

ORGANIZATIONAL AND ECONOMIC ASPECTS OF CLINICAL AND LABORATORY ACTIVITIES - POSSIBILITIES AND PERSPECTIVES OF OPTIMIZATION

Nikola Sabev

Bulgaria, „Angel Kanchev” Ruse University, Faculty of Public Health and Health Cares
nikola_sabeff@abv.bg

Denitsa Trancheva

Republic of Bulgaria, Town of Ruse, “Kanev” University Multi-Profile Hospital for Active Treatment,
deniza3@abv.bg

Abstract: “Clinical Laboratory” is an independent medical specialty, a dynamic clinical discipline of a scientific and applied nature. Laboratory researches, the results of which are objective indicators of the state of the organism, are of great importance in terms of modern medicine. Laboratory analyses help to achieve, within certain limits, such a result that can be used for the purpose of making the necessary *medical* decisions. “Laboratory Medicine” is a complex specialty, covering different directions: clinical chemistry, laboratory haematology, immunology, immunohematology, biology, drug monitoring and laboratory toxicology. A wide variety of techniques is used for the analysis of biological fluids, the composition and properties of different types of cells, tissues, organs and systems.

According to World Health Organization (WHO) data, in the past 20 years, the rate of morbidity within the population of nosologic units requiring high technologies and accuracy of diagnostic tests has increased. Modern revolution in clinical medicine complicates research methods and, as a result, increases significantly their value and cost.

Laboratory units are widely considered to determine the status of each national healthcare system. Effectiveness of laboratory diagnostic process can be ensured by two key elements – high-tech equipment and professional staff. A need exists for identifying and using internal reserves with a view to the optimization of work volume and structures of laboratory and diagnostic units, being a promising and the most realistic direction in the contemporary socio-economic situation.

The mission of Clinical Laboratory departments is focused both on the provision of fast, adequate and accurate medical-diagnostic assistance, as well as on making effective use of any available material and technical resources and personnel potential. The problem being studied, its importance and the analysis of Clinical Laboratory activity are an essential component of the vision for this activity: high quality of clinical and laboratory results, timely and accurate diagnosis, adequate, timely and effective medical decisions.

Main activities such as management; documentation of researches assigned and carried out; financial and economic aspects related to the valuation of laboratory analyses; tracking cost and available options for their optimization; reasonable time reduction for the production of laboratory analyses; introducing new high-performance technological equipment to improve the quality of laboratory activities and optimize the healing process have been researched and analysed in the Clinical Laboratory of “Kanev” University Multi-Profile Hospital for Active Treatment, Ruse.

Keywords: Clinical Laboratory, cost, analysis, quality

1. INTRODUCTION

Existing global and national experience guides the direction towards the increasing benefit of applying objective laboratory information in solving a wide range of clinical problems. In recent years, the use of laboratory researches has continued to grow. Data suggests that around 20 billion dollars for laboratory diagnostics worldwide is spent annually, providing up to 70% of the totality of objective diagnostic information. P. Wilding's opinion (1999) refers to the understanding of the essential role of laboratory medicine and is justified by the fact that clinical decisions especially in critical situations are largely based on the laboratory data obtained. Leading specialists in the field of healthcare organization point out the need of identifying a benchmark for the rationalization of analytical laboratory activities and diagnostics, improving the organization and studying the degrees of clinical benefit associated with the researches performed. The last years of the 20th century have seen an increase in the resources used in providing

medical aid. Significant financial costs and dissatisfaction with the state of modern healthcare cause serious concern and they are a serious problem affecting the world today. Two main trends give rise to the emergence of the need to develop a methodology for a comprehensive clinical and economic analysis in medicine: 1. Increasing healthcare cost (for the account of the aging population, constant penetration of new and more expensive technologies, as well as the growing expectations of patients) with limited opportunities for funding; 2. Irrational use in terms of scarce resources (for the account of applying medical interference without mandatory indication, as well as ineffective and unsafe technologies). Inefficiencies in the use of available resources are demonstrated both in the large investment projects and in the day-to-day activities of medical and healthcare services: 1. diagnostic procedures are conducted in stationary conditions, even if there is an option to be performed in outpatient conditions; 2. cheap but ineffective medications are prescribed leading to long-term treatment and increasing the incidence of complications, and ultimately raising the cost of treatment; 3. instead of ensuring continuity in the transition to outpatient treatment, hospitalizations become prolonged. Correct choice of strategy in the allocation of scarce resources can only be made on the basis of a thorough analysis of all available alternatives. In the contemporary stage of development of the healthcare systems, much attention is paid to the assessment of the quality of medical aid. According to the recommendations of the Quality Assurance Working Group at the WHO European Regional Office, the criteria used in assessing the quality of medical aid are represented by the following functions: professional performance of technologies referred to the diagnostic-healing process; patient risk; optimal use of resources; patient satisfaction. An efficiency of the diagnostic process in laboratories may be ensured by two key factors – high-tech equipment and professional staff. A need exists for identifying and using the internal reserves in order to optimize the work load and structure of laboratory-diagnostic units, as this appears to be the most promising and realistic direction in the contemporary socio-economic situation.

2. CONTEMPORARY DEVELOPMENT IN CLINICAL LABORATORY

Contemporary Clinical Laboratory is facing many challenges associated with the following management and organizational issues: increasing requirements for the provision of quality laboratory services at the lowest cost, shortened time for conducting laboratory analyzes, requirements for introducing more opportunities to explore the growing number of indicators, increasing the relative share of studies to the patient's bed. Solving these organizational problems and managing successfully the activities at the Clinical Laboratory, requires:

- To train highly qualified staff,
- To better automate the processes at the Clinical Laboratory,
- To build quality laboratory information system in order to create, to store and to transmit such laboratory information,
- To optimize the cost of reagents, consumables and equipment,
- To improve the quality at the Clinical Laboratory

Contemporary scientific literature confirms the thesis that 'Clinical Laboratory' is a specialty of growing significance and value in medicine. 70% of diagnoses are based on laboratory tests. Laboratory medicine, when used optimally, generates knowledge that would orient clinicians and lead to the most accurate results which would serve for proper treatment and monitoring of patients, and this, in turn, is the key to more cost-efficient and quality healthcare. According to many authors, the most important job for a Lab Manager is to ensure the provision of high quality services and a wide range of parameters to be tested in the laboratory which will serve as prevention, diagnosis, treatment and management of health, in particular of medical, activities. Provision of high-quality clinic-laboratory service is also the responsibility of each professional who works at the respective diagnostic structure. According to literature sources, laboratory medicine is based on exact sciences, such as chemistry, physics, biology and medicine. In its contemporary development, the majority of clinical and laboratory procedures are based on the use of physico-chemical and molecular-biological analyzes, that apply optical, immunologic, electrophoretic, chromatographic methods, as well as the "dry" chemistry methods, the technologies of automation of biochemical, immunological and haematological investigations. According to various authors, over the years, efforts have focused on the key issues in automation, standardization and quality control in the Clinical Laboratory. In recent years, there has been rapid development in the methods of Clinical Laboratory diagnostics. This development is determined by the overall trends in healthcare and modernization of technological factors. According to the scientific literature, the strategic guidelines are as follows:

- Improving the methods for clinical and laboratory diagnostics;

- Replacing the manual methods with automated ones, based on the development of computer technologies;
- Transition to objective quantitative research methods;
- Introducing technologies of medications monitoring and laboratory screening programs; integrating laboratory diagnostics with other medical disciplines;
- Improving the knowledge of clinicians in the field of laboratory medicine;
- Using the results of laboratory researches for a growing number of nosological forms as final medical diagnosis, taking into account the constantly emerging medical and technical achievements both within and outside the Clinical Laboratory.

In the pathway "from symptom to diagnosis", it will be required to create and develop rational schemes for an algorithm and complexity of testing a patient.

To achieve a high quality and efficiency of the laboratory process, the Lab Manager has to be responsible, knowledgeable about the Clinical Laboratory discipline, with financial savvy, able to assign tasks and monitor their implementation; to have clear and well-motivated suggestions to help solving the problems. The Lab Manager should strive and make effort that the medical laboratory, managed by him or her, provides modern services, aims at meeting the healthcare needs and optimizes the cares of the patient. The Lab Manager should be able to incorporate all the scientific and medical achievements in his/her practice, to be a role model of his/her subordinates and to demonstrate the value of his/her example in today's competitive environment.

In modern society, the researches and studies and the changes, occurred in economic development, show that Lab Professionals need to be well aware of the principles of sound management of financial resources and the possibility of their return. According to most authors in contemporary literature, 'Return on Investment' is a measure of profitability to assess how effective a capital investment is and it is calculated as a percentage of the 'Return on Capital - Investment'. The higher the Return on Investment, the higher the revenue from the invested resources and, accordingly, the profit. However, by comparing the opinions of different authors, no variable is as simple and clear as it seems. Both in our country and on the global scene, clinical laboratories face different challenges. In order to provide patients with the best care they should be responsible in tax terms and the management team should have highly financial competence and ability. 'Laboratory business' is a complex activity and among the elements, of which it is composed are: staff, financial resources, equipment, goals, ethics, and incentives. No manager has a complete information on each element, and therefore, the majority of decisions have to be taken following a very good judgment. Contemporary literature draws attention to two important factors in order to develop a proper financial management strategy of the Clinical Laboratory: assessment of the inter-laboratory environment and assessment of the changing extra-laboratory environment (199). Assessment of "extra-laboratory environment" factor is very important and covers: Evaluation of the laboratory's management, its place on the market in terms of defining the source of medical services, its role and the opportunities for an adequate response to the requirements of the environment. At the core of this assessment, the laboratory management team is required to assess the responsibility of the sources of financial resources in the laboratory – medical cash plans, health insurance funds, the hospital itself, the cash patients. The Lab Manager should be able to predict the amount of financial resources and factors of extra-laboratory environment that would affect these funds. In the contemporary literature now available, authors support the thesis that, it is the Lab Manager who will be exclusively responsible for the state of the Clinical Laboratory as a whole, its technical equipment, the labor remuneration of staff, the costs and return on resources spent by the laboratory, as well as for any problems related to the continuous increase of the workload, the quality of laboratory services, the avoidance of any further costs for reagents and consumables, associated with unnecessary automated workflow when assessing the 'inter-laboratory environment'. Many authors, in their works, acknowledge that the Lab Manager would not be able to cope without the support, skills and efforts of senior, middle and technical staff in the laboratory managed by him or her.

3. CLINICAL LABORATORY EXPENSES

Clinical Laboratories are typically considered to be a high-cost unit at the hospital. Conducted studies have shown that the majority of clinical laboratories, especially those located in a larger organizational sub-unit (hospital or clinic), have difficulty in obtaining accurate financial data. When reporting all the sources of laboratory revenue from the laboratory services performed and their financial returns, it is clear that the Clinical Laboratory generates significant amount of revenue and, to a great extent, it offsets the costs incurred. This is especially important for the healthcare facility in which the laboratory is located as there would be also units within its structure that do not

make a return but suffer losses. A Clinical Laboratory is facing a variety of financial challenges and the management team should understand the subtleties of these financial components. Costs are divided into several categories:

Variable Costs and Fixed Costs are the two categories of costs that refer to the amount of work performed in the Laboratory. ‘Variable Costs’ are those costs that will vary in proportion to the volume of testing, while ‘Fixed (Constant) Costs’ will not vary with the volume of tests performed. Variable Costs are the costs of reagents and consumables. According to the most of the authors, as the cost of performing laboratory tests remains invariable for a long period of time, it is defined as ‘Constant Cost’. In the literature, ‘Constant Cost’ is the cost of financial resources for payment of the work performed at the Clinical Laboratory. The sum of Fixed Costs and Variable Costs is the ‘Total Cost’ per test. Variable Costs will increase in proportion to the total volume, i.e. an increase in the number of laboratory tests will result in an increase in the variable costs. According to contemporary authors, irrespective of the number of analyzes performed ‘Total Fixed Costs’ will remain invariable, and in the long run, all costs will turn out to be ‘Variable’. It is considered that when the maximum testing volume, which the current fixed costs can handle, is reached, a stepped cost spike will occur in order to push the Fixed Costs to another level. This stepped phenomenon is due to the fact that the costs remain invariable around the bottom and top of the workloads, but nevertheless, at a certain level of workload, the possibility of converting Constant Costs into Variables Costs should not be excluded. According to commonly accepted definitions, at all levels of workload, Total Fixed Costs remain the same. Average unit cost per laboratory product, i.e. for one study, could also be both a ‘Variable Cost’ and ‘Constant Cost’. Costs made per unit product by the laboratory are of greater significance. Cost analysis per laboratory study allows to identify the cost fluctuations per study and hence to determine the laboratory's performance. According to the literature data, the workload affects both Fixed Costs and Variable Costs. Average cost per unit sample also includes Fixed Costs and Variable Costs and is dramatically reduced with the workload. This phenomenon is called ‘Economies of scale’. Economies of scale use the advantage of existing infrastructure of Fixed Costs so as to make the test cost lower by increasing the volume of the total number of researches. The ability to use this advantage is essential to the success of the Clinical Laboratory. Therefore, studies made by various authors show prove that the high laboratory productivity results in saving money and increasing the revenues of the healthcare facility.

Direct Costs and Indirect Costs are another category of the Total Cost. All costs incurred for laboratory tests and traceable to the reported results are classified as ‘Direct Costs’. Direct Costs will be the costs for reagents and consumables, staff salaries. To determine ‘Indirect Costs’ the most common is the definition that the costs of equipment, depreciation of buildings and technical equipment, health insurance, household utilities (electricity, water, lighting, heating, etc.) are attributed to the so-called ‘Indirect Costs’. These costs are not traceable to the test itself but are associated with the making of such test. Some authors also include in this category: laboratory information systems, licenses, training, materials for testing the suitability. Indirect Costs are:

Indirect costs, sector-specific– these costs include elements that cannot be easily identified by a specific test but are specific to the sector in which the research will be conducted. These elements include the payment to a manager, quality control, service contracts, supplies, costs, rental price.

Indirect costs, laboratory-specific – these costs include elements that contribute to the overall functioning of the laboratory: laboratory information systems, utilities, maintenance of the building stock.

Indirect costs, institutional-corporate – according to the statements of various authors, these costs are related to the operation of various facilities, equipment, fiscal and other aspects of institutional support, such as the costs allocated to the hospital as a whole – administration, support staff, etc. These Indirect hospital's costs are neither under the control of the laboratory, nor related to the amount of laboratory tests. To sum up the Total Costs Indirect Costs are added to Direct Costs. According to commonly accepted statements of various authors in modern literature, the Lab Manager should collaborate closely with the Hospital's Financial Department in order to accurately calculate the Indirect Costs and refer these to the Direct Costs associated with the making of laboratory tests. The Lab Manager himself/herself is not actively involved in the calculation of Indirect Costs that refer to the laboratory, as these are specified by the Financial Department. It is assumed that the main method of calculating the costs comes to: following the procedure of calculating the Direct Costs (labour, consumables, reagents), Indirect Costs specified, by the Financial-Accounting Department of the healthcare facility, are added thereto. Studies by different authors have shown that a relationship exists between Direct Costs and Indirect Costs on the one hand and between Variable Costs and Constant Costs - on the other hand, i.e., Direct Costs coincide with Variable Costs and Indirect Costs with Constant Costs.

4. CLINICAL LABORATORY REVENUE

Many authors consider the Clinical Laboratory to be a 'cost center', therefore, the exact revenue from clinical tests can hardly be calculated, but besides costs, the Laboratory generates also a lot of revenue for the healthcare facility. On the global scene, reimbursement ratios are different for patients with different types of insurance coverage, while laboratory services are sometimes part of a net payment system, which may make it difficult to get an accurate picture of the revenue from laboratory services. In healthcare sector, gross income from laboratory services consists of all prices and fees at the site's price list, both for stationary and for outpatient treatment. It is assumed that the net revenue received from the hospital from patients will be absolutely different from gross revenue. Stationary procedures and Outpatient procedures are reimbursed in a different way and it is important to make a distinction between these two. The amounts of cash patients who have chosen the respective laboratory where to do the necessary researches, at the request or by referral of the treating physician, are also included to the revenue from laboratory services. These cash patients are 'Outpatient' and their payments will not be made at a pre-determined rate of the health insurance fund/ company, but at the hospital's price list and at the laboratory's price list, respectively, of paid medical services.

5. CLINICAL LABORATORY BUDGET

To the efficient and sound financial management as well as to allow the return on resources, it is necessary to draft a laboratory budget, i.e. detailed and comprehensive financial plan of the laboratory, based on the expected amount of laboratory researches, the equipment required for their performance, the tasks assigned to the Lab Manager and staff. Although complex, this is the main process of each healthcare facility, including the Clinical Laboratory. In line with the above, the budget is an essential tool for maintaining an efficient and financially responsible organization, a task that the Lab Manager should take over – careful monitoring of funding, identifying and assessing areas for improvement. Most contemporary clinical laboratories have both Operating Budget and Capital Budget. Operating Budget consists of current revenues and expenses. Capital Budget includes funds for the purchase of apparatus or equipment, funds for maintenance and restoration. Capital equipment loses its value over time in the form of depreciation. It can be acquired in various ways, including – buying, leasing or leasing against reagents and consumables. The decision to choose the most appropriate approach is based on the following: annual budgetary constraints, interest rates, expected technology change, other considerations. The choice of the acquisition method not only affects the budget of the laboratory, but also dictates how it will be spent. A precise budgeting is required to purchase apparatus, laboratory facilities, to finance various investment projects. This process depends on the relationship between the Operating Budget and Capital Budget, and the Lab Manager's decisions. Lab Manager's decisions on the Capital Budget are also important from the point of view of the prospects for development of the Clinical Laboratory. In the laboratory budgeting, it is believed that it is important to take into account the following points: 1. clear goals for which the funds allocated to the laboratory will be spent; 2. degree of importance of these goals; 3. estimated revenue.

Making a good budget lies in the objectives of the laboratory and, accordingly, the health care facility on which territory it is located. Capital Budget claims represent significant investments. The laboratory budget is also dependent on the previous budgets as well as on their implementation. The Lab Manager's intention for new investments, new laboratory tests, new apparatus and modern equipment also matters, through the prism of the cost of the opportunity, the amount of investment and the expected return. Only when a precise answer to all these questions is given, then the manger and lab specialists will be able to draft a realistic budget.

6. CONCLUSION

Each Manager of a Clinical Laboratory should know and control the costs well, although the annual cost of laboratory reagents and consumables represents a small fraction of the total healthcare costs in the respective healthcare facility. Each Clinical Laboratory should have a well-established resource management and control system and choose the most cost-efficient approach to reduce the costs and increase the revenue. The finances controlling system of a laboratory is complex and no unambiguous and simple answers about the optimal cost reduction option could be given. A good management approach requires a combination of different approaches, as the implementation of each of them determines the significant investment in terms of time and effort by the whole laboratory team. Lab professionals should work in close cooperation with the clinicians in order to monitor and

correct any excessive use and misuse of laboratory testing, aiming to reduce the costs. When making a laboratory budget, it is necessary to go through the following very important preparatory stages:

- To assess the workload at the Clinical Laboratory;
- To calculate the costs required for the amount of laboratory activities;
- To calculate the total costs and rate of return on funds.

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