Katarzyna Kolasa

OBJECTIVITY OF REIMBURSEMENT DECISIONS -DOES IT ALWAYS HAS TO PAY OFF?

Medical University of Warsaw, Department of Pharmacoeconomics

ABSTRACT

Rising health care needs impose increased pressure on limited budgets of health care systems around the world. Not only life expectancy is improved, but also increases awareness of patients on modern treatments. It, as a result, leads to the constant search for ways to rationalize health services better attuned to the ability to pay.
THE PURPOSE OF THE STUDY. Analysis of the pricing and reimbersement criteria included in the Polish law.
MATERIALS AND METHODS. Based on a literature review to specify criteria for the allocation of resources in the health sector and to compare them to those included in the "Act on reimbursement of medicines, foodstuffs intended for particular nutritional and medical devices".
RESULTS. Economic criteria dominate the rules governing the reimbursement process of pharmacotherapy in Poland. Referring to the principle of equity they focus on the ability to improve health. Two aspects are repeated frequently: cost-effectiveness and impact on payer's budget.
CONCLUSION. Selection of the allocation criteria was carried out in the Polish law to a limited extend, which may give rise to difficulties in making objective reimbursement decisions.

Key words*: allocation of funds for health services, efficiency, equity, refinancing,*

INTRODUCTION

A report published by the Karolinska Institute revealed that the new drugs introduced to the market in the period 2000-2004 were waiting for reimbursement in Poland 2190 days on average, while in Hungary it was 214 days in 389 days-the Czech Republic, in Slovakia-453, and for example in Austria only 83 days (1). Other data show that only 7% of Polish patients suffering from multiple sclerosis receives disease-modifying drugs, while in most European countries this percentage is approximately 30 - 40%, reaching as high as 50% in Slovakia, or 70% in Germany, Austria, Switzerland and Lithuania (2). Similarly, in the case of rheumatoid arthritis. In Poland, the proportion of patients treated with innovative drugs is the lowest among all EU countries (3).

The most common explanation to the low scope of public funding for new therapies is limited financial resources. Repeated is argument that the budget allocated for health care is too small to be able to provide public funding for any new therapy. Several studies have shown, however, that early treatment with modern methods sometimes not only improves the prognosis for faster and more efficient return to the patient's health, but it can also bring cost savings. This is because the start of an early effective treatment often helps to avoid later complications of the disease that are burdensome for the patient and costly to society (18 ,19). Therefore, when making a decision to take public financing of a new medical technology is important to study its impact on all aspects of the disease.

The purpose of this publication was to evaluate the distribution rules of public funds for pharmacotherapies, as enshrined in the "Act on reimbursement of medicines, foodstuffs intended for particular nutritional and medicinal products in Poland" (Reimbursement Act) (4). The preliminary hypothesis of the research said that the scope of the Polish reimbursement decision-making criteria is limited. Failure to take into account all the benefits of the proposed treatment and the total costs of the disease can lead to suboptimal decision of allocation.

MATERIALS AND METHODS

The study was conducted in two stages:

1. In the first step, a review of the literature was made to define the criteria used in the allocation of resources for health services.
2. Secondly, an analysis of Reimbursement Act for aspects that are taken into account in the process of allocation of public funds. An attempt was made to determine which of the criteria revealed in the first stage, were adapted in reimbursement decision-making process in Poland.

The discussion elaborates the extent to which the adaptation of these criteria into decision-making in Poland contributes to the objectivity of the allocation of resources in the health sector.

RESULTS

The criteria for the allocation of resources for health services. In the literature, there is no unity on the criteria for the distribution of the public healthcare resources (5). Most discussions about the allocation of the health budget refers to the need for sound management of public funds. Many experts believe, however, that discussion cannot be limited to the problem of the effectiveness. Given the need for a broader look at the problem of allocating scarce resources, more and more refer to multi-faceted approach to decision-making (multi criteria decision making, MCDM) (6, 7, 8). It is a methodology that introduces the list of non-economic aspects of the reimbursement criteria such as innovation, social dimension of the patient's disease, the patient's adherence, and finally, equity. Due to the difficulties in the implementation of two or more, often contradictory aspects, experts point to the need to seek a balance between the two (called equity - efficiency trade off) (9).

The effectiveness of the system is interpreted as maximizing the health benefits within its budget on health care (10). An implementation of the economic criterion is to conduct cost-effectiveness analysis and assessment of the impact of a new therapy for the budget of the payer. The concept of equity may be defined in several ways. For some it is equality of access, pointing to the need to ensure equal access to the same health care needs. To adhere to the utilitarian approach it is the need to give priority to those with the greatest ability to improve their health. Finally, for those with egalitarian preferences is to provide equal health and equal improvement of health (10). Quantitative methods of implementation of the criterion of equity are still not proposed. Attempts to introduce non-economic criteria into allocative decisions are limited to weighing the health effects depending on the characteristics of the patient or other qualitative methods.

Adaptation of the allocation criteria in Poland. Analysis of the Reimbursement Act showed that key authorities responsible for the reimbursement of medical technologies are the Ministry of Health, the Agency for Health Technology Assessment and Economic Commission (Article 12) (4).

Under the Polish law, the drug manufacturer must provide a range of evidence on the proposed medication (4). Article 12 of the Act lists the 13 criteria that should be followed by the Minister of Health when deciding reimbursement. In order to answer the question, to what extent the principles of equity and effectiveness are followed in Poland, it was made the assignment

Tabela 1. Allocation criteria named in the Polish reimbursement act (Dz. U. Nr 122, poz. 696.)

	Effectiveness		**Equity**			
	Maximalizaiton of health	**capacity to benefit**	**disease severity**	**egalitarism**	**equity of access**	**procedural justice**
1	Health maximalization principle		Disease severity			
2	Price	Clinical efficacy	Alternative treatment options			
3	Payer's budget impact	Safety				
4	Cost effectiveness threshold (3x GDP per capita)	Risk benefit ratio				
5	External reference pricing					
6	Effective price in selected jurisdictions					
7	Cost of treatment					
8	Cost effectiveness ratios for reimbursed treatment options					

criteria set out in the Act for each definition. This is depicted in Table I.

Regarding the principle of equity Polish law generally refers to the principle of equity understood in the context of capacity to improve health. It was recognized also that appeal to the efficacy and safety is also an expression of concern for maximalization of health improvement. Linking reinbursement decision with efficacy will not always be in harmony with the granting of priority to people in the most advanced stage of the disease, or aimed at the implementation of equal access. Only two of the presented criteria were classified as the principle that refers to the burden of disease. These are the "clinical significance" and "availability of alternative medical technology."

Other definitions of equity have not found their place in the Act reimbursement, not so as in the case of an economic criterion. We have found as many as seven entries pointing to the principle of effectiveness, and two of them were repeated twice. They refer to the aspect of cost effectiveness, i.e. to obtain the greatest improvement in health within the budget, the remaining five concern protecting the budget of the payer, i.e. the analysis of the impact on the budget.

DISCUSSION

Overview of Reimbursement Act revealed that the economic criteria dominate in the rules governing the process of reimbursement of pharmacotherapy in Poland. Reference to the principle of equity focus on the ability to improve health. Both the implementation of the principle of effectiveness, as well as formulated the principle of equality leads to the conclusion that the most important goal of the legislator in determining the amounts of the refunds is to maximize the health benefits. It is also expressed explicitly in Article 12 of the Reimbursement Act: "to maximizing health outcomes within available public funds."

In the process of allocation of funds for drug therapies, two aspects were the most frequent: cost-effectiveness and affordability of the budget of the payer. It is therefore worth considering the consequences of the implementation of each of them on conducting an objective resource allocation for pharmacotherapies.

Cost-effectiveness. The most common approach to defining criterion of effeciveness in developed countries is the cost of obtaining an additional year of life adjusted for quality. To such an approach also refers Polish legislator. Addressing the need to protect the state coffers from excessive spending rule was introduced three times the GDP per capita as a cost effectiveness threshold in the act of reimbursement (4). This means that the only therapies that help the patient to get an additional quality adjusted life year (QALY) at a cost of no more than the mentioned above level, may qualify for a reimbursement.

There are few countries in the world that use explicit concept of cost effectiveness threshold when deciding on the allocation of public resources, such as England and Wales. British regulations are often seen as a model worthy to follow by other countries in the European Union. In contrast to the Polish, the British Agency for Health Technology Assessment (National Institute for Clinical Excellence - NICE) provides an interval within which should fit the result of cost-effectiveness analysis (11). This does not mean inability to obtain refunds for non-viable therapy nor the certainty of public funding for cost-effective medicines. It is recognized that the decision-making process is too complicated to simplify it to a plain calculation based on one economic criterion.

Keeping the allocation of resources on the basis of the threshold of cost-effectiveness favors such therapies which ensure the greatest improvement in health. As it is shown in the available studies, our public opinion favors a more egalitarian approach, preferring to meet the smaller health needs but for the greater number of patients (12). Making decisions based on cost-effectiveness threshold does not allow the inclusion of other criteria of equality than to maintain the ability to improve health in reimbursement decisions, and can leave the number of patients without access to innovative therapies. Again, the NICE shows how one can avoid subjectivity of allocation decisions as a consequence of the cost effectiveness threshold. Demonstrating understanding the risk of refusal of treatment for most affected groups of patients, NICE introduces separate guidelines for the pharmacological treatment, extending the patient's life by at least three more months, in which the expected survival without treatment is not longer than 24 months (13). Special instructions allow to abstain from the implementation of resource allocation based on the break-even point by assigning higher weights for health in this group then in other groups of patients.

Given the need for a more systematic approach to include a broad range of decision criteria, NICE goes a step further and plans to introduce in 2014 an approach "value for money" (called value based pricing) (14). A list of aspects established such as the burden of illness, therapeutic innovation and improvement and also an assessment of the impact of the introduction of new health services in clinical practice, due to the societal benefits (14). It was not decided yet whether these issues could be addressed by establishing the cost-effectiveness threshold range or by weighing therapeutic effects in relation to these benefits. However, it can be concluded that the reform of English reimbursement

system moves away from making decisions based on cost-effectiveness threshold. This is due to the belief that an objective resource allocation cannot be implement on the basis of one decision criterion.

Payer perspective. The cost effectiveness analysis can be done from the perspective of the payer or the public. In the first case it is a situation, when are analyzed only the benefits and costs of the proposed method of treatment to be incurred by the public payer. The second takes a broader perspective. That is, in fact, taking into account also the impact of the proposed treatment on the productivity of the treated person at the labor market (indirect costs), or to take into account the preferences of the public in valuation of health benefits. Polish legislator limits the analysis of the consequences of the new treatment to the perspective of the payer. It is evidenced by the number of records. Both article 12 and 17 of the Act of reimbursement says about the impact on the budget of the entity responsible for the financing of benefits from public funds and beneficiaries (4). At this same time it is hard to find records that refer to aspects of the activity in the labor market or using social preferences for the valuation of the health benefits.

Among a large group of experts, however, is the prevailing view that taking the perspective of the payer does not lead to objective decisions of allocation (15). It consists of two reasons. First, the social benefit from the introduction of new medical technologies into clinical practice is the sum of consumer surplus and producer surplus (16). While the first is formed as the difference between the marginal social benefit and the equilibrium price, the second is the difference between the equilibrium price and the marginal social cost. The marginal social benefit reflects the benefit from the use of the technology for all of its stakeholders such as patients, caregivers or employers. Marginal social cost arises from expenses for production and distribution of the proposed technology. Taking the perspective of the payer is assumed that the equilibrium price is equal to the marginal cost disregarding the consumer and producer surplus. This means in essence that these surpluses are treated as a loss to society, which is at odds with the theory of microeconomics. Supporters of the social perspective suggest that producer surplus is an incentive to invest in research and development, and should be treated as a premium for innovation. They argue that, by adopting the point of view of the general public, it is necessary to consider the relationship of producer surplus with the investment in research and development (dynamic efficiency).

The second major argument against the payer's perspective are social costs. This is because the consequences of the disease often go beyond the health system. For example, in Sweden, according to the available calculations, expenses related to sick leave, early retirement and death account for over 60% of the total cost of treatment of diseases (17). Disregarding the impact of new therapies on patient productivity in the labor market may lead to sub-optimal decisions. The literature abounds with studies that show how the proposed methods of treatment effects on reducing the indirect costs of the disease. For example, American analysis of *Birnbaum* made in relation to multiple sclerosis have shown that the costs of hospitalization and specialist care of the treated patient were almost 4,000 USD, while the untreated less almost 6,200 USD. At the same time the cost of sick leave amounted to about 2,200 USD in the one and 3,000 USD. in the another case.

The social costs do not arise only from the impact of new treatments on the productivity at the labor market (18). The consequences of the disease are also connected with the need to take care of the patient by others. Calculation of the World Association for the Fight Against Alzheimer's Disease, for example, showed that the average total cost of treatment of the disease is more than 32 000 USD (19). Although expensive operations are not required, there is a need for 24-hour patient care, provided by the family or appropriate services, so such a high cost. It was also calculated that early treatment contributes to the delay of the disease development, and thus also the need for 24 hours care. By providing access to treatment in the early stages of the disease, one can achieve savings of 10 000 USD. If the indirect costs is not taken into account to determine the cost-effectiveness of the treatment, it could be that early detection does not appear to produce the expected positive results. Disregarding the social costs can therefore lead to sub-optimal decisions.

SUMMARY AND CONCLUSIONS

We conclude that the economic criteria dominate the legislative provisions governing the reimbursement process in Poland. The hypothesis saying that the selection criteria for the allocation according to the Polish law was limited. Disregarding all the benefits of the proposed treatment and the total costs of the disease can lead to biased decision making. Please note, that the above analysis was limited only to evaluation of the allocation criteria presented in the Act Reimbursement ignoring other regulations, such as the guidelines of the Agency for Health Technology Assessment. The literature abounds with examples of how the range of evaluation criteria used can lead to subjective decisions of allocation. This is not only a Polish problem. Experts from around the world advocate public debate on the subject. It is believed that only when society representatives will be invited to actively participate

in determining the allocation criteria, one will expect a greater understanding of the problem of scarcity of resources and adaptation of the expectations of the public payer (20). Satisfaction with the functioning of the health system in Poland is one of the lowest among the 14 countries included in the study: Global Health Survey in 2011 (21). Postulated public debate about the allocation criteria can therefore not only help to improve the objectivity of the decision-making process, but also increase the level of social acceptance of difficult choices in the health sector.

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Address for correspondence:
Katarzyna Kolasa
Medical University of Warsaw
Department of Pharmacoeconomics
ul. Wigury 81, 02-091 Warsaw
kkolasa@wum.edu.pl on +48 781 881 007