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Mini-review

PHARMACOECONOMICS IN EVALUATING HEALTH CARE DECISIONS

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ABSTRACT

There is no public health system in the world that has enough resources required for satisfying its full potential. The continuously increasing costs in public health and the limited financial resources for its various implementations demand a judicious allocation of the available resources and their optimal use to achieve effectiveness in health services. Pharmacoeconomics, like a multi-discipline action field, unites the efforts of clinical pharmacologists, pharmacists, health economists, epidemiologists and others in search of a balance between the costs for health services and their results.
Pharmacoeconomic analyses offer information to the people working in the public health sphere and helps in making reasonable decisions in the most rational allocation of the limited financial resources.

Key words: opportunity cost, incremental cost, benefit, QALY, viewpoint.

INTRODUCTION

Pharmacoeconomics (PhE) is a branch of health economics dealing with costs and benefits of drug therapy. Its introduction and fast development in the last years reflect a troubling phenomenon on a world scale, i.e. the incessant increase in health costs and the inability of health institutions to fund them in the circumstances of limited resources. We are witnessing a growing disruption between the application of novel medical and drug strategies and insufficient budgeting for their administration. On a global scale drugs are the main funds of economy in health budgeting due to the following factors: 1. They take third place in the costing structure after salary expenses and capital depositions/charges. 2. Unlike the rest of the expenses they are easy to manipulate. 3. They can be measured easily. 4. They are fast growing. The establishment of a drug strategy should arise both from the principles of Evidence Based Medicine (EBM) and PhE analysis and evaluation. PhE serves as a link between medicine and market economy. The present review deals with the concepts, essential terminology and methods of health economy and PhE.

BASIC CONCEPTS AND TERMINOLOGY

The subject of PhE consists of the measurement and assessment of resource consumption in a certain drug therapy and the health benefits from it. The core of thorough PhE analyses is the comparison of alternative therapeutic methods via which the limited resources can be used most effectively; this in turn allows the largest amount of benefit for resource consumption to be obtained.

This itself is not precisely a matter of suspending the expense for drug therapy but rather of the optimal utilization of the available resources. In this aspect, PhE offers reliable and meaningful information and serves as a tool for decision making in the choice of a therapeutic approach (1, 2, 3, 4, 5).

Efficacy - denotes the theoretically probable benefit of medical strategy, established in ideal (experimental) circumstances.

Effectiveness - a specifically established benefit from the application of a certain medical strategy under certain realistic conditions.

Economy or productivity - the ratio between factual results and values of consumed resources.

Opportunity costs

Under the conditions of limited resources we are forced to make a daily choice and

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inevitably ask ourselves whether the way we use these resources is the most appropriate one since their use for one purpose means they cannot be used for another. By selecting one alternative we reject another so that we have to be certain that by spending our funds on a novel therapy we can obtain a greater benefit than by spending them on an already existent therapeutic strategy. Alternative costs are measured by loss of utilization of resources for better purpose (6, 7). For example if there are two possible alternatives: A- treatment of asthma and B- smoking cessation. The treatment of asthma is the best alternative for patients and cost of this treatment is = A. Smoking cessation is the next best alternative and its value is = B. The opportunity costs of A= benefits omitted because of a refusal of B.

Incremental analysis

$$ICER = \frac{(\text{Cost of A} - \text{Cost of B})}{(\text{Effectiveness of A} - \text{Effectiveness of B})}$$

This represents the differences in costs and benefits/ health outcomes when comparing two therapeutic programmes. There are four possible situations: 1. The new therapy is more effective and less expensive than the old one; 2. The new therapy is more effective and more expensive; 3. The new therapy is less effective and cheaper; 4. The new therapy is less effective and more expensive than the old one.

If one therapeutic intervention/strategy is more effective and cheaper than the other it is defined as dominant (situation 1) and should be preferable because it produces more benefits at a lower cost. In most cases we deal with situation 2 and 3. In such instances, in order to make a decision regarding the choice the incremental cost- effectiveness ratio (ICER) is evaluated.

This ratio assesses the cost for additional effectiveness of intervention/strategy A to intervention/strategy B. The decision depends on the decision maker's "ceiling ratio" for ICER in each health institution. This expresses the highest costs, which a certain health institution is able to pay for a certain health service.

There are no strictly determined recommendations for the ceiling of this ratio. In the countries with highly developed health economy there exist specialized institutions designating the guidelines for economic evaluations. For instance NICE (National Institute for Clinical Excellence) in England recommends health services with ICER about or beyond £30.000 per QALY (8).

Average cost effectiveness ratio

This reflects the medium value of the costs for production of a unit service within a single therapeutic programme.

$$\text{Average costs} = \frac{\text{Overall value of the recourses}}{\text{Number of health service units}}$$

Marginal analysis

This refers to changes in costs and benefits due to expanding or suspending with one unit a certain therapeutic programme (for example prolonging or shortening with one day the stay in hospital) (9).

Costs in economic evaluations

Direct costs: They are directly associated with the health service. They are divided into medical and non-medical costs. The medical ones comprise expense for staff salaries, drugs, and diagnostic tests while the non-medical costs are associated with budgeting

medical services such as transportation of patients and/or medical staff to and from the hospital. The direct costs can also be: 1. Fixed costs - ones for salary, maintenance of building, costs for laboratories, kitchens etc.

These costs mainly depend on the duration of a period and not on the amount of services in the evaluated period of time. 2. Variable costs - they depend on the amount of the services in the evaluated period of time. They include drugs' costs, acquisition costs etc. The costing of direct costs is the easiest since most of them have market prices or are reimbursed by the National Health Service. They are expressed in monetary units and are comparatively easily collectable data.

***Indirect costs*:** They are associated with absence from work, decrease in work ability due to illness, disability or death. In this context they can affect not only the patients but also their families and society as a whole. The calculation of indirect costs is more difficult than that of direct costs and there are more contradictions as to how they should be measured; therefore they are often ignored in practice (10). There are three approaches for calculation: 1. The human capital approach, 2. Alternative costs, 3. Friction costs.

The measuring of the human capital value is performed by changes in productivity. These changes are measured as the mean profit of work force, which would be lost or gained as a result of a health intervention. The method based on friction costs (called a friction cost model) evaluates the loss of productivity depending on the amount of time necessary for the organization to re-establish the initial level of productivity.

***Intangible costs*:** They are associated with disease and/or treatment-related limitations such as pain, suffering, fear, loss of quality of life. They cannot be measured in monetary units. The quality of life is most often assessed through specially designed questionnaires, which assess the physical and social functions, mental comfort, sexual functions etc. The most widespread questionnaires are the brief formats for quality of life assessment **SF-36, SF-12, SF-20, EURO-Qol etc.**

The sum of direct, indirect and intangible costs forms the ***total cost value***.

The assessment of medical therapy costs first of all requires determining the ***perspective*** (viewpoint) from which to perform the economic analysis (11). It has to be defined while even planning the study so as to determine the categories of costs that will be included in the analysis.
There are three basic perspectives.

1. The producer's perspective- this includes the costs for drug manufacturing.
2. The payer's perspective- the costs that have to be paid by a hospital, National Health Service (NHS), private health funds etc.
3. The social perspective- this is the broadest –scale aspect and includes the costs that society as a whole entity pays for the treatment of a certain disease.

For instance costs of staff salaries, costs of hospital bed day, drugs costs and costs of diagnostic tests have to be included in the analysis from perspective of the hospital. Taking into account the broader perspective of assurance companies the prices of drugs for ambulatory treatment must be included. The society perspective has to comprise all costs, including loss of disability.

The benefit that we expect from one therapeutic strategy can be measured in:

1. Natural units (e.g. years of life saved, cases of heart attack prevented, strokes prevented and peptic ulcer healed).
2. Utility (utility units)- this is often measured by QALY (quality adjusted life year), DALY (disability adjusted life years; for assessment of global burden of the disease) and HYEs (healthy year equivalent; at how many years life in absolutely health is equivalent life with a certain disease).

TYPES OF ECONOMIC EVALUATION

Cost-minimization analysis (CMA)

CMA compares the costs of alternative drugs or therapeutic programmes in which it can be proved that the obtained results are equivalent (12). The aim is to point the alternative with lower costs whose application will lead to minimization of the cost price of therapy. From methodological point of view this is the simplest type of economic analysis but rather rarely applied in practice. It is suitable when the value of therapy with trademark and generic products are compared.

Cost-effectiveness analysis (CEA)

This is a type of economic analysis where the outcomes of various therapeutic interventions are expressed in "natural units" (for example life years gained, loss of time in reason of disability, heart attack avoided, mm drop in Hg for blood pressure etc.)

The quality of life is also used as a measure of benefit. CEA is applied in programmes or drugs with a similar action

(for example two antihyperlipidaemic drugs). It is not possible to compare effectiveness in case the drugs possess a dissimilar action or effects, for example antihypertensive and effects against migraine, since these effects cannot be expressed in natural units, as the method requires. Unlike CMA, which specifies the less expensive alternative, in CEA the preferred alternative is not necessarily the cheapest. The main restriction in CEA is that it is one-dimensional – only one domain of benefits can be explored at a time and it is practically difficult to choose which single outcome best represents the effectiveness of the explored therapeutic programme. One possibility is to conduct a cost-consequence analysis, which is a particular type of CEA that evaluates multiple therapy outcomes and reports costs and benefits in a disaggregated form. In this way it permits the reader to choose a benefit for himself.

Cost-utility analysis (CUA)

In this type of economic analysis the increasing costs are compared with increasing health improvement measured by quality adjusted life year (QALY). The final result is expressed as cost per QALY. The QALY is an arithmetic value integrating both quantities of life and its quality in the remaining years. There are various methods of its assessment where health state is determined with values from 0=death to 1= perfect health. Up to one year in perfect health corresponds to 1 but if health is not perfect and its quality is lower, values of 0.9, 0.8 etc. may be obtained. For example, if the treatment X prolongs a patient's life with 10 years, but the quality of life is not perfect and decreases from 1 to 0.7 the value of QALY can be estimated in this manner: 10 life years gained x 0.7 quality of life = utility 7.0. If the treatment Y prolongs a patient's life with 5 years but quality of life decreases to 0.5 the value of QALY is 5 life years gained x 0.5 quality of life = utility 2.5. In this case QALYs gained from the treatment X are 7.0-2.5=4.5. The next step is evaluating cost per QALY by dividing the total costs for treatment X to the number of QALYs gained. (13). DALY and HYEs are more rarely used indicators.

Cost-benefit analysis (CBA)

This analysis requires a presentation of the costs and results in monetary terms. It can be applied to alternatives with fundamentally opposite or many different results. It allows the choice of this therapeutic programme, which benefit is greater than the costs.

Apart from already discussed full pharmacoeconomic analyses, there are also so-called incomplete pharmacoeconomic analyses. They include studies, which analyse only the costs (costs of illness), or only the consequences from a certain therapeutic programme or compare two programmes by only the effectiveness or only the costs (cost-identification analysis). Incomplete is also the analysis, which presents simultaneously costs and benefits but only for one therapeutic strategy and there is no comparative assessment of an alternative intervention.

Discounting

This is a technique used to reflect the present value of a cost or health benefit that will occur at some future date. It is not an adjustment for inflation. The effect of discounting is to give future costs and health benefits less weight in an economic analysis. Determination of the most appropriate discount rate for cost in economic analyses is still being debated by health economists, though typically rates of 3% to 5% are used. Most health economists agree that it is reasonable to select a central “best estimate" of the discount rate, such as 2%, and to then determine the effect that high and lower rates (e.g. 2% to 6%) have on study findings and conclusions.

Sensitivity analysis

It is an important analytical tool for checking whether the conclusions of a certain study are changed in case the assumptions made vary. It is necessary for checking strength of the pharmacoeconomic results in relation to influence of internal and external factors.

CONCLUSION

Health economics and its branch, PhE, must be considered as means to solve one of the basic questions asked to Health Institutions, namely: how to make a balance between costs for health services and the expected benefits of them. The aim is a maximum health benefit for the community to be delivered considering the existing limited financial resources. The economic evaluations help the health professionals to choose best by making informed decisions about pharmacotherapy of the diseases.

ABBREVIATIONS

CBA - Cost-benefit analysis
CEA - Cost-effectiveness analysis
CMA - Cost-minimization analysis
CUA - Cost-utility analysis
DALY - disability adjusted life years
EBM - Evidence Based Medicine
HYEs - healthy year equivalent
ICER - Incremental cost- effectiveness ratio
NHS - National Health Service
NICE - National Institute for Clinical Excellence
PhE - Pharmacoeconomics
QALY - quality adjusted life year

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