Posters

P01 - Accreditation and laboratory management

P01-01

Increasing profitability of a specialized medical biochemistry laboratory

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Introduction: Laboratory's profitability is expressed as the operating profit, which is the final result of profit and loss account. Operating profit may be increased by organizational changes, i.e. by monitoring all laboratory expenses and processes.

Methods: The annual profitability of the specialized Medical Biochemistry Laboratory at General County Hospital in Našice, Croatia, in the study period 2007-2010 was evaluated using the profit and loss account, which included three basic elements: revenue, expenses, and their difference. Revenues were realized from reimbursements for laboratory tests performed, and expenses included all expenditures required for the realization of the annual revenue.

Results: The Laboratory's operating profit in 2007 was HRK 719,926, and the operating margin was 12%, (profit expressed as percentage), showing that the laboratory made profit and that, after the deduction of all operating expenses per 100 units of revenue, it retained 12 units of profit from performing its basic operating activities. In 2008, the operating profit increased to HRK 3,415,269 and operating margin increased to 39%, which is a 4.7-fold increase in comparison with the previous year. In 2009 and 2010, operating profits were HRK 3,049,245 and HRK 3,149,922, respectively, and the operating margin was 36%.

Conclusion: The analysis of the operating business performance of the specialized Medical Biochemistry Laboratory at General County Hospital in Našice showed that laboratory's profitability could be increased and maintained only by implementing organizational changes, without any technological investments. This finding could help other laboratories in Croatia to increase their profitability.

P01-02

Six sigma in clinical laboratory: analytical process management – focus on reduction of response time

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The philosophy of Six Sigma quality can be seen as a strategy that achieves perfection in products and processes. This holistic view was a new tool for the Clinical Laboratory, which in the context of business competitiveness concerns the relentless pursuit of perfect products by establishing an organizational advantage in various aspects. The product of the clinical laboratory is the result of quality from the service until the delivery of the report of the results. From the standpoint of the user, there are two perceived characteristics: accurate and unambiguous results, and the time of delivery. The Six Sigma project developed in Centro Medicina Laboratorial Dr. Germano de Sousa can bring great benefits to the analytical process, in the management of the analytical process of clinical laboratory, focusing on response time, and maintaining the quality of analytical results. According to the studies of reproducibility and repeatability, along with sigma metric as an index of performance we want to standardize the analytical repetitions performed per parameter to confirm the results, thus reducing the process time and reducing costs as the cost of using / technical occupation, additional expense of reagents and possible repeated harvesting by insufficient amount of biological sample. The use of a Six Sigma strategy in the clinical laboratory, not just being used as a metric for performance analysis, but in the context of case management provides a stand-

ardization of a complex and multidisciplinary, aligns the goals of quality and costs, focusing on customers and the health system´s financial organization.

P01-03

Development of the balanced scorecard of a software program for the management of quality indicators

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Background: Indicators related to laboratory processes represented in a balanced scorecard (BCS) can be obtained in an automated, fast and effective way through the Omnium software, for the continuous improvement of the quality.

Materials and methods: (17) indicators are calculated monthly from variables (70) registered daily in the tab of each patient of the laboratory computer system and indicate a resulted incidence. Areas, processes, fields and aggregators are defined in the BCS module of Omnium. The computer application Omnium (Roche) acts as DataWareHouse selecting, filtering and transforming data from Omega (Roche) and generating results from each indicator with its goal classified by colors. A browser displays the BCS in aggregators, fields, processes, areas and indicators, and a BCS tree graphically represents it to obtain the requested information, to study the evolution.

Results: 17 indicators are used: 6 of quality of the application, 4 of extraction, 4 of processing and transport, 1 of reception, 1of validation time and 1 of response time. The objective of each preanalytical indicator is < 0.3%, alarm indicator between 0.8 and 1.3, and danger indicator >1.3%. In the period January-May of 2012 all our indicators were below the target except "Samples not received", which value was 1.35.

Conclusions: With "Omnium", we obtain indicators of monthly automated extraction framed in a BCS organized in variables, indicators, areas, processes and fields. Staff knows their monthly indicators, evolution and goals for the following month. The browser and the BCS tree allow a better monitoring of the indicators evolution.

P01-04

Artificial urine – possibility or a good try

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Background: Based to our knowledge, external quality control assessment for urinalysis in most schemes is organized through sending pictures of urine sediment into laboratories. Although useful in testing of element recognition, this approach doesn't cover the whole process of urine sediment preparation. The aim of our study was to prepare artificial, low infective sample in order to test whole process of urine sediment analysis.

Materials and methods: We suspended small amount of human blood, epithelial cells from buccal mucosa and baker's yeast in saline fluid. This mixture was distributed into 13 samples and given for sediment analysis to a 13 professionals into 4 laboratories on the same day.

Results: As we expected, most of professionals managed to recognize all elements added into saline. Overall agreement for erythrocytes was 13/13, for epithelial cells 12/13, for leukocytes 10/13 and for yeasts 9/13. Relatively low agreement on yeast recognition might be due to growth of cells in samples that were examined last and also because of similarity of these elements to erythrocytes. Raters that didn't find any leukocytes are from laboratory that reported smaller amount of urine used for

analysis. Some of raters reported artefacts and salts that were not present in the samples. Also, they were confused with morphology of yeasts and complained about morphology of erythrocytes.

Conclusion: This approach has potential to develop into quality control of the total process of urine sediment analysis. However, because the transport conditions could influence composition of samples it could be applied locally.

P01-05

Accreditation according to standard UNE-EN-ISO 15189: 2007. Evaluation of a program in biochemistry

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Background: Accreditation of laboratories and the improvements in their results have been running quality systems for the continuous assessment and long-term accuracy of measure procedures by the results of the external quality control (CCE).

Materials and methods: We collected annual results of studied analytes sent by the Centre of Calculation of External Quality Control. The CCE has been processed monthly during 2011 in a Modular Cobasc711 where 23 parameters have been evaluated. These data allow us to know for each analyte: number of total data, deleted by aberrant, average and standard deviation. We studied rates of standard deviation, the total Error (%) according to desirable specification based on biological variation and performance techniques using the z-score.

Results: 276 results annually obtained for 23 different techniques included in the external quality control program have been evaluated. According to the standard deviation rate (IDS) we have established three groups: <1 IDS, 211 results (76.45%); 1-2 IDS, 60 (21.74%); 2-3 IDS, 5 (1.81%). An acceptable IDS is considered to be +/- 2. We obtained a 98.19% of acceptable results and a 1.81% of non acceptable results. 18 techniques (78.26%) obtained a specification of excellent quality by calculating the total Error (%) and 5 (21.74%) a desirable specification. In terms of performance, 14 parameters (60.87%) presented a satisfactory z-score rate (Pz < 2).

Conclusions: During 2011, the 98.19% of the results were acceptable (+/- 2IDS). All parameters were below the desirable Total Error according to specifications based on biological variation. 14 studied parameters (60.87%) obtained a satisfactory performance (Pz score<2).

P01-06

Information systems implementation: impact on the pre analytical phase of laboratory work

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Background: Laboratory Information System (LIS) BioNET which has been applied at the Department of Laboratory Diagnostics (KZLD) Clinical Hospital Centre (KBC) Zagreb since 2006 is upgraded with an electronic module that provides a record of nonconforming samples. Before the upgrade, every pre analytical error was paper-based and the department from which sample was sent was informed by phone. Electronic reporting of pre analytical errors is easier and simpler. Information about error is immediately distributed by HL7 communications protocol to hospital information system and accessible for a clinician.

At the same time, KBC Zagreb was introduced with an integrated hospital and business information system (BIPSI). The clinical departments have started with assigning electronic laboratory referrals

and labeling samples with barcode. HL7 communications protocol automatically transmits all requests to LIS which generates the barcode label.

Materials and methods: Laboratory Information System (LIS) BioNET, hospital and business information system (BIPSI), HL7 communications protocol

Results: In this way the sample is identified only once - at the department where is taken. The time of pre analytical phase is reduced as well as incorrect labeling.

Conclusions: Results of the implementation of these information systems are reduced number of pre analytical errors, faster elimination of recorded errors and consequently better patient care.

P01-07

Structured handoff at shift change in a clinical laboratory

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Background: It is estimated that 60-70% of medical decisions are based on clinical laboratory results. The laboratory therefore plays a crucial role in patient safety. As miscommunication during shift handover is a well-known risk in other high-risk environments, we developed a structured handoff procedure.

Materials and methods: We implemented a structured handoff for the clinical chemist on call. On-call shifts last for one week (24/7). The clinical chemist on call is in-house during office hours and can be reached by mobile phone outside office hours. The handoff was based on best practices in other high-risk environments, such as air traffic control and nuclear power plants. The following procedure was developed:

- The incoming clinical chemist assesses the status of the lab.
- The outgoing clinical chemist prepares the handoff.
- In case of calamities the handoff is delayed.
- Handoffs are not to be interrupted, and take place in a separate room.
- Handoff is an equal responsibility for incoming and outgoing clinical chemist.
- At every handoff a checklist (current state of laboratory staffing, IT, technical and analytical issues, non-conformities, service level, patient cases for handoff, and cases for continuous education) is used.

Results: The use of a structured checklist provided a continuous and thorough overview of the status of all relevant laboratory aspects to the clinical chemist on call.

Conclusions: The structured handoff resulted in several improvements: shorter duration and less escalation of IT, technical and analytical quality issues, improved service towards clinicians and contribution to continuous education.

P01-08

Effects of laboratory automation – report from a university hospital subjected to great changes

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Background: Akershus University Hospital in the greater Oslo area has 758 somatic and 345 psychiatric beds. From 2011, the population served increased with 140,000, and the uptake area is currently 455,000. Approximately 40% of the hospital's laboratory analyses are for the primary health care services. Automation of most laboratory analyses and the preanalytical phase was implement-

ed as we moved into a new hospital building in 2008.

Materials and methods: Our system for nearly total laboratory automation implemented in 2008, has automatic centrifugation, enGen and Vitros chemistry instruments from Ortho Clinical Diagnostics, immunochemistry from Beckman Coulter Inc. and a hematology trac from Sysmex Corporation. Workload and turnaround time (from receipt of the sample to reporting of results) were recorded.

Results and conclusions: Automation led to reduced turnaround times for most in-house analyses and enabled handling of a 30% increase in workload without additional staff. Previously most of the primary healthcare samples were analyzed the following day. After automation they were analyzed the same day. Turnaround time for primary healthcare samples was at least 12 hours less after automation. Automation enabled allocation of more resources to research and setting up new analyses. The sudden increase in hospital workload had not been possible without automation of laboratory procedures.

P01-09

Rationalization of spenditure in laboratory department in primary health care system in Serbia

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Background: Clinical biochemistry is a science which task is in vitro analysis human biological materials in order to determine potential risk of illness, to confirmed or exclude presence of illness, to monitor progression of illness, for therapeutic drug monitoring, or to predict outcome of the therapy. Number of tests is in progress every year and that has an impact on dynamic of organizational changes in the laboratory. Significant increase of number of tests leads to increase of financial resources which should be spent on clinical-biochemistry laboratories. During the time of limited financial recourses in which we are streaming to equally availability of health care system and increasing quality of service, it is necessary to make a balance between real clinician need for test request, quality of the result and spenditure of financial resources.

Resume: Rationalization of spenditure is observed from these aspects:

- laboratory as a service with IT user requests
- with clinician requests
- communication between clinicians

Laboratory as a service which is fulfilling user request is monitored from the management aspect with procedures, orders, quality control system. In this segment, laboratory work processes are introduced and how it is possible to provide rationalization in the laboratory.

Conclusion: By using these aspects, rational use of laboratory diagnostic services and rational use of resources in the treatment of patients with different diagnoses can be achieved, as well as the quality improving of health care and services that are provided to the patient.

P01-10

Microsoft Access database management of laboratory accreditation

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Laboratory accreditation management is a complex task producing many documents that need to be well and systematically organized. We build

a system organized through several Microsoft Access database applications that produce, organize or simply manage different types of accreditation documents. Frontend applications are available on every laboratory computer and access permissions are defined through login system. The database data are located on central file share server.

Document hierarchy and managing are performed trough searchable Documents database that keeps all documents organized by types, accreditation fields, and laboratory organizational units. Every document in a database is easily accessible through Intranet access.

Laboratory equipment is organized through another application database that enables managing of every laboratory part of equipment, including planning of periodically equipment calibration.

Laboratory tests data are managed through Database of measurement procedures, which also serves for reporting of yearly test reevaluations and is a data serving application for laboratory web pages for Internet available test catalogue.

Laboratory personnel is managed through database which contains possibilities of yearly appraisement for every employee, managing education, personnel test performance skills and equipment training.

Nonconformities and maintenance of laboratory equipment are managed through another database which replaces the need for paper form evidence for almost any type of information that needs to be collected on daily or periodically basis.

Paper forms and paper documents are drastically reduced after 5 years of implementing such informational system. Retrieving the statistical report for almost any type of collected data is performed by a button click.

P01-11

Do we meet quality specifications based on biological variation?

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Background: Responsibility of the clinical laboratory professionals is to assure the highest possible quality of the reported results. Consensus recommendation on the quality targets in laboratory medicine, which was released after the Stockholm Conference, supports the hierarchy quality model. In this concept, a model higher in the hierarchy should be preferred over lower one. Since in our laboratory the analytical performance is evaluated according the manufacturer recommendation, the lowest model in hierarchy, we aimed to compare our analytical coefficients of variation (CVa) against criteria for imprecision based on biological variation (CVb).

Materials and methods: Imprecision of 20 biochemistry parameters was monitored by analyzing two levels of commercial quality control material, three times per day, over one year. CVa obtained for each parameter was evaluated against quality specifications based on biological variation.

Results and conclusion: Comparison against biological variation was as follows: five parameters met optimum quality specifications CVa<0.25 CVb (bilirubin total and conjugated, CRP, CK and lactate); seven parameters met desirable quality specifications CVa<0.50 CVb (AST, ALT, amylase, CK-MB activity, lipase, urea, TnT) and three parameters met minimum quality specifications CVa<0.75 CVb (glucose, potassium, LD). The rest of the monitored analytes did not meet quality specifications based on biological variation. The results showed that it would be possibly better to adopt the highest model with more stringent criteria.

P01-12

Patient safety in the clinical laboratory: an analysis of patient/specimen identification errors

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Background: Patient identification and specimen labeling represent one of the most critical area in patient safety and is an increasingly visible mission for clinical laboratories. The aim of this work is to assess patient identification and specimen labeling improvement after implementation projects using longitudinal statistical tools.

Materials and methods: Patient/specimen identification errors were categorized by a multidisciplinary health care team. They were grouped into 3 categories: A: specimen/requisition mismatch, B: unlabeled patient identifications, C: misidentification patient. These types of identification errors were compared preimplementation and postimplementation for 3 patient safety projects: 1) Development of Identification Patient and Specimen Process to follow by all the professionals implied; 2) reorganization of phlebotomy; 3) introduction of an electronic event reporting system. We use trend analysis and student t-test.

Results: Of 46,632 total requests analyzed, requisition mismatches, unlabeled patient identification and misidentification patient represented 1.6/10,000, 5.8/10.000, and 4.1/10.000 of errors, respectively. Student t-test showed a significant decrease in the two most serious errors, mislabeled specimens ($P < 0.001$) and misidentification patient ($P < 0.001$) when compared to before implementation. Trend analysis demonstrated decreases in all 3 error types for 18 months.

Conclusions: The applied strategies have demonstrated to be effective in the improvement of the identification of the patient in the analytical requests. However, we must continue working in this strategy, with all the implied professionals and trying to reach the objective of which the 100% of the requests they are identified correctly.

P01-13

Risk management in laboratory. Failure models and effects analysis of identification patient errors

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Background: Patient and specimen identification errors are a key concern for patient safety. Failure Models and Effects Analysis (FMEA) is a tool that prospectively identifies process steps at risk for patient safety errors and permits proactively design strategies for improvement. The aim of this work was: Establish the weighted risk factors for identification patient and specimen phlebotomy process using FMEA.

Materials and methods: A multidisciplinary health care team was working in this area, reviewed phlebotomy and specimen collection process. Steps included the following: 1) diagramming the process, 2) brainstorming potential failure modes and their effects, 3) prioritizing failure modes, and 4) identifying root causes of failure modes.

Results: FMEA identified several factors that contribute to a higher likelihood of error than indicated for laboratory phlebotomy draws. The highest risk process steps were comparing preprinted, barcoded sample labels with Patient Identification and comparing them with information order sheets (RPN scores for both, 280). Moderate risk was checking patient identification for 2 identifiers and prelabeling specimens were also high risk, with RPN scores of 175. The distractions and tiring may also contribute to increased risk not explicitly noted in process steps.

Conclusions: FMEA indicated that patient identification error was the most risk-prone process step. It validates the importance of patient identification in health care. The FMEA is a very effective tool as risk management, in identifying where risk existed for patient–specimen identification errors. It also helped to create a clear partnership with other health care professionals.

P01-14

Risk management in medical laboratory. Appliyng root cause analysis of patient and specimen errors

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Background: Mislabeled laboratory specimens and errors in patient identification represent one of the problems with greater index of factor of risk in causing harm in the patient, such as repeat phlebotomy; repeat diagnostic procedure; increase of demand others diagnostic procedures, delay in a necessary surgical procedure or diagnostic. The aims of the present work was to identify system vulnerabilities in specimen collection, processing, analysis, and reporting associated with patient misidentification involving the clinical laboratory.

Materials and methods: We reviewed multiple cases of incorrect patient identification on laboratory specimens. Specimen errors were categorized by a multidisciplinary health care team. A qualitative analysis was performed on 31 root cause analysis reports. Data were categorized by the 3 stages of the laboratory test cycle.

Results: Patient misidentification accounted for 25 of 31 adverse events. 23 misidentification events occurring in the preanalytic phase the causes were: specimen mislabeling during collection (N = 20), laboratory tests were ordered for the wrong patient (N = 2) misinformation from manual entry on laboratory forms (N = 1). There was one event in the postanalytic phase in which results were reported into the wrong patient medical record (N = 2).

Conclusions: Patient and or specimen misidentification in medical laboratory were due to a limited set of causal factors in all 3 phases of the test cycle. A focus on these factors will inform systemic mitigation and prevention strategies.

P01-15

IRATA - program for managing off-balance sheet warehouse

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Background: The Department of Laboratory Diagnostics (KZLD), Clinical Hospital Centre (KBC) Zagreb has introduced a validated result that represents the total consumption of reagents required to make an analysis of certain parameters. For this reason, the company IRATA has made a program for off-balance sheet warehouse for managing goods and materials.

Materials and methods: The protocol for stock management software IRATA.

Results: Before introducing IRATA program, keeping goods in stock was done in Excel tables. After introduction of the IRATA program, traceability for each reagent was obtained from entering the warehouse to the issuance to the analyzers by quantities and material costs and also by the serial numbers and expiry dates. IRATA program allows simple and rapid inventory at any time, trace consumptions by reagents for each clinical unit in KZLD or by the suppliers of reagents. The program is a useful tool

for daily, monthly or yearly reports on the consumption of reagents and validated results.

Conclusions: By introducing IRATA program for managing stock, recording of overall process within all clinical units in KZLD was significantly facilitated. The inventory of goods was significantly simplified, and for accreditation (ISO 15189), essential reagents traceability by serial numbers and expiry dates of arrival at the laboratory to its application to the analyzers was obtained.

P02 – Cardiovascular diseases

P02-01

CETP, LDL particle size and intima media thickness in patients with coronary heart disease

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Background: Cholesteryl ester transfer protein (CETP) plays a key role in reverse cholesterol transport and high density lipoprotein (HDL) metabolism. Predominance of small, dense LDL particles is associated with an increased risk of atherosclerosis and coronary heart disease (CHD).

Aim: to determine the potential relationship between the CETP concentration and low density lipoprotein (LDL) particle size and their association with intima media thickness (IMT) in patients with CHD.

Materials and methods: Lipid parameters, CETP concentration and LDL particle size were determined in 100 healthy subjects (control group) and in 100 patients with CHD, aged 43 to 77 years. Plasma CETP concentrations were measured by an enzyme-linked immuno-sorbent assay with two different monoclonal antibodies. LDL subclasses were separated by nondenaturing polyacrilamide 3-31% gradient gel electrophoresis.

Results: CETP concentration was higher in patients compared to controls (2.02 ± 0.75 mg/mL *vs*. 1.74 ± 0.63 mg/mL, $P < 0.01$). Mean LDL particle size (nm) was significantly smaller in patients than in controls (24.5 ± 1.1 *vs*. 26.1 ± 0.9; $P < 0.001$). There was no relation between LDL size and CETP concentration ($r = -0.18$, $P = 0.072$). Age, diastolic blood pressure, CETP concentration and LDL particle size were independent factors for determining IMT by multiple linear regression analysis. They accounted for 35.2 % of the observed variability in IMT.

Conclusions: CETP concentration and LDL particle size were independent factors for determining IMT. CETP might play a role in determining lipoprotein distributions, but did not seem to be the sole factor in the formation of small LDL particles.

P02-02

NT-proBNP in anthracycline-induced cardiotoxicity in children

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Background: Anthracyclines (doxorubicin, daunorubicin and idarubicin) are highly efficacious antineoplastic agents for various malignances in children but their usefulness has been limited by cardiotoxicity causing cardiomyopathy and heart failure. The aim of this study was to assess the diagnostic accuracy of N-terminal-prohormone brain natriuretic peptide (NT-proBNP) in recognizing anthracycline related cardiotoxicity in children. **Materials and methods**: Serum levels of NT-proBNP