAL ORDERING OF LABORATORY PARAMETERS: MONOGRAPHY & PILOT STUDY

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In January 2015 the monography »Rational Ordering of Laboratory Parameters« was issued. From rational ordering insurance companies expect cost reduction, laboratories minimal business devastation and clinicians as few as possible complications. Each clinician makes his / her test ordering decision in complex psychological situation with cognitive and time limits and possible social complications: this is why the test orderings sometimes look not rational at the first glance. Monography was written 7 iterations: 1 First draft was written by laboratory specialists (January – April 2013) 2 The proposal was commented by clinical experts (May – October 2013), 3 The commented draft was presented at the Annual Conference of Slovak Society of Laboratory Medicine (SSLM) for 350 clinicians and laboratorians (November 2013), 4 Proposals from the presentation were implemented (December 2013 – June 2014), 5 Restructuring and profiling of the final version was accomplished (July – October 2014), 6 Final version was presented at the Annual Conference of SSLM for 250 participants (November 2014), 7 In January 2015 monography was issued. Monography covers 8 clinical fields (figure behind each chapter title indicates the number of laboratory parameters included): Internal medicine (135), Endocrinology (32), Haematology (46), Immunology (17), Infections (20), Extravasates (31), Urgencies (28), Molecular diagnostics (22). For each clinical field adequate laboratory parameters were selected. For each selected parameter the adequate diseases and clinical circumstances were defined where ordering of given parameter is justified. Pilot study tests laboratory parameters used in the field of internal medicine: percentage and absolute numbers of not justified indications for 10 most frequently ordered substrates display following results: glucose 19% (936), urea 52 % (2 411), potassium 16% (750), sodium 16% (734), creatinine 15% (705), bilirubin 53% (2 384), CRP 30% (1 297), uric acid 47% (1 886), cholesterol 84% (3 286), triglycerides 85% (2 964). The monography was prepared by 4 editors, 18 authors, has 185 sides, and contains 316 most frequently used laboratory parameters in 8 clinical fields: it is an attempt to create a consensus between clinicians, laboratorians and insurance companies. From the total number of 43 680 ordered tests in a pilot study assessing the consequences of using in the monography defined rules for clinical practices 40 % (17 315) was not justified. Based on provisional results health insurance companies and Department of Health of Slovak Republic are interested to use the monography as guideline for rational ordering of laboratory tests at national level.

HARMONIZATION OF PREANALYTICAL PHASE-WHERE ARE WE NOW?

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Laboratory testing is an integral part of the clinical decision-making process, and results of laboratory testing often strongly influence medical diagnoses and therapies. Laboratory diagnostics develop through different phases which start from test ordering (pre-preanalytical phase), collection of diagnostic specimens (preanalytical phase), sample analysis (analytical phase), results reporting (postanalytical phase) and interpretation (post-postanalytical phase). Pre-analytical errors account for up to 70% of all mistakes made in laboratory diagnostics, mostly because of problems in patient preparation and identification, sample collection and handling, interferences, transportation and storage. The most of the pre-analytical errors are the result of non-standardized procedures and lack of harmonization. The improvement of this field of laboratory medicine is a great task and challenge for laboratory professionals. European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) through its Working Group Preanalytical Phase (WG PRE) draws attention about the need of harmonization of the preanalytical phase and has aim to take the lead in catalysing various international projects in this field. Beside the goal of EFLM WG PRE in promotion of the importance of the of the preanalytical phase of laboratory medicine, EFLM WG PRE works on conduction of surveys to assess the current practices related to some preanalytical variables,

definition of the best practices, production of recommendations for some critical activities and their implementation. The initials projects of EFLM WG PRE were survey of national guidelines, education and training on phlebotomy in European countries and observational study on compliance of blood sampling procedures with CLSI H3-A6 guidelines with aim to identify the most critical procedures which need urgent modification and improvement. The knowledge that only a minor part of European countries have their own written nationally accepted protocols (guidelines, recommendations) for venous blood sampling and the fact that the existing international guidelines and recommendations are not providing clear and unambiguous guidance for all steps during blood collection led to making EFLM WG-PRE Recommendation for venous blood sampling with the aim to provide a simple, condensed and evidence-based recommendation for the venous blood sampling. EFLM WG PRE also issued the articles with which draws attention to the importance on harmonization of fasting requirements for blood sampling, patient identification and tube labelling. Future activities of EFLM WG-PRE will be specifically address on all other preanalytical issues, such as paediatric and neonatal sampling, appropriate test selection and test profile requesting, sample handling, management of unsuitable specimens, transport and storage, application of quality indicators as well as organizing symposia, workshops, webinars or trainings. The EFLM WG-PRE emphasizes the importance of joint action of laboratory professionals, healthcare practitioners, manufacturers and standard writing bodies in supporting the development of universally applicable standards for the preanalytical phase and their worldwide implementation. One of the most important activities of EFLM WG PRE is also a collaboration with national societies as well as with other EFLM WGs: WG for Harmonization of the Total Testing Process, WG-Postanalytical Phase, WG Guidelines, WG-Accreditation and ISO/CEN standards on a rise awareness on significance of the preanalytical phase among all participants in the health care system which will be markedly reduce the potential risk of preanalytical errors and substantially improve patient safety.

EXTERNAL QUALITY ASSESSMENT FOR THE PREANALYTICAL PHASE

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To demonstrate their compliance, accredited laboratories are continuously required to undergo internal and external assessment. External assessment is ensured through regular participation in proficiency testing programs. According to 15189 accreditation standard, external quality assurance programs (EQAS) should provide clinically relevant samples that mimic patient samples as much as possible, Moreover, they need to have the ability to assess the entire examination process, including pre-and post-examination procedures. Whereas external quality assurance programs for analytical phase of the total testing process have long been established, pre-and post-analytical EQA programs have only very recently been developed and are now increasingly implemented. There are three basically distinct types of EQA schemes: a) Type I: Registration of procedures; b) Type II: Circulation of samples simulating errors, and c) Type III: Registration of errors and/or adverse events. Type I EQA is relatively easy to conduct, as it requires little or no resources. This approach is mostly based on survey data collected from participants. Surveys are performed to assess practices and policies and may even include some case scenarios. Such approach underlines the educational role of EQA. Type II EQA is the most challenging, as it requires knowledge, resources and infrastructure necessary to produce real samples with matrixes potentially interfering with the measurement procedures. These samples are circulated to the study participants and they are required to demonstrate their policy respective to the type of the sample problem. Commutability, stability and homogeneity of the sample are only some of the issues related to this approach. Type III approach is based on collecting data about pre-analytical quality indicators through some standardized registration system, over a given period of time. In the feedback, participants are provided with data on their performance and they are able to compare their own results to the results of their peers. Clearly, each type has some advantages and shortcomings. This lecture shall provide an overview of basic concepts in preanalytical EQA, their challenges and some most important benefits and drawbacks of each approach.

QUALITY INDICATORS-EXPERIENCE OF IFCC WG »LABORATORY ERRORS AND PATIENT SAFETY« ON PROJECT »MODEL OF QUALITY INDICATOR«

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The increasing attention paid to patient safety, and the awareness that the information provided by the laboratory impacts directly on treatment received by patients, has made it a priority for clinical laboratories to reduce their error rates and promote an excellent level of quality. Quality improvement is now a part of the daily routine for laboratories professionals, but quality cannot be improved without being measured. Measures of events under observation closely depend on the method used for data collection and on staff involvement. Quality indicators (QIs) are widely recognized as an effective tool in indicating potential problems and good performance. In recent years, the arising awareness of the importance of extra-analytical phases on the correctness of laboratory information has imposed clinical laboratories to keep under observation all activities of the Total Testing Process (TTP) and the use of QIs as a suitable monitoring and improvement tool. Different experiences of the QIs use in Laboratory Medicine are available in literature in which is demonstrated that the effectiveness of the QIs use is strongly linked to data collection method, data processing procedure used, appropriate analysis of results, and implementation of suitable corrective actions. The achievement of a consensus on the typology and the limits of acceptability for QIs, above all for the extra-analytical processes, should allow a reliable comparison to be made between the data collected from the different laboratories, the definition of state-of the-art and the achievement of effective benchmarking for the development and the application of standardized operative procedure and scientific recommendations for managing the various critical processes. In order to promote the harmonized use of QIs and reduce errors in laboratory testing, the IFCC Working Group on »Laboratory Errors and Patient Safety« (WG-LEPS) implemented, since 2008, a project to define a common Model of QIs (MQI) managed as an External Quality Assurance Program (EQAP) in which the confidentiality is guaranteed. The purpose of the project is to design a routine, formal, proactive system of monitoring based on standardized data collection, in order to define the state-of-the-art and quality specifications for each QI independent of the size of organization and type of activities. An EQAP is now ongoing through the: use of a common MQI; collection of data by a dedicated website (www.ifcc-mqi.com) which assures the confidentiality of the data treatment and notification; reporting of statistical data and laboratory results evaluation. The efficacy of the use of QIs is demonstrated by the improvement found in performance in the last years. The use of QIs within the framework of an EQAP, in fact, provides laboratories a tool to monitor and assess the extra-analytical activities, as well as the support processes and outcome measures and allows the identification of risks predisposing to errors resulting in patient harm. Further efforts should be made to achieve a consensus on the road map for harmonization and a significant decreasing of errors in TTP. All laboratories, at international levels, have been called to participate in and contribute to the success of the project.

APPLICATION OF BIOLOGICAL VARIABILITY

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Over the past decades a lot of literature data has studied facts that are important for generation and application of biological variability (BV) of the measurand. The aim of this work is to thoroughly explain main applications of BV in daily laboratory practice. We studied one of the most useful tools that has been developed in recent years and originates from the »Ricos' database« (www.westgard.com and www.biologicalvariation.com), based on an ever-evolving literature review of BV of the measurand. General needs for diagnosis and monitoring in clinical chemistry are satisfied by setting quality specifications based on within- and between subject BV. General applications of BV include specifications for desirable allowable total error, imprecision and bias. Other important applications include: evaluating the clinical significance of changes in consecutive results from an individual, assessing the usefulness of population-based reference values, determining which sample (e.g. serum, plasma, first-morning urine, 24-hours urine) is optimal for analysing a specific constituent, selecting the best test among several for a specific clinical purpose (e.g. diagnosis, monitoring), selecting the most informative units of expression for each analyte for reporting result, determining the number of analyses needed to establish an individual's homeostatic set point and validating new procedures in a clinical laboratory. Usefulness of application of BV contained in fact that laboratory could provide additional information to clinicians about changes in patient's status and provide high quality and safety in laboratory testing that has a prominent role in high-quality healthcare.

DRUG INTERFERENCES WITH CLINICAL LABORATORY TESTS

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Drugs prescribed to patients may interfere with laboratory findings which often makes the interpretation of the results difficult. Interference is defined as the effect of the endogenous or exogenous substances present in the sample, with the tests that are used for the determination of various analytes in biological samples. The most important endogenous compounds that interfere with laboratory results are haemoglobin, bilirubin, lipids and paraproteins, while those exogenous are drugs. Medications, being designed to be biologically active and given in high pharmacological doses, have a high probability of reacting with analytes or reagents. Metabolites of drugs may cause interferences and are as important to consider as the parent drug. One way to prove the presence of interference with the applied methods to determine a given analyte using reference method recommended for a given biochemical parameter. Another option is the simultaneous determination using two different methods, where if the obtained results are different the interference present is confirmed. The third way to confirm interference is the addition of a given analyte in the high and varying concentrations of a given biological sample. Then, using methods of linear regression analysis, the interference could be confirmed by drawing graphics and measuring the slope of the curve. Different types of exogenous substances may influence the biochemical result obtained in terms of a positive (increasing the real value) or negative impact (reduction in real value). An example of positive interference is the reaction of cephalothin and cefoxitin with Jaffe method for the determination of creatinine while vitamin C negatively interferes with glucose-oxidase method for glucose determination. Clinicians don't always have time or opportunity to check the possible effects of drugs on the results of laboratory tests. This may lead to erroneous conclusions, unnecessary additional laboratory tests and examinations, and even unnecessary drug treatments. In 1987, the IFCC tackled this problem and put forward recommendations made by an expert panel. According to those recommendations, the information should be available interactively via data terminals, and it should be possible to integrate information from databases into local computers and into routine hospital work. The Drug Laboratory Effect (DLE) coding scheme has turned out to be a very suitable way to describe the knowledge of drug effects on laboratory tests in a format used by computer software. Drugs are coded using both the ATC code, which is the international standard for drug coding, and generic drug name in English. In conclusion, drug effects on laboratory tests should always be considered when interpreting laboratory results. An online reminder system is useful in displaying potential drug effects alongside test results.

SYSTEMATIC AUTOMATED SAMPLE INTERFERENTS TESTING – A STEP TOWARD IMPROVEMENT OF EXTRA-ANALYTICAL PHASE

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The quality of sample is often compromised by presence of interferents such as hemolysis, lipemia and icterus. Results from such samples may be inaccurate and potentially affect patient care, so reliable detection of interferents presence is one of crucial preanalytical steps. This article presents a literature overview on causes of hemolysis, lipemia and icterus in sample, mechanisms of their action, and especially methods of detection of these interferents and recommendations for further management of unreliable samples. Also there are some experiences from comparison of working process before and after automated HIL testing implementation in primary healthcare laboratory. Traditionally, presence of interferents is visually estimated. It's not confident, is technician dependent and time consuming. Later years, laboratory analyzers offer automated detecting of interferents present in sample, known as serum indices or HIL testing. For systematic approach, ordering of HIL test should be automated through laboratory information system. Furthermore, each laboratory should define some rules for the appropriate action when interference is detected. There are at least 3 benefits laboratory can get with automated HIL testing: more reliable discovering of interferents present, less time consumption with better turn around times, more data for decision making during validation of patients results. Unfortenately some questionarries have shown that a lot of Serbian laboratories still use visual estimation of interferents, so there is a space for improvments. There should be a consensus at national level on methods of detection of interferents presence and also national recommendations for further management of affected samples and results.

THE MANAGEMENT OF PROCESSES IN THE PREANALYTICAL PHASE. THE EXPERIENCES OF THE INSTITUTE FOR LABORATORY DIAGNOSTICS »KONZILIJUM«.

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The trends in modern laboratory practice impose demands which on one hand mean a high level of automation, reduction of sample volume needed for testing, an increase in the analytical sensitivity of methods, while on the other hand they require the speeding up of the testing process, reducing the time needed for validating the results (Turnaround time – TAT) and on top of that reducing the costs of testing but surely not on the account of the accuracy of laboratory results. There are a number of factors which affect the accuracy of the results obtained in a medical laboratory. From the point of origin they can be grouped into three phases: preanalytical, analytical and postanalytical. The first phase, i.e. preanalytical begins with the patient ordering a test and ends when the sample arrives at the appropriate lab section. We can split the preanalytical phase into two parts: The first part (sometimes called the pre-pre-analytical phase) includes the test order, choice of method, patient and sample identification, sample collection, handling and transportation to another section where it is prepared for testing (centrifuging, aliquoting, diluting, sorting...). While the processes of sample preparation take place in the laboratory and are controlled by the staff, the »re-preanalytical« processes often take place outside the laboratory and are not under her direct control. It is well known that the biggest number of mistakes in a laboratory (32–75%) occur during the preanalytical phase. By analyzing the processes from the point of risk assessment on the possibility of mistakes happening, we can get valuable information concerning the measures needed to be taken in order to avoid and reduce them. Nevertheless, despite all the measures a laboratory implements and even fulfills the SRPS EN ISO 15189:2014 standards and good laboratory practice, mistakes in this phase still occur. Our own experience has shown that one of the causes is legislation, which has not been regulated in a proper way when it comes to private laboratory practice. In order to review the causes and arrive at possible solutions we have compared the experiences and issues, with which we come in contact in an attempt to fulfill the demands and expectations of our patients, with the experiences of a laboratory in New Zealand considering the fact that this country was among the first in the world to begin the accreditation of medical laboratories.

IMPROVING THE IMPACT OF LABORATORY TEST RESULTS – ARE WE BRAVE ENOUGH?

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The impact of laboratory tests has been traditionally summarized in the now famous »70% claim« which states that »Laboratory medicine data influences 70% of clinical decisions« (1). Although almost impossible to verify, this claim has proven soothing to the laboratory professionals worldwide when in doubt about the meaning of their work. However, should we really remain satisfied with this non-systematically proven claim and confine ourselves to high quality number production? Is there a way to ensure that the impact of laboratory data gets followed through, all the way towards directing, modifying or excluding treatment? The immediate logical answer lies in the close contact between laboratory and clinical professionals whenever feasible. This is the preferred solution for specialised tests which are not done in huge quantities and thus patients might be reviewed individually. Autovalidation is indispensable in this context, allowing selected more complex patient cases to be specifically attended by laboratory specialists (this is particularly applicable for hormones, tumour markers, TDM or other tests performed on automated platforms). Clusters of laboratory data might not immediately suggest a possible diagnosis to the busy clinician, nor do they necessarily possess the knowledge about further tests that might be performed in order to confirm or exclude the diagnosis. Laboratory reports with interpretative comments are therefore highly desirable, well received and appreciated by clinical staff and should be encouraged within laboratory environment. The comments about possible preanalytical errors or influences on particular laboratory test results should also be always clearly stated in order to prevent misinterpretation (2). Imagine a patient on proton pumb inhibitor therapy who receives a chromogranin result which is 70% above the upper reference level, or a patient

with psoriasis whose serum SCC result comes back clearly elevated. A simple statement within the laboratory report that therapy or certain conditions significantly elevate the values of those tumour markers makes a world of difference, both to patients and their families and more often than not also to the attending physicians. On the other hand, the comments concerning postanalytical phase often require more expertise and clinical data, which might be obtained by contacting the clinician - something laboratory professionals ought to do much more often. What remains to be done is to design and conduct more studies which will focus on the clinical impact of either direct contact or interpretative comments on laboratory reports - in other words on how the value of laboratory medicine could be undisputably proven in a measurable way. Laboratory professionals must beyond any doubt strive to be more visible and take initiative in communicating their skills in any way possible, and there is probably no simpler way to do it than to show our knowledge every day - boldly and without hesitation directly on laboratory reports.

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MANAGEMENT OF CRITICAL-RISK RESULTS IN LABORATORY MEDICINE – A TOOL FOR IMPROVEMENT CLINICIANS' DECISION

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The management of critical-risk results (CRR) – laboratory results that require immediate medical attention and action because they indicate a high risk of imminent death or major patient harm- is considered as a significant patient safety factor. The Task and Finish Group on Critical Results of the European Federation of Clinical Chemistry and Laboratory Medicine collected information on the practice of eight hundred and seventy one European laboratories in CRR management and analysed the alert lists (ALs) of almost 400 laboratories in 2012. This presentation will discuss the observed CRR management practices in the light of the recommendations of the recently published standard CLSI-GP47. The fundamental requirement of CLSI-GP47 on the necessity of organisational-specific ALs and CRR reporting policy was found fulfilled. However, wide variations were seen between laboratories in those aspects how they developed their ALs as well as in terms of which tests laboratories selected for inclusion in ALs. The most important unconformities in designing of ALs were that thresholds were often not set on broad consensus in institutions and timeframes in reporting linked to certain values were seldom indicated. Wide variations were also observed in the reporting process of CRRs among laboratories. Their policies were not always based on the patient clinical condition. Only a third of the respondents established practices for proper documentation or monitoring of the performance of their CRR notifications. There is a definitive need for training courses on CLSI-GP47, when laboratory professionals can acquire patient-risk based approach in AL development and CRR management.

* On behalf of the Task and Finish Group on Critical Results of the European Federation of Clinical Chemistry and Laboratory Medicine and the Australasian Association of Clinical Biochemistry

URINALYSIS: WHAT THE CLINICIANS NEED AND WHAT LABORATORY CAN OFFER?

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In recent years, great emphasis have been made in quality improvement in urinalysis. Correct procedures in pre-analytical phase of urinalysis have been defined in order to achieve best quality of samples for analysis. New technologies for examination of urine have immerged enabling more rapid and more standardized results. They also introduced different ways of result reporting depending on the method of analysis used. In 2000th European Urinalysis Guidelines have been published under the auspice of the European Confederation of Laboratory Medicine (ECLM) and in 2009th Clinical and Laboratory Standards Institute (CLSI) has published the third edition of Urinalysis; Approved Guideline. These guidelines contain useful practical recommendations for standardized urine analysis in order to produce consistent reference intervals for the harmonized interpretation of results. Close co-operation between laboratory and clinicians is recommended not only for delivering rapid and reliable result, but also for meeting new clinical requirements by introducing new tests, technologies, ideas.

CRITICAL VALUES REPORTING: A VIEW FROM PRIVATE LABORATORIES

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Critical values, also known as panic or alert values, are defined as those for which reporting delays can result in serious adverse outcomes for patients. The reporting of critical values is an important phase of the total testing process. Furthermore, laboratories are responsible for detecting potentially life-threatening results, for notifying them to healthcare professionals, and improving the timeliness of reporting and the receipt of results. The importance of critical values reporting has been recognized by international accreditation and regulatory bodies. The EN ISO 15189:2012 standard require that laboratories must establish documented procedures for the immediate notification of examination results that fall within established »alert« or »critical« intervals to responsible physician or other authorized health professional, and the International Federation of Clinical Chemistry and Laboratory Medicine Working group on laboratory errors and patient safety included notification of critical values as a mandatory process indicator for evaluation and monitoring of post-analytical quality in the consensus list of quality indicators. There is no standard list of laboratory test included in this indicator, nor are there standard critical value limits for specific laboratory tests. In addition, there is no universal requirements for critical value reporting. Since accreditation standards give just general guidance and national recommendations for critical values reporting procedures are not available in Serbia, laboratory professionals are often confronted with many problems in the reporting of critical values, including establishing clinically relevant criteria for critical values, resolving difficulties in locating an ordering healthcare professional when a critical value is obtained, and ensuring that the responsible healthcare professional understands the severity and implications of a critical result for patient.

SOLUTIONS FOR MONITORING PERFORMANCE IN PRE-PRE AND POST-POST ANALYTICAL PHASES

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The total testing cycle is based on the original brain-to-brain loop concept described by Lundberg and all activities have traditionally been separated into three phases (pre-analytical, analytical and post-analytical). To identify activities associated with the formulation of a clinical question and the initial selection tests and to separate from the activities related to the collection/transport some authors have introduced the concept of »pre-pre-« analytical phase. Also, in order to separate reporting from the correct interpretation and application of the test results in the best interest of the patient introduced the concept »post-post-« analytical phase. Managing these extra-laboratory phases of the total testing cycle is the next challenge for medical laboratories. The development of automation and information technology in laboratory medicine has allowed laboratory professionals to become the epicenter of the diagnostic process. Health information technology is essential for effective communication to coordinate of patient care due to its ability to capture, aggregate, and report data to enable more standardized and efficient reporting results and assessment of performance at both the patient and population levels. In »pre-pre-« analytical phase laboratory professionals need to be fully engaged with the clinical practice in test utilization process and assist clinicians with test ordering and ultimately improve the quality and efficiency of patient care. Laboratory professionals must become comfortable and confident in conversations with clinical colleagues to gain information, cancel a test, or suggest ordering a different test. These interactions are necessary for controlling test utilization. There are a variety of solutions available to aid in managing »pre-pre-« and »post-post-« analytical phase as described from Atlas Medical (Atlas Development Corporation): »clean« test orders and tailored results reporting, patient service center efficiency, advanced electronic medical record connectivity and multi-lab connectivity. Also there is the new generation clinical expert intelligence system like the Ripple Down (Pacific Knowledge Systems) which integrates patient data with a knowledge base that is managed by clinical domain experts to deliver patient specific reports recommendation and alerts. With a focus on becoming a recognized leader in healthcare quality medical laboratories are constantly looking at ways in which it can provide faster and more effective patients centric services.

MANAGING LABORATORY DEMAND – PRACTICAL EXPERIENCE

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Improvements in the public healthcare system have resulted in a rise in life expectancy, but also a rise in health spending which is not always justifiable. Healthcare spending has grown beyond our economy and beyond our capacity to generate resources. This situation has been made worse by the economic crisis, which has meant fewer economic resources to finance healthcare. The solution has been health cuts; clinical laboratories have been targeted, despite the fact that most studies show that the cost of laboratory tests is small in relation to global health expenditure (1, 2). In our laboratory, which caters for all the tests requested by the public health system in the local healthcare area, this was 3.2%. Apart from accountable costs, other unaccountable costs such as opportunity, transmitting and processing information should be taken into account. The concepts of medicine based on clinical laboratory proof should be added to financial request management (3). It is therefore, in the present economic crisis and cuts, essential to use the right tools to do what is necessary and cut out what is not necessary. Restricting requests and making them more relevant should be seen as an opportunity to offer better information and costs that can be assumed. This presentation shows the application of strategies to improve requests in real cases in laboratories in the Institute Catalán de la Salud de Cataluña, classified according to the outline proposed by A. Fryer, F. Hanna and S. Smellie (4, 5). Among the pre-laboratory strategies included are citizen health education in the form of information available to users in health centers, »Canal Salud« (a web with information checked by health professionals), healthcare webpages and information provided by laboratories. There is a search for collaboration between clinics which have educational information and participation with them in the selection

of tests and elaboration of diagnostic protocols and monitoring of major health issues. Examples are provided from the request guide (e.g. interactive electronic request in computerized medical records) including guidelines and establishing deadlines for repetition of tests for different types of patients and cases. Strategies employed inside laboratories are revised (generation and elimination of tests) as well as post laboratory, including the impact of test results on the patient's progress and the evaluation of results not received.

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CLINICAL AWARENESS ABOUT PRE AND POST ANALYTICAL PHASE ON NORTH ANATOLIAN UNION HOSPITALS CENTRAL LABORATORY

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Since laboratory errors are mostly due to the extra analytical processes, interaction between laboratory and clinicians is an important issue for patient safety (1–3). Recent years diagnostic methods became sophisticated and technically improved. In this context, the need for sharing of expertise between different parts of the delivery of health services became more essential (4). The total testing process is based on »brain to brain loop« concept, described by Lundberg (5, 6). Total activities in this cycle have been separated into three phases.(pre-analytical, analytical and post-analytical) In some publications some additional phases described like »pre-pre« and »post-post« analytical phases (7, 8). The error rates in pre-pre and post- post analytical phases are those respectively: 46–68%, 25–46% (9) Pre-pre analytical phase has a special feature between all phases. This is the phase that patient meets with clinician before sampling. Preparence of patient for the lab testing begins with this special moment. The management of total lab cycle starts with the interaction between clinician and the patient. Because of the high relative risk of errors in preanalytical phase, the importance of this meeting will have big impact on making all steps accurate and saving time for getting invaluable results. Another high risk point is post-post analytical phase and the main roles in this phase belong to again clinician and laboratory specialist together. Communication between these two parts has a high importance for preventing the errors. In this context, we designed a pilot study for determination of the clinician awareness of importance of preanalytical factors, and their confidences to the laboratory process. We prepared a questionnaire that contains 20 items each, and delivered by email (between 09.09.2014 and 31.10. 2014) to Internal Medicine, Surgery clinics and Emergency Units of 10 hospitals which have approximately 30.000 outpatients daily. The questionnaire is planned to determine of clinician awareness of preanalytical variables, importance of communication with laboratory, and the thoughts of clinicians about training on all laboratory process. The Survey of 5-Likert Scale, (Strongly disagree, Disagree, No knowledge, Agree, Strongly agree) was designed and the study was completed by 158 clinicians. »Strongly disagree and Disagree« answers were evaluated as »disagree« and »Agree and Strongly agree« answers were evaluated as »agree«. Total percentage of agree, disagree and »No knowledge« answers calculated for each of statement. We estimated reliability of survey by Cronbach's alpha coefficient (10). In this research, the Cronbach's alpha coefficient was 0.68, the scale was found very reliable. The SPSS Version 21 Statistical Package was used for statistical analysis. 158 clinicians were participated. Related to preanalytical phase: 93% of clinicians are informing patients about the preparation for specimen collection; 47% know the importance of specimen storage conditions, while 36% don't have any knowledge; 83% are aware of the importance of specimen collection time

and 78% have knowledge of biological variation while 18.3% don't know; 35% assure the effectiveness of quality control and 63% are confident for the laboratory results; Related to laboratory directors: 50-51% have satisfaction from easy communication with laboratory directors and their interpretation of the test results; Related to training: 87% agree with training, but 54% are thinking clinicians must participate in trainings; 72 % are thinking participation of only phlebotomists is enough. Although validity should be improved in this pilot study, it can be concluded that, training of staff, including clinicians on extra analytical variations is invaluable tools and the contribution of laboratory directors by interpretation of test results is needed.

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COMMUNICATION BETWEEN CLINICIANS AND MEDICAL LABORATORY – REGIONAL POINT OF VIEW

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Communication between clinicians and medical laboratory professionals is vital for providing appropriate and best possible patient care. Unfortunately, the clinicians' understanding of the influence of different test principles and their limitations, as well as the awareness of the impact of preanalytical sample handling on patients' results, are usually unsatisfying. On the other hand, the medical laboratory professionals usually are not sufficiently engaged in providing information on these issues to their fellow clinicians, which could raise this cooperation on a higher level. In order to better understand and get a clearer view on communication and level of cooperation between clinicians and medical laboratory specialists in providing the best possible patient care in four regional countries, the Society of Medical Biochemists of Serbia conducted a survey. Two corresponding questionnaires were distributed between clinicians and medical laboratory specialists in Serbia, Croatia, Bosnia and Herzegovina (BiH), and Macedonia. The multiple choice questions were related to the overall satisfaction of cooperation with clinicians/medical biochemists, the way of communication, the distribution of instructions for preparation of patients for laboratory testing to clinicians by the laboratory, the design of the request for laboratory testing and containing information, reflective testing, turnaround time (TAT), interferences in laboratory testing (hemolysis, lipemia, icterus, etc), interpretative comments, critical values reporting, testing methods reporting, ordering of the obsolete testings, reference values reporting, delivery of laboratory testing reports, the significance of cooperation of clinicians and medical biochemists in definition of diagnostic algorithms, instructions and recommendations for optimisation of healthcare services, the opinion whether the laboratory diagnostics aids the diagnosis. From Serbia, the total of 1364 clinicians and 234 medical biochemists participated in the survey; 160 clinicians and 20 medical biochemists from BiH; 55 clinicians and 12 medical biochemists from Macedonia; and 23 clinicians and 60 medical biochemists were from Croatia. All questions were compared between four countries by Chi-square test. Clinicians from BiH had significantly less positive responses to most of the questions, while their Macedonian colleagues had the most positive responses. Interestingly, there were no such distinctive differences between countries concerning the answers of medical biochemists, where the overall percetange of positive responses was higher. In order to reduce the number of variables, factor analysis was performed for clinicians' answers. The Kaiser-Meyer-Olkin measure of sampling adequacy was 0.907. The factor analysis distinguished four composite clusters from the original 23 questions, that explained 48.7% of the total variance. These factors were interpreted as (1) »opinion regarding the TAT and cooperation with biochemist«, (2) »familiarity of clinicians regarding preanalytical errors", (3) »interpretation of the reuslts by biochemist«, and (4) »data on the instructions regarding biomarkers«. The correlation between the factor scores and the clinician satisfaction regarding laboratory service was investigated by Pearson's correlation analysis. All examined factors showed significant positive association with clinicians' satisfaction regarding laboratory service. The association between factor scores and the high clinicians satisfaction regarding laboratory service were assessed using logistic regression analysis. In uni-

variate analysis higher scores for clinicians' oppinion regarding the TAT and cooperation with biochemist predicted higher clinicians' satisfaction regarding laboratory service in all examined countries. The odds ratios for Factor 1 were the highest in Serbia and BiH (OR 3.6 and OR 3.7, respectively). Also, odds ratios were the highest in these two countries regarding Factor 2 (OR 1.5 and OR 1.8, respectively), Factor 3 (OR 1.8 and OR 1.5, respectively), and Factor 4 (OR 1.2 and OR 1.6, respectively). These results suggest that in Serbia and BiH the satisfaction of clinicians with laboratory service depended on TAT, familiarity with preanalytical errors, interpretation of patients results by biochemist, and on instructions regarding biomarkers. Multiple linear regression analysis confirmed these results, since all four factors were independent predictors of high clinicians satisfaction regarding laboratory service in Serbia ($R2=0.448$). For BiH, Factors 1, 2 and 3 were independent predictors of clinicians satisfaction ($R2=0.507$), while for Macedonia only factor 1 was the significant predictor ($R2=0.251$). Results of the survey represent a good information source for laboratory professionals regarding the issues clinicians have the most interest in, and a starting point for improvement of communication critical for appropriate patient care.