

HOW ISO-15189 LABORATORY ACCREDITATION ASSURES PATIENT SAFETY? KAKO ISO-15189 AKREDITACIJA LABORATORIJA OSIGURAVA BEZBEDNOST PACIJENTA?

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Summary: Healthcare is a complex profession involving the state-of-art technology and sometimes leading to unintentional harm. Many factors contribute to the occurrence of medical errors. Patient safety is one of the most serious global health issues and defined as the absence of preventable harm to a patient during any process of medical care. The frequency of medical errors is higher than expected. It has been concluded that the majority of medical errors are not because of the individual attitudes but mainly caused by faulty systems or processes leading the staff to make mistakes or fail to prevent them. Patient safety is a shared responsibility comprised of many stakeholders such as society, patients, nurses, educators, administrators, researchers, physicians, government and legislative bodies, professional associations and accrediting agencies. Medical laboratory services are essential to patient care and need to be available to meet the needs of both patients and caregivers. ISO-15189:2007 Medical Laboratories-Particular requirements for quality and competence, an internationally recognized standard containing requirements necessary for diagnostic laboratories to demonstrate their competence to deliver reliable laboratory services. It applies quality system requirements to the clinical laboratories with a strong focus on responsiveness to the needs of patients and clinicians. Applying the performance improvement strategies focusing on different phases in total testing process will significantly reduce the errors and therefore will improve the patient safety. In this way, laboratory professionals contribute to improvement of safety and outcomes of care by working in interdisciplinary approach manner.

Keywords: patient safety, clinical laboratory, ISO 15189

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Kratik sadr`aj: Zdravstvena zaštita je kompleksna profesija koja uključuje najsavremeniju tehnologiju i ponekad dovodi do nenamerane štete. Mnogi faktori doprinose pojavi medicinskih grešaka. Bezbednost pacijenta je jedan od najozbiljnijih problema globalnog zdravlja i definisana je kao odsustvo štete po pacijenta koja se može sprečiti u toku bilo kog procesa medicinske nege. Frekvencija medicinskih grešaka je veća od očekivane. Zaključeno je da se većina medicinskih grešaka ne javlja zbog pojedinačnih stavova već je uzrok uglavnom u nesavršenim sistemima ili procesima koji navode osoblje da pravi greške ili da ne uspeva da ih predupredi. Bezbednost pacijenta je zajednička odgovornost mnogih činilaca kao što su društvo, pacijenti, sestre, edukatori, administratori, istraživači, lekari, vlada i zakonodavna tela, profesionalna udruženja i agencije za akreditaciju. Usluge medicinske laboratorije su esencijalne u zbrinjavanju pacijenta i moraju da zadovolje potrebe i pacijenata i zdravstvenih radnika. ISO 15189:2007 Medicinske laboratorije – Posebni zahtevi za kvalitet i kompetentnost je međunarodno priznati standard koji sadrži zahteve neophodne da bi dijagnostičke laboratorije pokazale svoju kompetentnost za pružanje pouzdanih laboratorijskih usluga. Primenjuje zahteve sistema kvaliteta na kliničke laboratorije sa snažnim fokusom na odgovoru na potrebe pacijenata i kliničara. Primena strategija za poboljšanje učinka koje se fokusiraju na različite faze kompletnog procesa testiranja će značajno smanjiti greške i tako doprineti bezbednosti pacijenta. Na ovaj način, laboratorijsko osoblje doprinosi boljoj bezbednosti i ishodom zbrinjavanja kroz interdisciplinarni pristup.

Ključne reči: bezbednost pacijenta, klinička laboratorija, ISO 15189

Patient safety at a glance

Healthcare is highly complex profession today and is often delivered in a pressurized and fast-moving environment. It involves state-of-art technology but at the same time different decisions from different healthcare professionals. Sometimes, unintentional harm could occur. The problem of adverse events in

healthcare is not new but the subject has remained largely neglected. Patient safety is one of the most serious global health issues and defined as the absence of preventable harm to a patient during any process of medical care. Reports show that, in developed countries, one in every ten patients is harmed during medical care. On the other hand, this figure is much higher in developing countries when compared to well-developed ones.

A variety of factors contributes to the occurrence of medical errors. The main reason for which preventable errors occur is the complexity of medical care, involvement of staff, hospital equipment and procedures (1). The type of the errors is divided into four main categories: a) diagnostic errors, b) treatment errors, c) prevention errors and d) others (1).

Use of outdated tests or failure to employ correct tests leads to delayed diagnosis or failure to take result-based measures to monitor or test the disorder. Treatment type errors are related with the performance of procedures or tests. Application of incorrect treatment, drug dosage errors or incorrect method of drug administration leads to inappropriate care of patients. Failure to provide prophylactic treatment or inadequate monitoring or follow up of the treatment leads to prevention errors. Failure of communication or any system failure in healthcare facility also leads to preventable errors.

The frequency of medical errors is higher than expected. The first serious report concerning medical errors and patient safety was published by the Institute of Medicine (IOM) in 1999 (2). *To Err Is Human: Building a Safer Health System*. This publication has broken the silence that has surrounded and masked medical errors and prioritized the concept of »patient safety« not only in the United States but also in other countries in the world. The creation of World Alliance for Patient Safety by The World Health Organization (WHO) is a significant step to improve the safety of healthcare in all Member States (www.who.int/patientsafety). It has been estimated that, 44.000 to 98.000 deaths occur each year in hospitals because of preventable medical errors. That is more than deaths from motor vehicle accidents, breast cancer or AIDS. Apart from the cost in human lives, preventable medical errors have been estimated in a total cost of \$17 to \$29 billion per year (3–5). This estimate places the medical errors among the leading causes of death in the USA (6, 7). Loss of trust and satisfaction in healthcare system by patients as well as by healthcare professionals is the result of error costs.

IOM report provided the main factors contributing to medical errors (2). The first one is a fragmentation or decentralization of healthcare system leading to creation of the unsafe environment for patients and prevention of safety efforts. The second factor is an accreditation process which pays insufficient atten-

tion to prevention of the errors. The third factor is a medical liability system discouraging the medical staff from revealing the mistakes. This leads to prevention of systematic errors. The last factor is the third-party purchasers of healthcare, which discourage healthcare organizations to improve both safety and quality (2).

One of the IOM report's main conclusion is that the majority of medical errors is not because of individual attitudes but mainly due to faulty systems or processes leading staff to make mistakes or fail to prevent them. In order to prevent mistakes, designing of all healthcare system levels safer is fundamental, to make it harder for the staff to do something wrong and easier to do it in a right way. When an error occurs, blaming the staff does not make the system safer and does not prevent others from making the same error (2).

For better safety, IOM report recommends four-step approaches (2). I. Due to lack of a single governmental agency for improvement and monitorization of the safety issues, the healthcare is about a decade or more behind many higher-risk industries on the basis of fundamental safety issues. For this reason, the national awareness should be established to organize a leadership to improve the knowledge about the patient safety. II. Nationwide mandatory error reporting systems should be developed. Healthcare staff should be encouraged to participate in these voluntary reporting systems. In this way, identification of errors and learning from errors will provide incentives to healthcare organizations to implement internal safety systems. III. Through regulatory and related mechanisms, such as licensing, certification or accreditation, the minimum performance levels for healthcare staff should be defined to raise expectations for improvements in patient safety. IV. Healthcare organizations must develop a »culture of safety« to improve the reliability and safety of care for patients (2).

After the release of IOM report, both public and private healthcare systems have tried to elevate performance standards. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) enforced the standards focusing on patient safety by revision of the existing standards and developing new safety standards. As a part of its accreditation process, JCAHO requires evaluation of the factors leading to errors by root-cause analysis. JCAHO encourages but does not require hospitals to report adverse events (8). Among healthcare services, clinical laboratories are particularly important because physicians make their decisions mostly in accordance with the laboratory results. In this context the media always intend to remind to mistakes of laboratories (9). In April 3, 2004, Walter F. Roche wrote an article in Baltimore Sun. The article indicated that the testing problems in the city community hospital,

Baltimore Hospital, an affiliate of the University of Maryland Health System, were far more widespread than had previously been indicated. It has been explained by hospital officials that questionable HIV and Hepatitis C results might have been given to more than 2000 patients. In addition, questionable test results for sexually transmitted diseases such as gonorrhea and chlamydia were provided. In some cases, the inspectors found out chemical reagents with the expired shelf-life. Because the test results were issued despite errors, equipment malfunctions, inadequate training and sample mishandling, the Baltimore Hospital faced with \$ 10000-a-day fine unless it corrected the problems. Laboratory errors became the subject of many articles in the media. An article by Weber and Ornstein in Los Angeles Times in December 7, 2004, explained one doctor's long trial for dangerous mistakes. In October 3, 2007, a case of a woman who had double mastectomy for breast cancer was reported in The New York Times by Tara-Parker Pope. She had learned that her results were mixed with someone else's test results, that is, she had never had cancer at all (10). An important question has been asked by Leslie Pepper in Good Housekeeping: Can you trust your lab results? She explained mixed-up samples, misread slides, contaminated specimens, etc. (11).

Reported medical errors are only a part of the iceberg. The majority of errors is not reported correctly. For example, most recent article by Robert Pear in The New York Times in January 6, 2012 demonstrated that hospital employees recognized and reported only one out of seven errors, accidents and other events causing any harm to Medicare patients while they were hospitalized (12). The investigators found many serious problems, including some that caused patients to die, which were not reported.

Who is responsible for patient safety?

Patient safety is a shared responsibility comprised of many stakeholders such as society, patients, nurses, educators, administrators, researchers, physicians, government and legislative bodies, professional associations and accrediting agencies (13) and even the media. All these stakeholders are responsible for patient's care to be safely delivered and no harm to be done.

It has been also estimated that hospital boards have important responsibilities to supervise the safety and quality care provided in their institutes (14). Although they implied quality, they did not measure it but paid relatively very little direct attention. The competence of the board for safety issues is decision-making related to medical staff credentialing and an oversight function (14).

How much are clinical laboratories responsible for medical errors? Unfortunately, there are limited

data about medical errors originating from the clinical laboratories. However, laboratory-related medical errors are not innocent and can lead even to death of patients. To decrease the rate of laboratory-related medical errors, we have to focus on the quality of clinical laboratories in a wide perspective.

Quality in medical laboratories

The term of quality management has specific definitions in different business areas. It ensures that the organization of a product is consistent and accepted to have four main components: quality planning, quality control, quality assurance and quality improvement (15). Quality management is mainly focused on product or service quality and also the ways to achieve it. Quality management dates back to periods of Shewhart and Deming in the early twentieth century. Walter A. Shewhart, by using the statistical methods, created a method for quality control in production processes. W. Edwards Deming proposed that any process needed to be analyzed to identify any sources of variations leading to products or services that do not meet the expectations of customers. He recommended a continuous feedback loop, known as PDCA cycle: Plan, Do, Check, Act. Deming, in his book »Out of the Crises« set up 14 points which are a basis for transformation of the American industry. Although these 14 points were devised for manufacturing industry, most of them could be easily applicable for improvement of laboratory medicine management.

Deming did not use the term »Total Quality Management« (TQM) in his book but most of the central ideas of TQM, contained in the book, launched the movement. As TQM has gained prominence, the product planning step has expanded to include the evaluation of customer needs.

'Total testing process' is a multistep process that begins and ends with the patient's needs. Originally, it was described by Lundberg (16, 17) and then simplified as follows:

- Pre-pre-analytical phase
- Pre-analytical phase
- Analytical phase
- Post-analytical phase
- Post-post-analytical phase

The steps included in this loop starts with the brain of the physician who selects the laboratory tests and completes with the transmission of test results to the ordering physician (18). Accreditation agencies require from laboratories to take responsibilities not only in analytical phase, but also in non-analytical phases; and, pre- and post-analytical phases where most of the errors occur (19).

Healthcare is a hazardous area and in the United States, the overall defect rate is estimated to be 31%–69% (20). Error rates are frequently described as sigma concept. The analytical phase of the laboratory is the best sector in healthcare with close to 5 sigma performance (20, 21). In order to accomplish better laboratory medicine processes, all phases of total testing process should be considered (22, 23). It has been estimated that pre- and post-analytical phase errors are at least 4–5 times more than those observed in the analytical phase and half of all errors are observed in pre-analytical phase (24–29).

The common causes of errors are classified as follows (30):

- I- Pre-pre-analytical errors: 46–68%
- II- Pre-analytical errors: 3–5%
- III- Analytical errors: 7–13%
- IV- Post-analytical errors: 13–20%
- V- Post-post-analytical errors: 25–46%

Currently, this classical approach is not adequate for clinical laboratories. Pre-pre-analytical and post-post analytical phases are more metaphorical for laboratory staff than other phases of total testing process. We recommended clinical pre-analytical phase for pre-pre-analytical phase, laboratory pre-analytical phase for pre-analytical phase, laboratory post-analytical phase for post-analytical phase and clinical post-analytical phase for post-post-analytical phase (31).

Errors in healthcare are often of concern when they threaten the patient safety. Previous studies suggested that 24%–30% of laboratory errors affect patient care and actual patient harm occurs in 3%–12% of the time (32, 33).

Medical errors are the failure of planned actions to be completed and the majority of them are caused by faulty systems, processes and conditions leading people to make mistakes. In order to increase performance standards, safety improvements by implementing safety systems recommended. These recommendations are translated in specific requirements to promote patient safety by US-based accreditation bodies and international standards (16).

Joint Commission International (JCI) is an international branch of the Joint Commission and has been working with variety of health care organizations in over 80 countries since 1994. All accredited organizations are expected to implement the International Patient Safety Goals (IPSGs). The purpose of these goals is to improve patient safety. There are six goals, four of which are related to clinical laboratories. The first two goals are related to extra-analytical phase of the total testing process (34). The first IPSG is related to correct identification of the patient. It forces health organizations to develop any approach to improve patient identification accuracy. Without any doubt,

the most critical part of pre-analytical phase is sample collection from the patients (35, 36). Identification processes are important when giving any medications, blood or blood products or any other treatments or procedures or taking blood or any other body fluids for clinical testing (34). JCI recommends at least two identifiers for a patient: name, identification number, birth date or others (34). It has been also recommended not to use room numbers or locations as patient identifiers (34). It has been found that identification errors are common in inpatient settings (37). Up to 1 in every 18 identification errors leads to adverse events (38).

The second IPSG is to develop an approach to improve the effectiveness of communication among caregivers (34). It is definite that effective communication reduces errors and improves patient safety. The communications are electronic, verbal or written. But, verbal orders or the ones given over phone always result in errors. This second goal is related to pre- and post-analytical phases of total testing process. The other communication type with tendency to occurrence of errors is reporting back of critical test results in post-analytical phase. It is expected that the health organization should develop a policy or procedure for verbal and telephone orders including writing down or entering into computers the orders or test results and confirmation that what has been written and read back is accurate (34).

The third IPSG is to improve the safety of high-alert medications. Another clinical laboratory-related IPSGs are to ensure the correct side, correct procedure and correct patient surgery (IPSG 4) and reduce the risk of health-care associated infections (IPSG 5). The last IPSG is to reduce the risk of patient harm resulting from falls (IPSG 6) (34).

The College of American Pathologists (CAP) Laboratory Accreditation Program is an internationally recognized program helping laboratories to achieve the standards of excellence to positively impact patient care. The program is based on rigorous accreditation standards that are translated into detailed and focused checklist requirements. The questions in the checklist are very clear and evidence of compliance are required.

In July 2011, The CAP Laboratory Accreditation Program released enhanced checklists used in accreditation inspection processes of laboratories to meet the Centers for Medicare and Medicaid Services (CMS) requirements. In January 2012, The CAP issued new edition of the Accreditation Checklists. Neither have there been any content changes, but an additional section has been included in the Laboratory General Checklist to incorporate biorepository industry practices.

The Laboratory General Checklists refer to monitoring of the laboratory patient safety goals for

pre- and post-analytical laboratory processes (34). These goals are as follows:

1. Improve patient and sample identification,
2. Improve the verification and communication of life threatening or life altering information,
3. Improve the identification, communication and correction of errors,
4. Improve coordination of the laboratory patient safety role within healthcare organizations.

Item GEN.20365 deals with that the laboratory has to document these goals related to patient safety (39). Item GEN.20316 requires monitorization of the key indicators of quality. The key indicators are as follows:

1. Patient/specimen identification,
2. Test order accuracy,
3. Stat test turnaround time,
4. Critical value reporting,
5. Customer satisfaction,
6. Specimen acceptability,
7. Corrected results,
8. Surgical pathology/cytology specimen labeling,
9. Blood component wastage,
10. Blood culture contamination.

Out of these indicators, 1st, 2nd, 6th, 8th and 10th indicators are important for pre-analytical processes whereas the 3rd and 4th indicators are important for post-analytical processes. Turnaround time solely covers all three phases of total testing process and may be accepted as an excellent single measure of laboratory performance (34).

Item GEN.20348 deals with the monitorization of pre-analytical processes in the laboratory, whereas item GEN.20364 requires monitorization of post-analytical processes (39). Pre-analytical variables start with the physician's order. The other examples are: accuracy of transmission of physician's orders to the laboratory, specimen transport and preparation, requisition accuracy, quality of phlebotomy services, and specimen acceptability rates (39). In post-analytical phases, variables including the accuracy of data transmission across electronic interfaces, reflex testing and turnaround time from test completion to posting either in printed form or electronic form and interpretation of reports need to be monitorized (39).

There are also other items related to total pre- and post-analytical phases of total testing process. Item GEN.40490 requires the individual collecting a specimen to positively identify the patient prior to specimen collection. Checking at least two different identifiers before collecting the sample need to be confirmed. It is recommended that the patient's identity should be verified by asking the patient to introduce

himself/herself. It is also strictly recommended that the patient's room number should not be used for identification purposes. Item GEN.40491 also emphasizes the uniquely identified samples to minimize the sample mix-ups and mislabelling. Items GEN.40535 and GEN.40540 require quality systems for correcting the problems identified in specimen transport. Items GEN.41320, GEN.41330 and GEN.41340 are related to post-analytical phase and specify that the laboratory need to have procedures for immediate notifications of critical test results and verification by read-back (39).

ISO-15189:2007 Medical Laboratories – Particular requirements for quality and competence

Medical laboratory services are essential to patient care and need to be available to meet the needs of both patients and caregivers. ISO-15189:2007 specifies requirements for quality and competence particular to medical laboratories; it is an internationally recognized standard containing the requirements necessary for diagnostic laboratories to demonstrate their competence to deliver reliable laboratory services. It is based on ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories and ISO 9001 – Quality management systems – Requirements. Below is the historical evaluation and relation of ISO 15189 to ISO/IEC Guide 25 and ISO/IEC 17025.

The history of ISO/IEC Guide 25: General requirements for the competence of testing and calibration laboratories began in 1977 at the International Laboratory Accreditation Conference (ILAC) held in Copenhagen, Denmark. Guide 25 was a document developed to provide minimum requirements to laboratories on both quality management and technical requirements for accurate and proper operation of the laboratory. Until 1990, Guide 25 was revised three times. ILAC has been responsible for developing all three editions of Guide 25. Since ILAC itself does not publish international standards, all these drafts have been turned over to the International Organization of Standardization (ISO) and the International Electrotechnical Commission (IEC) for review, approval and publication as ISO/IEC guides (Process and Product Quality Conference, TAPPI Proceedings, 1996, Survey on the implementation of ISO/IEC Guide 25 by national laboratory accreditation programs. Maureen Breitenberg, U.S. Department of Commerce, 1994). The European version of Guide 25 was European Standard EN 45001:1989 – General Criteria for the Operation of Testing Laboratories.

The first edition of ISO/IEC 17025 in 1999 replaced both ISO/IEC Guide 25 and EN 45001. ISO/IEC 17025 was prepared by the ISO Committee on conformity assessment, called CASCO. It contained all the requirements for testing and calibration laboratories have to meet them in order to show that

they have a management system, they are technically competent and they are releasing technically valid results. The second and latest edition of ISO/IEC 17025 was published in 2005. It has been evaluated that the requirements in ISO/IEC 17025 standard are more mandatory than those in Guide 25. The standard contains: initial requirements, management requirements and technical requirements (International Standard ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories. Second Edition, ISO, Switzerland, 2005).

ISO Technical Committee TC 212 – Clinical laboratory testing and in vitro diagnostic test systems developed ISO 15189 as an international consensus document. The scope of this committee is to standardize and guide in the field of laboratory medicine and in vitro diagnostic systems including the quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance. TC 212 includes 31 participating countries and 22 observing countries (www.iso.org).

It has been evaluated that the existing standard, ISO 17025 – General requirements for the competence of testing and calibration laboratories, had not adequately addressed the structural and operational needs of medical laboratories, although it is an excellent standard for research or industrial laboratories. By this work, harmonized laboratory practice standard has been intended for laboratories around the world.

ISO 15189 adds five more critical criteria on medical laboratories: advising on sample type and testing, interaction with clinical staff, providing evaluations on test results, providing information on sample collection procedures and ethical approach.

Patient safety and ISO 15189: Our experience, some examples

Acibadem Labmed Clinical Laboratories were established in 2002. It provides laboratory services in the fields of clinical chemistry, microbiology, molecular microbiology, hematology, blood banking, coagulation, flow cytometer, immunoassays, immunoblotting, immunofluorescence testing and in advanced analytical fields such as, HPLC, LC-MSMS and MALDI-TOF, for Acibadem Healthcare Group Hospitals and Outpatient Clinics and also other healthcare providers located in Turkey and abroad. The laboratory services are being provided in a set up comprised of a core laboratory and more than 20 satellite laboratories. Acibadem Labmed Clinical Laboratories are the first ISO 15189 accredited clinical laboratory in Turkey (40). The process of certification started in 2004 after being assessed and certified by SGS (Supervise Gözetme Etüd Kontrol Servisleri A.S., Istanbul, Turkey), upon meeting the requirements of ISO 9001: 2000 Quality Management Systems. We were

audited in the scope of accreditation of Acibadem Healthcare Group according to JCI standards in February 2005. We were successfully audited by Deutsche Akkreditierungsstelle Chemie (DACH) in October 20, 2005 and were honored to be the first clinical laboratory awarded the ISO 15189 accreditation standard in Turkey (40). The audits in the first 5 years were completed by DACH. In 2010, the second five-year period was started by audits by TÜRKAK, The Turkish Accreditation Body.

Ensuring the total testing process will secure the patient safety by producing the accurate test results. According to obtained data, up to 60%–70% of all problems in laboratory medicine were attributed to pre-analytical phase (41). But, pre- and post-analytical errors account for up to 93% of total laboratory errors (42).

As previously mentioned, the first JCI-proposed IPGs is about correct identification of the patient sample with at least two identifiers (34). Article 5.4 evaluates the pre-examination procedures in ISO 15189:2007 (43). According to this standard, concerning the clinical pre-analytical phase, the list of available laboratory examinations should be provided as requesting forms or electronic equivalent. The physicians in particular should be offered the selection of correct test/tests, the correct preparation of the patient, identification of the primary sample, the filling of consent forms when applicable, information and instructions provided to patients for their own preparation before primary sample collection.

In our system, there are bi-directional data transfer between hospital information system (HIS) and laboratory information management system (LIMS). Our healthcare group encourages electronic orders and tends to be a paperless organization. For this reason, all physicians have to select test orders in HIS after completing the examination of patient. Demographic data, such as name and surname, protocol number for each patient, birth date and national identification number are the unique identifiers used for each patient. This allows correct selection of test/tests from the correct patient.

According to Standard, procedures for demographic identification of a patient, the unique identification of the patient sample, type and amount of the primary sample and anatomic site of the origin of the sample, primary sample collection with descriptions of the primary sample containers and any necessary additives and labelling of the primary sample are needed.

Our monthly-updated test catalogue provides important information about the name and the code of the test, the primary sample type, the minimum required volume of the sample, the transport conditions of the sample, the methodology applied for the analysis and working and reporting times for the

requested test. In addition, important requirements, such as rejection criteria, stability information and others are also mentioned when applicable.

Registered patient data in HIS are transferred to LIMS and LIMS determines the primary sample containers, the minimum number of containers and allocates a unique 10-digit sample accession number. This sample accession number is valid for the samples to be taken at one party. The LIMS produces labels containing interleaved 2 of 5 or code 128- bar codes where applicable and also three different identifiers for a patient: name and surname, birth date and sample accession number. These bar codes are easily readable by barcode readers and by the analyzers in the laboratory. This allows correct test analysis from the correct patient sample unless there is no mislabelling. The printed labels are stuck on requested amount of containers before sampling. The phlebotomist also checks for the similarity of identifiers and labels each container before sampling to prevent any discordance between sample type and patient identification. While LIMS produces labels, at the same time it gives important information about patient preparation during sampling, important rejection criteria or any important issues on sample transport, if present (44–47).

An important issue in the pre-examination phase is the traceability of the primary sample. In our system, starting from the ordering physician who registers the requested test/tests into the HIS, all steps including the phlebotomist who takes the patient's sample, the staff who brings the samples to the laboratory and the laboratory technician who accepts the samples into the LIMS are registered and easily monitored. The system log contains data including the user name of the staff in LIMS, the date and the time and the action taken.

The transportation of the samples to the laboratory within the time frame suitable for the requested analysis, within the temperature interval to preserve the integrity of the sample and also to ensure the safety for both carriers, general public and the receiving laboratory is necessary, and according to Standard, the laboratory needs to have a document for these issues. We use special bags to carry the samples. These bags have two different parts inside and one part is used for the sample transportation at ambient temperature and the other part is used to carry the samples which need to be refrigerated. This part contains a special section for the cooling pack around which the samples are placed in perpendicular position. The frozen samples are carried separately in a tight container with dry ice to prevent thawing. Each part of the carrying bag contains a data logger to register the temperature changes during the transportation of the samples. Special software is designed for the sending and receiving laboratories to start and stop the data collection, respectively, by registering

the logger into the system. This allows us to trace the frozen and the refrigerated samples to be used for critical analysis.

Once samples are accepted into the laboratory, first the sample container integrity is checked. If there was any broken container or leaked sample or any unlabelled sample, according to »Sample Acceptance and Rejection Criteria«, these samples would be rejected and the sending laboratory would be immediately informed and new samples would be requested. All these steps are registered into LIMS. The preparation of the samples suitable for the requested analysis is carried out according to written procedures. After this preparatory step, the samples are visually checked for the presence of hemolysis, lipemia, icterus, etc., and again according to »Sample Acceptance and Rejection Criteria«, these samples, if rejected, are registered into LIMS and the reason for their rejection is recorded as well.

The analytic or examination phase is the most controlled phase in total testing process. The laboratory should use examination procedures appropriate for analysis. The published procedures in textbooks or in peer-reviewed journals or in any accepted guidelines could be used. In case of using in-house developed procedures, an extensive validation of the procedure is needed and validation studies need to be fully documented. According to ISO 15189 Standard, the laboratory should use only validated procedures suitable for intended analysis. All procedures should be documented and available for any workstation for relevant staff (43). The sub-headings need to be mentioned in the documents. It is also mandatory that selected test procedures should yield satisfactory results before being used for real patient samples for medical decisions.

The validation of quantitative and qualitative methods of analysis are being carried out according to »Method Validation and Measurement Uncertainty Procedure« in our laboratory. Almost full validation procedures are applied for in-house developed methods whereas the verification of the manufacturer-validated methods is carried out. In verification procedure, intra-assay and inter-assay precision studies and accuracy studies are performed. The results are evaluated according to RiliBÄK. RiliBÄK, a set of quality regulations, is actually the Guidelines of the German Federal Medical Council. They provide minimum requirements for quality of the quantitative test results in medical laboratories. Although the RiliBÄK quality requirements are synchronized with ISO 15189 principles, the RiliBÄK also sets tolerable errors or uncertainty recommendations. The RiliBÄK guidelines, following the laboratories, are encouraged to mention the error specifications directly on their control charts (48–50).

For the assurance of quality of examination procedures, the internal quality control systems and

interlaboratory comparison studies or organized by the external quality assessment schemes according to ISO/IEC Guide 43-1 are mandatory. For the internal quality control system, we devised a new test-specific decision limit for accepting or rejecting the runs based on data of within-subject biological variation (51). It is estimated that the value of healthy within-subject biological variations is constant, irrespective of the methodology, the area in which the study has been performed and the number of subjects included in the study. We believe that the control limits based on biological variations are reliable and cost-effective and easily usable in accredited laboratories (51). Our laboratory is subscribed to more than 200 different external quality schemes from **RfB** (Referenzinstitut für Bioanalytik, Bonn, Germany), **Instand e. V.** (Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e. V., Düsseldorf, Germany), **ECAT** (External quality Control of diagnostic Assays and Tests, Leiden, The Netherlands), **CDC** (Centers for Disease Control and Prevention, Atlanta, GA, USA), **ERNDIM** (European Research Network for evaluation and improvement of screening, Diagnosis and treatment of Inherited disorders of Metabolism, Maastricht, The Netherlands), **UKNEQAS** for Blood Transfusion Laboratory Practice (Sheffield, UK), **DEQAS** (Vitamin D External Quality Assessment Scheme, London, UK), **NIST/NIH Vitamin D Metabolites Quality Assurance Program** (National Institutes of Standards and Technology, Gaithersburg, Maryland, USA), CDC's **EQUIP** (Ensuring the Quality of Urinary Iodine Procedures, Centers for Disease Control and Prevention, Atlanta, GA, USA) program, CDC's **LAMP** (Lead and Multi-Element Proficiency, Centers for Disease Control and Prevention, Atlanta, GA, USA) program and **RIQAS** (Antrim, UK). When control criteria are not fulfilled, corrective actions are implemented. Interlaboratory comparison studies are also carried out between the central laboratory and satellite laboratories. When the external quality schemes are not available, the exchange of samples with other accredited laboratories is done.

When the analysis is completed, storage and safe disposal of the samples are required. We keep the respective samples at least one week at 2–8 °C and then 3 weeks at –20 °C. The archive program implemented in LIMS determines the storage duration and localization of each sample in refrigerators and deep freezers.

Laboratory management is responsible for the formatting of reports either in electronic or paper form and shares the responsibility with the requester for ensuring that the reports are received by appropriate individuals within an agreed time interval. The ISO 15189 Standard also implies which parameters need to be included (43). It has been also recommended that the quality of the received primary sample would be included in the report if it was unsuitable

for the analysis or produced any adverse effects on results.

Another important issue for patient safety could be the transfer of critical test results from clinical laboratory to those responsible for patient care. As previously discussed, the second IPSPG recommends development of an approach to improve the effectiveness of communication among caregivers (34). It is clear that the effective communication reduces errors and improves patient safety. The ISO 15189 Standard recommends implementation of procedures for immediate notification of physicians or other clinical staff responsible for patient care, when results are within pre-defined critical intervals (43). In our system, we defined critical values for each analyte. It is documented in the »List of Critical Test Values«. When any test result falls within the critical result interval, the primary caregiver of the patient is immediately informed and the action taken is registered into LIMS. In this way, we easily monitor the time interval between the critical result approval by laboratory physician and phoning time to the relevant caregiver.

According to ISO 15189, turnaround times reflecting the clinical needs should be defined. We register turnaround times for each analyte into our LIMS. After sampling, a patient and caregivers know when to receive complete test results. Periodically turnaround times are reviewed according to feedback from physicians and revised times later announced.

Laboratory staff is important in the continuation of the laboratory performance. For this reason, laboratory management is responsible for job descriptions, including the qualifications to perform specific job functions. The laboratory director must possess adequate knowledge and experience to guide the laboratory. The laboratory management should provide appropriate training for technical staff and assess the competency at regular intervals. We provide both classroom trainings and e-trainings for each technical staff. At the end of each training session, they receive examination questions. If any attendant does not fulfil pre-defined score, he/she will take the training course again. All trainings for each staff are planned on a yearly basis and documented.

Conclusion

In the new millennium, reducing the medical errors and improving the patient safety have become an international concern. We remind you once again of the famous Latin phrase, *primum non nocere*: first, do no harm. It has been experienced that the key of the best solution lies in the quality principles. The ISO 15189 Standard is a highly disciplined approach to implementation and sustaining of changes in clinical laboratories. It applies the quality system requirements to clinical laboratories with a strong focus on responsiveness regarding the needs of patients and

clinicians. Applying the performance improvement strategies focusing on different phases in total testing process will significantly reduce the errors and accordingly will improve the patient safety. In this way, laboratory professionals contribute to improvement of safety and outcomes of care by working in interdisciplinary approach manner. Awareness which is the primary component of patient safety projects and key

factor in ensuring successful implementation should not be ignored.

Conflict of interest statement

The authors stated that there are no conflicts of interest regarding the publication of this article.

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