ESTIMATING QALYS IN THE WESTERN REGION OF ROMANIA – THE CASE WITH INTERVENTION

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***Abstract**: Currently, we are in the process of experimenting a diversification and refinement of the consumer's expectations, as well as a growing demand for innovative, quality products and customized services, exacerbated by rapid technological change affecting both them and the producers. It is also the case of health services that, with Romania's accession to the EU, must align to the European requirements. In the context of limited public resources and growing healthcare needs, socio-economic criteria are necessary for substantiating allocation decisions. With the continuous increase in costs of medical interventions but also the expansion of the range of treatment options available, there is a need to develop and use a range of tools to help establish treatment adopted in the context of justifying the benefits resulting from its implementation. In health, the greatest difficulty for the documentation of investment projects is the main overall effect measurement and evaluation - improving quality of life. Although treated in the literature in terms of specialized clinical trials, there is not currently a methodology to address the economic evaluation of investment projects in health. In this sense, our study's objective is to develop and test a framework to estimate the most appropriate indicator that assesses improvements in quality of life due to healthcare investment projects. We have started with an extensive literature review that allowed us to identify the most recommended indicator in this sense - quality adjusted life years (QALYs) and also to develop and test a conceptual framework. We then realized a survey on 131 medical professionals form the Western Region of Romania, for the two main medical causes of decease, and based on the information collected we calculated the QALYs following a medical intervention. The values obtained reflect the impact of healthcare interventions in terms of quality of life improvements and have a high informational content being useful for those involved in policy making and building institutional capacity in terms of public resources allocation.*

***Keywords**: cost-benefit analysis, economic analysis, public healthcare, quality adjusted life year, quality of life.*

***JEL classification:** D61, H43, I15, I18, I31, J17, O22.*

1. Introduction

The addressed issues arise from the current situational context in terms of funding needs of the national public service sectors (especially health sector) due to limited public resources and allocation decisions in the absence of clear and socio – economic grounded criteria.

Romania's accession to the European Union (EU) in 2007 has rendered health and health services offered to the member states of the EU to become a frame of reference for Romanian citizens. Currently, the Romanian health system responds

inefficiently to the major health problems of the population, the financing of the health system being characterized by an inefficient use of resources.
A key issue in addition to underfunding is the arbitrary use of resources, the inequitable allocation between different regions, types of health services and even between different health institutions. Since new treatments and interventions are rarely more effective and less expensive than previous approaches, developing tools to guide decision making on health resource allocation process has become imperative in this regard.
In the context of healthcare valuation, specific methodologies have been developed, the most appropriate being the cost - benefit analysis (CBA). Cost-benefit analysis method is seen in the literature as a method of economic evaluation of social impacts of investment projects (especially those in the public domain) in areas such as health, education, environment, industry, transport, tourism and agriculture. In health, the greatest difficulty for the documentation of investment projects is the main overall effect measurement and evaluation - improving quality of life. Although treated in the literature in terms of specialized clinical trials, there is not currently a methodology to address the economic evaluation of investment projects in health. In this sense, our study's objective is to develop and test a framework to estimate the most appropriate indicator that assesses improvements in quality of life due to healthcare investment projects.
In order to fulfill the paper's objective, we have started with an extensive literature review, approaching the topics of healthcare economics, cost benefit analysis and quality of life and their study in the specific literature which allowed us to develop and test a conceptual framework.
Even though the originality of our research does not rely on the method applied (questionnaire survey), our results and conclusions have a high informational content and can be useful for those involved in policy making and public resource allocation decision makers.

2. Literature review. Theoretical framework

The scientific concerns on the issue of cost-benefit analysis and its implications on the decision to fund a social project with environmental impact can be found in the literature since the early nineteenth century, yet it still is the subject of a continuous research due to uncertainties and difficulties identified in the background of the methodology especially in the case of healthcare interventions.
Thus, the research's starting point is health economics, a field of economics that studies what health is and what is its value (Evans and Lipp, 2009).
Recent research in health economics are focused on studying the opportunity of the state's intervention in the health sector by (Shiell et al., 2002, Buxton et al., 2004, Cyril and Nason, 2009):

- Ensuring the volume of medical services for which the effectiveness is demonstrated by clinical records and by improving the health safety of patients (micro-level perspective);
- Ensuring the volume of medical services at the lowest cost per unit of effect, recognized as effective in terms of technical equipment and in terms of the existence of medical staff;

- Providing resources according to actual healthcare needs, leading to the realization of the best value in health insurance by allocating those resources on the basis of effectiveness and medical priority.

Research interest in the health economy soared despite previous theories that the health resources should not be limited because in the future available resources will be sufficient to meet health care needs (Fuchs, 1986). This guidance is based on public resource allocation issues as public bodies are operating in both restrictive constraints of public resources and what is socially acceptable and economically feasible.

From this point of view, the cost - benefit analysis method provides information to substantiate the allocation of resources in order to maximize the health of the population (Borghi, 2008).

Recently, the research efforts have focused on this area, being driven by the possibility for public bodies to access national European structural funds to develop public services, being as such imposed the development of cost-benefit analysis (whose binding is derived from official documentation required in this case) starting from a well-established theoretical basis.

The need for health economic evaluation is outlined also by economic consequences of poor health status since health contributes to social welfare as follows: individuals prefer health status as high (thus health directly affects utility); consumption of goods and services is partly influenced by health (corresponding marginal utility of consumption is partly a function of health status); in lack of a high health status, other economic objectives - such as revenue growth to ensure access to goods and market services - may be compromised.

These observations underline the ways in which health problems can influence in a negative manner choices and preferences of households, businesses and governments aiming to maximize welfare.

In the public sector, and thus public health sector, cost-benefit analysis aims to appreciate the impact of governmental activity on the welfare of society in general and individuals and groups, in particular, taking into account ethics and efficiency issues in evaluating any project (Robinson, 1993).

In the public sector, public choice is oriented towards the interests of the majority and thus it affects the economic efficiency of human activity. In order to improve the economic performance of a society, public interventions are required.

But often these actions can cause negative socio - economic effects, suggesting the need to substantiation decision making process by undertaking a cost - benefit analysis.

The interest of the research results from the large number of papers published in the literature and from the international organizations' surveys that propose the determination of the impact a cost-benefit analysis has on the decision to implement a project regardless of the target (either public or private).

Thereby, from the relevant international and national studies, we have identified a set of guidelines and recommendations for developing CBA which although contain sector-specific elements required to be applied, follow the same methodology regardless of the issuing body (table 1).

Table 1: **Guidelines for CBA**

Author(s)	Guideline
International CBA guidelines	
Department of Health, England, 2006	**Cost Benefit analysis of health impact assessment - final report**
Department of Finance and Administration, Australia, 2006	**Handbook of Cost Benefit Analysis**
Treasury Board, Canada, 2007	**Canadian Cost-Benefit Analysis Guide: Regulatory Proposals**
European Commission, 2008	Guide to Cost - Benefit Analysis of Investment Projects
Department of the Army, 2011	Cost - Benefit Analysis Guide
National CBA guidelines	
North-East Regional Development Agency, 2004	Guidelines in elaborating a cost-benefit analysis for projects with European funding
Ministry of Finances, 2008	The National Cost - Benefit Analysis Guide

For healthcare interventions, currently there is no common understanding regarding the evaluation of the most important impact or benefit of these projects – citizens' quality of life. Measuring quality of life and survival not only allows on the one hand that patients, physicians and policy makers choose between curative intent treatment options without mitigating side effects or alleviating symptoms without healing surplus worth in life expectancy, and on the other hand, to choose between two treatments with similar survival benefits but with different side effects.
However, numerous studies and researches identify as a quality of life measurement indicator – quality adjusted life years (QALYs).
Defined as a summary measure of health outcome for economic evaluation, which incorporates the impact on both the quantity and quality of life (Whitehead and Shehzad, 2010), the concept was first used by Zeckhauser and Shepard (1976) in the context of public policy evaluation topics and developed by Klarman et al. (1968) through an assessment of the effectiveness of dialysis study. It was Pliskin et al. (1980) that defined the term in the sense discussed today, therefore helping to demonstrate the usefulness of a medical intervention.
The paper's goal is therefore to propose a methodology to estimate the quality of life indicator identified – quality adjusted life year (QALY).

3. Research methodology

3.1. Research problem and hypothesis

The use of QALY in the economic analysis of health investment projects suppose an answer to the following research question: What is the number of QALYs gained for each medical specialty through health interventions?
It should be noted that there is no common opinion in the national but especially international research on this topic regarding such an approach, we only identified disparate estimates for QALY for specific medical conditions (for example Miller et al., 2009).
Since determining the QALYs gained through health interventions necessitates a

prior determination of the number of QALYs when no intervention is considered and the QALYs with intervention, in this paper we concentrated our efforts in identifying the number of QALYs when interventions are considered. Our prior research in this field aimed at determining the number of QALYs in the case without intervention (Pantea and Gligor, 2012a). As such, the research hypothesis is the following: The number of QALYs with intervention is higher than the number of QALYs without intervention.

3.2 Survey design

Our following concern was to identify the research method that enables testing and validating the assumptions in the context of the paper's objectives. Thus, following an analysis of the methods indicated by the literature review, we conducted a quantitative research, the instrument used for data collection being the questionnaire.

As stated by Pantea and Gligor (2012b), to estimate the number of QALYs for a group or a population the following types of information are needed:

- Descriptions of the various types of perceived health status in life;
- The duration of each health state;
- Estimation of utilities for each state for a group or an analyzed population.

With regards to the medical conditions that we included in our research, we started with an analysis of the statistical information provided by the Newsletter No. 11 of 2011 of the National Center for Public Health Statistics and Informatics which sets out the causes of death by age and gender of the population. Thus, we selected for this research only the first two main causes of death in Romania – diseases of the circulatory apparatus (60% of total deaths) and tumors (20% of total deaths), the selection criterion being the disease with the highest percentage in total deaths.

A second point of interest was to determine a common scale for both medical conditions in terms of evolutionary stages since each condition's stage is different in features and pathology. The objective was to create a common framework that allows comparisons between medical specialties, which we developed as follows (Pantea and Gligor, 2012b):

- Stage 1 - the initial stage: the first signs of disease onset, when medical interventions are often completely noninvasive and determine a complete recovery;
- Stage 2 - the advanced stage: requires invasive interventions which sometimes cause a partial or complete treatment of the disease;
- Stage 3 - final stage: reserved prediction, reduced ability to use medical interventions.

Based on the informational needs, we have developed the investigating tool necessary to achieve the established objectives that ensures the collecting of all the mentioned data.

Thereby, we developed a questionnaire that approaches two informational needs: on the one hand, respondents' perception regarding patients' quality of life after medical intervention and the identification of the associated quality of life utility in the three stages of the two diseases analyzed.

The target population consists of medical professionals since they are the only ones able to assess form a medical standpoint and in an objective manner the patients' quality of life after medical interventions. Restrictions of high amplitude and resource consumption in analyzing the total target population, led to a smaller sample population represented by healthcare professionals working in major hospitals in

the Western region of the country.
In table 2 we illustrated the process of operational definition of the questionnaire's variables.

Table 2: **Operational definition of variables**

Questionnaire theme		Variable	Variable operational definition
Perception of patients' quality of life after medical interventions	**Diseases of the circulatory apparatus – Stage 1**	**Health state utility**	**0 – Worst health state** **1 – Best health state**
	Diseases of the circulatory apparatus – Stage 2	**Health state utility**	**0 – Worst health state** **1 – Best health state**
	Diseases of the circulatory apparatus – Stage 3	**Health state utility**	**0 – Worst health state** **1 – Best health state**
	Tumors – Stage 1	Health state utility	**0 – Worst health state** 1 – Best health state
	Tumors – Stage 2	Health state utility	**0 – Worst health state** 1 – Best health state
	Tumors – Stage 3	Health state utility	**0 – Worst health state** 1 – Best health state
Respondent's profile		Profession	**Medical doctor**
			Resident physician
			MD
			Medical specialist

In order to demonstrate the reliability of the measurement scales, we calculated the α Cronbach coefficient an obtained an average of 0.77. Since solciological surveys consider satisfactory a value higher than 0.7, we demonstrated the reliability of the proposed scales.
On the basis of information on the utility associated with quality of life after surgery and considering time as life expectancy in Romania (values for 2011), we can calculate QALY for the case with intervention using formula 1.

$$\textbf{QALY with intervention} = = \sum_{t=a}^{a+L^i} Q_t^i \qquad \textbf{(1)}$$

where,
t – time period;
a – age;

L^i - the period over which the individual enjoys the benefits of treatment;

Q_t^i - a vector of health-related quality of life weights predicted (or observed) for each time period t following the intervention.

4. Data analysis and results

The process of data collection was realized by direct research, which allowed us to eliminate the risks related to invalid questionnaires and to ensure the defined sample volume. The data was collected from January to February 2013 and processed using SPSS 17. Out of 150 questionnaires delivered to 10 major medical units from the Western Region of Romania, we collected 131 valid questionnaires, thus a 87% response ratio.

The investigated population analysis according to the variable 'profession' reflects a following structure: 22% medical doctors, 23% resident physicians, 29% MDs and 26% medical specialists.

The starting point in processing the collected data was to establish their homogeneity level by calculating for each variable the central tendency indicators (mean, median, mode) and dispersion indicators (minimum, maximum amplitude, variance, standard deviation). The results obtained indicate a high homogeneity of data as amplitude, variance and standard deviation values are below one and close to 0. The fact that the values of mean, median and mode indicators are approximately equal underlines the symmetry in data distribution and justifies the use of their average values in determining the utility for each stage of the medical conditions considered.

Identification of time spent in each stage was based on the increase in life expectancy percentage due to medical interventions that each respondent identified according to specified criteria.

After calculating tendency and dispersion indicators, the results obtained allowed assessment of the increase in life expectancy percentage as average values observed.

The calculation of life after surgery, by age, followed the reasoning explained as follows:

Average life expectancy after diagnosis = Age × Average life expectancy at diagnosis

Years of life lost = Average life expectancy – Average life expectancy after diagnosis

Years of life gained = increase life expectancy % × Years of life lost

Average life expectancy after intervention = Average life expectancy at diagnosis + Years of life gained

The calculated values for average life expectancy after intervention, based on the above reasoning, reflect a significant difference between the average lifespan at diagnosis and life expectancy after surgery, both on stages of the disease and types of medical conditions.

In order to calculate quality adjusted life years with intervention, we applied formula 1 using quality of life related utility values (Qi) previously determined by statistical methods and average life expectancy values after intervention (DI) based on data collected and processed in the previous step (table 3).

Table 3: QALYs with intervention

Medical condition	Age group	Qi	Di	QALYs
Stage 1				
Diseases of the circulatory apparatus	under 24 years	0,9	46,23	**41,61**
	25 - 34 years		37,79	**34,01**
	35 - 44 years		29,31	**26,38**
	45 - 54 years		20,68	**18,61**
	55 - 64 years		11,98	**10,78**
	over 65 years		3,52	**3,17**
Tumors	under 24 years	0,71	31,41	**22,30**
	25 - 34 years		25,84	**18,35**
	35 - 44 years		20,25	**14,38**
	45 - 54 years		14,69	**10,43**
	55 - 64 years		8,78	**6,24**
	over 65 years		3,06	**2,17**
Stage 2				
Diseases of the circulatory apparatus	under 24 years	0,77	36,41	**28,04**
	25 - 34 years		29,84	**22,98**
	35 - 44 years		23,27	**17,92**
	45 - 54 years		16,30	**12,55**
	55 - 64 years		9,56	**7,36**
	over 65 years		2,95	**2,27**
Tumors	under 24 years	0,55	25,19	**13,85**
	25 - 34 years		20,55	**11,30**
	35 - 44 years		15,92	**8,75**
	45 - 54 years		11,36	**6,25**
	55 - 64 years		6,83	**3,76**
	over 65 years		2,31	**1,27**
Stage 3				
Diseases of the circulatory apparatus	under 24 years	0,57	29,01	**16,53**
	25 - 34 years		23,71	**13,51**
	35 - 44 years		18,41	**10,49**
	45 - 54 years		13,11	**7,47**
	55 - 64 years		7,81	**4,45**
	over 65 years		2,51	**1,43**
Tumors	under 24 years	0,43	17,38	**7,47**
	25 - 34 years		14,28	**6,14**
	35 - 44 years		11,18	**4,81**
	45 - 54 years		8,08	**3,47**
	55 - 64 years		4,98	**2,14**
	over 65 years		1,88	**0,81**

Although the values for QALYs with intervention are reduced from one stage of the disease to another and different according to the medical condition studied they are significantly higher than those for QALY without intervention that we calculated in a previous research (see Pantea and Gligor, 2012b).
Thus, the results validate our research hypothesis and allow us to substantiate that in terms of quality of life, healthcare investments have an important social and health impact.

5. Conclusions and discussions

The reference point of our research is the study of optimal resources' allocation (especially the case of structural funds) for the production of benefits to the society. Since by definition, resources are limited, the healthcare systems faces this condition every day, aspect that led to the development economic evaluations as key component of decision making. In this sense, the need for a common measurement unit that allows comparisons between different sectors of healthcare and even beyond has conditioned new instruments for benefits appraisal including quality adjusted life year, indicator that serves as a tool in channeling public resources to health interventions imperative for the population.
As we previously underlined, our research and results are issues currently addressed only from a theoretical point of view. As demonstrated for two major medical conditions that affect peoples' quality of life and average life expectancy, QALY captures health gains generated by treatments.
The usefulness of our results comes from allowing guidance for the public prioritization process in terms of resource allocation by substantiating the process on forecasts of patients' clinical outcomes. Also, the information provided enables comparisons regarding the effectiveness of different medical interventions for the same health problem by estimating the duration and quality of life gained through treatment.
The limitations of our research arise from the relatively modest sample investigated, which might generate a low capacity to generalize the results. In this sense, our study opened opportunities for further research, such as widening the population investigated, calculating QALYs for other medical conditions that affect human health and calculating QALYs gained for the medical conditions targeted.

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