ABSTRACT: The primary endpoint was to highlight concerns about the current state of improving the quality of services of medical analysis laboratories in Romania, in line with European Union requirements, the implementation of sustainable economic development strategies, such as implementation of the quality management system satisfying the quality requirements, environmental protection, patient’s biosecurity and knowledge management - continuing medical education of the medical laboratory personnel.

1. INTRODUCTION
The purpose of applying quality control programs in a modern medical laboratory is to assess the performance of laboratory and medical techniques used (Laura Sciacovelli, 2004). On the other hand, Anders Kallner (2001) estimates that laboratory accreditation is a successful approach for improving quality management in medical laboratories.

The opinions expressed in the literature according to which criteria applied in evaluation of the medical laboratory performance should be: effectiveness, efficiency, continuity of care, patient safety, the medical staff and patient satisfaction [1].

Implementation of quality management systems in organizations contribute to increasing efficiency and effectiveness [3].

Taking into account this approach, the paper highlights the results of a study conducted in collaboration with the Association for Quality in Laboratory (CALILAB) during 2009-2010 on a sample of 90 laboratories, about the concerns for improving the quality of services provided by medical laboratories in Romania.

The main objective of the study carried out during 2009 - 2010 was to highlight the current status of services to improve the quality of medical analysis laboratories in Romania, in line with European Union requirements, the implementation of sustainable economic development strategy. The main sustainable economic development strategies take into account: implementing quality management system satisfying the quality requirements, environmental protection, patient and employee’s biosecurity and knowledge management - continuing medical education of the medical laboratory personnel.

The research was conducted in the context of the process of improving the quality of services provided by medical laboratories in Romania has been greatly facilitated in the last years, most notably through: the definition of national health programs, adoption of a unitary quality control procedure for such services, and implementation of management systems, of continuous training programs for the staff, providing the possibility of accessing European funding programs.

2. INTERESTS TO IMPROVING THE QUALITY MEDICAL SERVICES IN ROMANIA
Health sector is one of the most dynamic, which has changed dramatically in recent years due to changes recorded in terms of: patient expectations, quality health services, social models, public policies and technological progress.

Because quality has become a measure of performance and health care facilities in Romania, their concerns for implementing a quality management system, compliance with a quality control program and continuous professional training of medical personnel has become increasingly apparent. In the medical laboratory quality control is the base of the quality pyramid (Figure 1).

![Figure 1. Quality pyramid](image-url)
This aspect led to involvement of the health care institutions in implementing a quality management system that meets the requirements defined in standards EN ISO 9001:2008, SR EN ISO 17025 and EN ISO 15189:2007 and the application with more responsibility of the quality control procedure for medical services [5].

Thus, the involvement of medical laboratories in the accreditation process, as an objective measure for quality assurance and improvement process of these services is emphasised by the constant increase in the number of RENAR accredited medical laboratories – RENAR being the national accreditation body in Romania, as shown in the study elaborated by this body, in the period 2008 - 2011 (Figure 2).

Progress in laboratory science is largely the result of contributions from scientists with adequate education and specialization in the field, naming specialists in clinical chemistry and laboratory medicine [2].

Starting from this remark of a specialist in the field, we point out that in recent years in the health system in Romania, especially in the field of medical laboratories, efforts have being made to improve the quality of medical services by developing a training continuous system for the professional staff, along with measures for development of legislation aimed at ensuring the quality of services, implementing a quality management system, endowment of laboratories with performance devices.

3. RESEARCH METHODS USED

To achieve the objective of the research together with the Association for Quality in Laboratories (CALILAB) we conducted a study during 2009-2010 on the basis of a questionnaire, for a representative sample of 90 medical laboratories.

The questionnaire included eight categories of questions relating to:

- compliance with quality requirements by applying reference standards ISO 17025, ISO 15189, ISO 9001;
- motive for engaging medical laboratories into external quality assessment schemes;
- contribution of external evaluation programs of the quality to quality improvement of medical test results;
- respect to biosecurity requirements of the patient and the employee;
- continuing medical education of medical staff from medical laboratories;
- use of continuous improvement techniques, such as - system of suggestions and proposals for improvement;
- existence of a system to assessing staff satisfaction;
- existence of a system of indicators for assessing the quality of services provided by medical laboratories;
- existence of a customer satisfaction rating system.

4. RESEARCH RESULTS

The paper presents the results of the questionnaire data processing on the following questions:

- Do you meet the quality requirements by applying the reference standards ISO 17025, ISO 15189, ISO 9001?
- Which is the reason that your laboratory participate in external quality assessment programs?
- How do you assess the contribution of applying external quality assessment programs to improving the quality of medical test results?
- Do you comply with biosecurity requirements of the patient and your employee?
- Do you participate in continuous improvement / continuing medical education?
- Do you use continuous improvement techniques, such as – a system of suggestions and proposals for improvement?
- Is there a staff satisfaction rating system?
- Is there a system of indicators for evaluating the quality of services provided by medical laboratories?
- Is there a system of evaluation of customer satisfaction?

4.1. The research results regarding compliance with quality requirements by applying the reference standards

All surveyed laboratories responded to this question, observing a growing interest on the application of standards for quality management systems SR EN ISO 9001:2008, SR EN ISO 17025 and / or SR EN ISO 15189:2007 (Figure 3).

Thus, 86.67% of medical laboratories included in the study had a quality management system implemented and the laboratory is accredited by RENAR according to ISO 15189 and 13.33% of the laboratories are in the process of RENAR accreditation.

It was also noted the laboratories concern regarding the evaluation criteria mentioned in the implementing rules of the framework contract within the section "quality of medical services."

Figure 2. Evolution of the number of RENAR accredited medical laboratories, in the period 2008-2011

Figure 3. Research results on the status of compliance with quality requirements by applying the reference standards
4.2. The research results regarding the reason for participation of your laboratory in external quality assessment programs

All laboratories surveyed considered helpful and useful the participation in external quality assessment programs organized by CALILAB.

In addition, all laboratories participating in the study believed that the main reason for their participation in external quality assessment programs is improving of quality of medical test results and consequently the quality of services they provides.

4.3. The research results on assessing the contribution to improving the quality of medical test results by the application of external quality assessment programs

Research has revealed that all laboratories surveyed rated as very important the contribution of external quality assessment programs to improving the quality of medical test results.

4.4. The research results regarding the biosecurity requirements of the patient and employee

With regard to biosecurity requirements for both patient and employee, each medical laboratory is required to comply with legislation in force. Thus, all medical laboratories surveyed responded positive to this question.

4.5. The research on participation in continuing medical training programs

The base for implementation and application of continuous vocational training programs / continuing medical education is represented by the professional organizations, the College of Medical Doctors in Romania, in the case of doctors, and for biologists, chemists and biochemists, the professional organization is the Order of Biochemists, Biologists and Chemists involved in the Health Care System in Romania - OBBCSSR and Order of Nurses and Midwives involved in the Health Care System in Romania.

Specialists who work in medical laboratories in Romania have the right for free practice only after university graduation and post-university studies graduation specific for medical laboratory and annual participation in continuous improvement programs / continuing medical education programs certified and accredited by each professional organization.

Monitoring of continuing medical education of each and every member entitled to free practice within the medical laboratory in Romania is made annually by the professional organization.

Research conducted during 2009-2010 period showed that all medical laboratories surveyed said they participate in continuous improvement programs, observing compliance with the minum number of hours per year of continuing medical education required.

4.6. The research results on the use of continuous improvement techniques, such as – a system of suggestions and proposals for improvement

The research on continuous improvement techniques, such as – a system of suggestions and proposals for improvement showed that 60 laboratories, which corresponds to a rate of 66.67% of the 90 surveyed use different techniques for continuous improvement such as questions directed to patients or questionnaires posted on the website of the laboratory, in which patients are asked to respond to a series of questions about the quality of services provided by the medical laboratory, as well as suggestions and proposals for improvement.

The results of this research are presented in Figure 4.

![Figure 4](image_url)

Figure 4. Research results regarding the use of continuous improvement techniques

4.7. The Research results regarding the existence of a staff satisfaction rating system

Regarding the existence and use of a staff satisfaction rating system, a small percentage - 12.22%, meaning 11 of the medical laboratories surveyed said they are using a system to assess staff satisfaction.

The highest percentage of laboratories, 77 in number, corresponding to a percentage of 85.56% responded that in the laboratory they are working, the management does not use a system to assess employee satisfaction. This is confirmed by the mobility of personnel employed in medical laboratories, personnel who frequently change jobs.

This is due primarily to financial and economic conditions seen during this period, in which the material motivation is low. In this research were also included two representatives of two laboratories that responded they do not know if the laboratory they are working in is using a system to assess staff satisfaction, because they were new employees. The results of this research are presented in Figure 5.

![Figure 5](image_url)

Figure 5. Research results on the existence of a staff satisfaction rating system
4.8. The research results regarding the existence of a system of indicators for evaluating the quality of services provided by the medical laboratories, the existence of a customer satisfaction rating system.

The research on the existence of a system of indicators for evaluating the quality of services provided by medical laboratories - the existence of a customer satisfaction rating system showed that 40 laboratories, which corresponds to a rate of 44.4%, out of the 90 participating in the study identified and use a system of indicators for evaluating the quality of services provided by medical laboratories.

The results of this research are presented in Figure 6.

Figure 6. Research results on the existence of a system of indicators for quality of services provided by medical laboratories

A higher percentage of medical laboratories surveyed, 60 laboratories, which corresponds to a rate of 66.67%, monitor customer satisfaction through direct questions addressed to patients or questionnaires filled in by patients or posted on the website of the laboratory.

5. CONCLUSIONS

Following a questionnaire-based survey conducted during 2009 - 2010 by CALILAB, on a sample of 90 medical analysis laboratories in Romania, the results obtained are:

- the quality of services provided by medical laboratories in Romania has improved after joining the European Union;
- an increased interest and involvement in medical laboratory training programs and learning methods is observed;
- a small percentage - 12.22%, meaning 11 out of the 90 medical laboratories surveyed said they use a system to assess staff satisfaction.

Considering the results from this study, we propose to supplement the measures to improving the quality of services provided by medical laboratories, which currently apply, namely the identification and use of a system for evaluating employee satisfaction.

The research conducted by the Association for Quality in Laboratory-CALILAB, have a pioneering nature in Romania, supplying for the first time information on the evolution of quality health services provided by medical laboratories, based on a multi-criteria evaluation system.

The results of this research may represent a starting point for a better base for decisions on directions for improving the quality of services provided by medical laboratories in Romania.

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