

Clinical and Economic Analysis and its Role in Healthcare Quality Management

¹G. Arustamyan, ¹E. Yegorov, ¹S. Lipsky, ²E. Razumovskaya and ²L. Gimranova

¹Lomonosov Moscow State University, 1-46 Leninskie Gory, Moscow, 119991, Russian Federation

²Kazan Federal University, 18 Kremlevskaya, Kazan, 420008, Russian Federation

Abstract: The increasing costs of public health and a growing demand for high-level medicine require the development of efficient economic methods of evaluation and quality management. This article proves that the Clinical and Economic Analysis (C&EA) is the most efficient in terms of cost-benefits. Furthermore, the article defines the role of C&EA by using the principles of evidence-based medicine. A comparative study of the Russian and European experience of C&EA is carried out, with an emphasis on Russian healthcare problems. The article concludes that a modernized C&EA methodology should be introduced, taking into account the European – particularly the French – model of healthcare.

Key words: Clinical and Economic Analysis • Healthcare quality • Efficiency evaluation methods • Quality management • Medical and economic standards • Comparative efficiency.

INTRODUCTION

The last third of the twentieth century was marked by a large-scale shift in the management of national economies, especially the social sector. The emergence of new ways of capital production, the acceleration of innovative processes and the increased accumulation of intangible capital changed the investment policy development vector in the most crucial way [1]. The new targets for the investment include the concentration of human and material resources in the sphere of the human capital reproduction, creating the basis for the development of advanced economy and knowledge society. Therefore the most active of today's national economies are developing based on the priorities of investing in human capital, accelerating innovative processes and forming a new structure of the reproducible wealth.

All this generated a need to solve a number of social problems, encouraging many national governments to review their views on public healthcare management, the public healthcare being a core strategic element for the formation and reproduction of national health capital and fostering public health.

It is common knowledge that individual health, as well as the health of the public is a factor, stimulating the growth of social and economic potential of a nation. In view of the above the issue of improving the control over the quality of medical care undoubtedly becomes one of the top strategic national priorities. The new federal law “On the Fundamentals of Public Healthcare” adopted in 2011 defines the quality of medical care as “the aggregate of characteristics that reflect the timeliness of medical care, the correctness of methods of prevention, diagnostics, treatment and rehabilitation chosen in the course of medical care and the degree of implementation of the planned result” [3].

Despite the reforms and the modernization of the national public healthcare, the issue of providing high quality medical care to the Russian public is still pending. According to foreign research data the provision of high quality medical care results in additional 5 years of living.

The main difficulty lies in a fragmentary nature of the implemented reforms. It is essential to understand that the mission of the state here is mainly to provide the conditions necessary to achieve high quality and efficient medical care outcomes, taking into account the possibilities to increase state financing of the public

healthcare. This necessitates the use of economic methods of regulation and improvement of the Quality of Medical Care (QMC).

Clinical and Economic Analysis in Public Healthcare Management: Background, Key Concepts and Methods:

The discussion of the possibility to use economic regulation in public healthcare is more than half a century old. Nonetheless, no systematic economic analysis was used in this sphere till ninety fifties. It is in the fifties that the Americans C. Arrow and M. Friedman conducted a research that proved a possibility to practically apply economic methods in public healthcare. On one hand economic analysis became an information tool used in decision-making partaking to financing and resource allocation, while on the other hand the analysis contributed to the accelerated implementation of social reforms.

A continuous growth of prices for medical services and medications during the sixties and the seventies made the decision-makers develop the price control mechanism, thus initiating discussions about cutting the medical care costs and making the researches define the concept of medical care's economic efficiency.

The imperative need to develop a systematic analysis of economic advantages of different medical technologies has been formed as a result of the establishment of state-controlled mechanisms in the sphere of public healthcare. This led to the development of cost-benefits, cost-effectiveness and cost-utility economic analysis models in the period from mid-fifties to the seventies.

The active development of clinical epidemiology in parallel with the enhancement of tools to assess the efficiency and safety of medical intervention contributed to the emergence and practical implementation of the concept of evidence-based medicine [6]. The use of evidence-based medicine allows for the application of unbiased criteria of medical efficiency in economic evaluation of alternatives intended to improve the quality of medical services.

The key provisions of the evidence-based medicine formed the basis for the practical use of C&EA tools in daily operations of the medical institutions. Today C&EA is an essential component in the system of medical care quality management, as its main task is to rationalize the choice of medical technologies on the basis of the integral evaluation of their clinical and economic efficiency.

Nevertheless, the variety of alternate terms used in Russian and foreign literature makes the development of integrated approaches to the performance of a medical-economic research no easy task. The main problem lies in shifting the emphasis of such research to the field of drug supplies, which is often taken for pharmacoeconomics. Still, the methods of pharmacoeconomic analysis can and are used actually to evaluate all types of medical intervention.

In essence the Clinical and Economic analysis is a comparative analysis of two or more medical technologies (pertaining to diagnostics, prevention, treatment and rehabilitation) on the basis of a comprehensive integrated accounting of the medical intervention results and associated costs. The main goal of C&EA is to ensure the achievement of best results in conditions of insufficient financing, i.e. the rational spending of resources, while maintaining the high quality of medical services.

The development of C&EA methods and the implementation of C&EA results in medical practice became a milestone in the process of healthcare quality reorganization and public healthcare management in a number of foreign countries. The C&EA methods became most popular in the developed countries, to be used as the main tool to ensure the balance between the provision of high quality medical care and the insufficient financing available for the public healthcare systems.

The Clinical and Economic analysis is performed on the basis of two criteria any C&EA should meet, namely the following:

- The comparative design, i.e. an analysis of at least two methods of treatment.
- The cost and result analysis (of clinical efficiency and safety) of each methods of treatment analyzed.

Generally the C&EA methods fall into basic and auxiliary. The basic methods are used to calculate the cost/results ratio:

The Cost-Effectiveness Analysis (CEA): According to Professor Shamshurina this method is particularly useful for medical establishments in conditions of insufficient financing, meaning primarily the Russian medical organizations in the process of modernization of regional public healthcare systems.

In order to make a choice in favor of one of the treatment technology, it is necessary to analyze the cost effectiveness increment, known as the incremental approach.

The Cost-Minimization Analysis (CMA): This C&EA method implies a comparison of two or more treatment options (technologies), which are identical in terms of results, but varying in cost.

This method is not used nationwide due to impossibility to publicly reconcile the variety of medical and economic parameters. The method can be used regionally to develop different industry-specific programs, such as in-patient department substitution technologies programs for Russian regions.

The Cost-Utility Analysis (CUA): This method is a variation of the cost-effectiveness analysis, implying the assessment of results in view of their utility for individuals and for the public in general. This method is used when the effectiveness can't be evaluated in monetary terms. The QALY (Quality-Adjusted Life Years) index is often used to calculate the utility ratio.

The main drawback of this method is inaccuracy of utility indexes assessment which considerably limits its field of application.

The Cost-benefit Analysis: As different from the above-listed methods of Clinical and Economic analysis, the cost-benefit analysis is used to evaluate costs and effectiveness (benefit, or utility) in monetary terms exclusively. Being the simplest version of the economic evaluation, this method is most suitable for comparing costs and benefits at macro level. This can be exemplified by the organization of prevention programs where the cost of vaccination results in savings relative the cost of treatment of infectious diseases. This method is to be used for the economic evaluation of the development of programs intended to prevent the most widespread chronic non-infectious diseases in Russia at different levels.

The auxiliary methods to assess the effectiveness of public healthcare include the following:

The Cost of Illness Analysis (COI): This method implies the accounting of all costs related to different stages of treatment, as well as the cost of the entire treatment. The cost of illness analysis is used mainly to develop a system of standards for diagnostically-integrated groups which are essential for the development of up-to-date medical and economic standards in Russian public healthcare system.

The ABC-analysis is a method of ranging different medical technologies per the cost of each of them in the overall cost structure, starting from the most costly ones

and ending with the least costly, subdividing them into three groups: group A is made of technologies the cost of which amounts to 80% of the total costs; group B is made of technologies the cost of which amounts to 15% of the total costs; group C is made of technologies the cost of which amounts to 5% of the total costs.

The ABC-analysis results form a basis for the development of programs and corrective actions pertaining to the improvement of the quality of medical care available at the Russian medical establishments after the internal and external control and inspection of the medical care quality and the implementation of advanced training programs for medical employees, said programs broken down into priority illness groups, which is the current priority for the Russian public healthcare system.

The efficiency of the ABC-analysis can be improved by combining it with VEN-analysis. The VEN-analysis allows for the assessment of rationality of the costs related to medical technologies. To perform the assessment, all medical technologies are subdivided into three categories, meaning Vital, Essential and Non-essential.

The ABC/VEN-analysis and its results provide a clear nationwide picture of the efficiency of implementation of the state programs. Determining the most costly medical technologies (category A in ABC-analysis) which at the same time are not efficient enough (category N in VEN-analysis) will facilitate the development of scientific recommendations on the use or non-use of such technologies in medical practice. In Russia this is important for the sector of paid medical services and in cases of costly surgery if any alternatives are available.

According to Order No 494 of the Russian Ministry of Public Health, dated 22.10.2003 the clinical pharmacists are required to perform ABC and VEN analyses of medicines on a regular basis, but it is still too early to say that these methods have become a control tool used in daily medical practice and domestically produced non-expensive, but often ineffective medicines are the best proof of this.

Modeling is a method of process or phenomena study based on the implementation of a formalized model to assess and calculate the medical technologies application dynamics. There are different types of modeling, including computer-based, mathematical, analytical, statistical, imitational, etc. Keeping in mind the developments of electronic communications in Russian public healthcare system, the implementation of computer technologies and computer modeling in medical practices becomes all the more promising.

Broken down by the forms of representation (design), the models most frequently used in C&EA fall into Markov's Model and the Decision Tree Model.

The Decision Tree is a diagram representing all possible outcomes of a specific situation. This model is usually used to describe the treatment of an acute disease. The use of the model implies the availability of a number of alternative options with different outcomes.

The Markov's Model allows for a description of a number of discrete conditions and transient states within a period of time. These models are often used in pharmacoeconomics due to the greater flexibility, compared to the decision tree models.

Modeling during pharmacoeconomic studies proves efficient in cases where there is a lack of clinical data to perform a full-scale comparative analysis.

A sensitivity analysis is a method used to assess the impact produced by different factors (such as the dynamics of the treatment side-effects, the fluctuations in the price of drugs, etc.) on the end result of a medical process (recovery/aggravation of a patient's condition).

A preference of any C&EA methods depends on a number of factors, namely the purpose of the analysis, the availability of data and the medical case (disease) under examination. But the thing that really matters, especially in Russia, is not so much the performance of C&EA, but the implementation of C&EA ideology in medical practice, meaning the awareness by all members of the medical community, the public healthcare system's management bodies, the organizations responsible for the compulsory medical insurance and the R&D institutes of the Russian Academy of Medical Sciences of the importance of C&EA for the efficient modernization and innovative development of the system of medical establishments and for the improvement of the quality of medical care available for the public.

A rational combination of different types of C&EA will contribute to the effectiveness of medical care at all organizational levels of the public healthcare system.

The Use of C&EA in the Russian Public Healthcare System: In the end of the seventies and in the eighties of the last century a number of surveys, assessing social and economic efficiency of state medical care programs appeared in the Soviet medical literature. Based on an "isolated" approach to the issue of efficiency the results of those surveys made the understanding of the integrated nature of the issue all the more complicated [9].

The end of the nineties was marked by the growing interest for the search and development of economic regulators of the public healthcare system. It became evident that the growth of financing of the medical service and the improvement of its quality are not interrelated directly. Therefore a necessity arose to implement a comprehensive medical and economic assessment of effectiveness, resulting in the establishment of an industry standard known as "Clinical and Economic Research. General Provisions (OST 91500.14.0001-2002). In accordance with paragraph 2, this industry standard is a compendium of rules for conducting Clinical and Economic research and for documenting and representing its results. By adhering to the rules specified in the OST, a medical professional or a medical establishment guarantees the reliability and safety of research results, providing for the protection of rights and health of the individuals involved. Besides, the standard is open to corrections in conditions of dynamically changing and improving methods of assessment of economic efficiency.

Economically developed countries C&EA methods used in combination with evidence-based medicine form a basis for making decisions as to the use of medical technologies in practice, followed by integrating such decisions into national standards.

Foreign C&EA Practices (As Exemplified by France):

The French practices of using economic regulators in medical care quality management are worth a closer look. The French system of public healthcare is based on a budgetary-insurance model. The key factor that ensures the efficiency of the French public healthcare model is the high quality of medical care, evidenced by high satisfaction of the French society with the organization and functioning of the national public healthcare system. According to Eurobarometer Research Center 98% of the French population is satisfied with the quality of medical care in the country, having no intention to use medical services in any other country. The satisfaction index for EU-15 and EU-27 countries varies from 89 to 83 percent.

The successful use of C&EA tools is demonstrated by the French model of organization of the medical care quality management. In 2008 the French Supreme Commission for Public Healthcare launched a program called Le Projet HAS 2009-2011, with the priority to improve the medical and economic analysis of activities performed by medical professionals in medical establishments. Pursuant to the law adopted in 2008, the

Commission for Public Healthcare is authorized to assess the quality of medical care from the point of view of its efficiency and the prioritization of diagnostic and therapeutic services provided. These issues fall within the competence of two bodies, meaning the Commission for Economic Evaluation of Public Healthcare (Commission évaluation économique et de santé publique (CEESP)) and the Service for Medical and Economic Evaluation of Public Healthcare (Le service Evaluation médico-économique et santé publique (SEMESP)).

The C&EA used in France is based on 3 principles, meaning independence and fairness; accuracy and reliability of research data; interdisciplinary approach and transversal nature.

The mission of the Commission for the Evaluation of the Public Healthcare is to organize and perform Clinical and Economic analyses that consist of 3 stages:

- A comparative analysis of two or more types of medical interventions (or medicines) used for a particular disease. The analysis is performed in order to choose the most efficient and least expensive treatment.
- A cost-utility analysis, involving the comparison of economic efficiency and inherent risks (suitability of a treatment for a patient, the absence of complications, etc.).
- A full-scale Clinical and Economic analysis which takes into account the medical effectiveness and the cost of a particular treatment, including organizational and ethical aspects of the intervention.

The C&EA final results are taken into account in developing guidelines for the organization of medical practices (such as the strategies for the identification and prevention of HIV infections), or during re-evaluation of drug therapy alternatives.

CONCLUSION

The context of the current reforms of the system of public healthcare in Russia makes the implementation of C&EA methods really urgent. In the opinion of the leading national and foreign experts the C&EA is a fundamental element for the development of standards and a system of medical service quality indicators. According to the national and international practice, the prescription of medicines without taking into account the requirements of the standards often leads to inefficient financing.

During the development of a staged plan for the transition to the new principles of organization of a system of improvement of medical care quality, the public healthcare system officials should take into account the foreign experience (French, in particular) in the formation of a unified national policy on medical care quality management. The formation of an independent body responsible for the healthcare quality management and a mechanism for the accreditation of medical establishments will facilitate the following: the establishment of the required C&EA standards to ensure high quality of the latter; the formation of mandatory requirements for the representation of C&EA results to state bodies responsible for decision-making in price policy and the reimbursement of costs related to the provision of medical care.

In the opinion of David M. Eddy, the professor of the Stanford University, the efficient policy in the sphere of public healthcare should be based on recognizing the fact that a transfer should be made from the principle “to do for a patient everything that does him/her good” to the principle “to do for a patient something that will be useful for him/her and a group of patients, while not harming the others”.

To solve the problems of the quality of the national public healthcare system, we need systematic efforts and periodic control over the achievement of targets. It is necessary to balance the quality and economic efficiency of medical care, which is possible using a multi-disciplinary approach.

REFERENCES

1. Van Der Meer, J., J. Van Den Bos and J. Mackenbach, 1996. Socioeconomic differences in utilization of health services in a Dutch population: the contribution of health status. *Health Policy*, pp: 1-18, 37.
2. Safiullin, L.N., G.N. Ismagilova, N.Z. Safiullin and N.G. Bagautdinova, 2012. The development of welfare theory in conditions of changes in the quality of goods and services. *World Applied Sciences Journal*, 18(Special Issue of Economics): 144-149.
3. Bagautdinova, N.G., I.V. Goncharova, E.Y. Shurkina, A.V. Sarkin, B.A. Averyanov and A.A. Svirina, 2013. Entrepreneurial development in a corrupted environment. *Procedia Economic and Finance*, 5: 73-82.
4. Shah, H.M. and K.C. Chung, 2013. Archie Cochrane and his vision for evidence-based medicine. *Date Views* 21.04.2013 www.ncbi.nlm.nih.gov/.

5. Shpigel, A., 2004. Clinical and economic analysis and the development of the formulary system based on evidentiary medicine: enhancement of the antihomotoxic pharmacotherapy. *Journal of Biological Medicine*. 1: 3-4.
6. Order of the Ministry of Health of the Russian Federation dated 22.10.2003 #494 «On the improvement of the medical practice of clinical pharmacologists» Date Views 22.04.2013 www.lawru.info/legal2/se14/pravo14864/index.htm.
7. Chevreul, K., I. Durand-Zaleski, S. Bahrami and C. Hernández-Queved, 2010. Health care systems in transition: France, 12(6).
8. Novenkova, A.Z., N.V. Kalenskaya and I.R. Gafurov, 2013. Marketing of Educational Services: Research on Service Providers Satisfaction. *Procedia Economic and Finance*, 5: 667-676.
9. Safiullin, L.N., G.N. Ismagilova, D.Kh. Gallyamova and N.Z. Safiullin, 2013. Consumer benefit in the competitive market. *Procedia Economic and finance*. 5: 667-676.
10. Fantino, B. and G. Ropert, 2008. Le système de santé en France. Diagnostic et propositions. P.: Hors Collection.
11. Safiullin, M.R., L.A. Elstin and A.I. Shakirova, 2012. Evaluation of business and economic activity as a short-term forecasting tool. *Herald of the Russian Academy of Sciences* 82 (4): 290-294.
12. Les Rencontres HAS 2010. 2 & 3 décembre 2010. Cité des Sciences et de l'Industrie, Paris-La Villette. Date Views 23.04.2013 www.has-sante.fr.
13. Larionova, N.I. and Yu.A. Varlamova, 2013. The Trends of Household Economic Behavior in International Comparison. *Procedia Economic and Finance*. 5: 737-746.
14. Eddy, D., 1990-1992. The Clinical Decision Making: From Theory to Practice. *JAMA*. 120: 263–268.