

ATTITUDES TOWARD SUPPLEMENTARY CRITERIA IN THE REIMBURSEMENT PROCESS IN POLAND

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Since 2005, health technology assessment (HTA) has been integrated into the pricing and reimbursement system in Poland. One of the most important distinctions of the Polish HTA process is the adoption of a single cost-effectiveness (CE) threshold implicitly established by the Appraisal Body of the Polish HTA agency (1). A recommendation to lower the price of a proposed drug to achieve an incremental cost per quality-adjusted life-year (QALY) threshold of $3 \times$ gross domestic product (GDP) per capita was proposed on several occasions by the Polish HTA agency in the past (1). From January 2012, an explicit single threshold was introduced as part of a novel healthcare act. A newly established Reimbursement Body is mandated to take into account the $3 \times$ GDP per capita per QALY threshold, along with HTA guidance and the price of a drug, during its negotiations about reimbursement conditions with a manufacturer.

In deciding the types of health care to cover from public resources, value judgments inevitably have to be made. The relative benefits associated with the different outcomes of the healthcare system must be compared. Applying an explicit threshold for incremental cost per quality-adjusted life-year (QALY) is a useful decision rule in this regard. It refers to the trade-off between additional cost and additional benefit with a new intervention that is considered to represent value for money in a given health-care system. The introduction of a specific threshold clarifies the “rules of the game,” reducing the possibility of arbitrary and “ad hoc” decision making and increasing the efficiency of resource allocation (2).

Yet, there are also several arguments against using a unique threshold to determine reimbursement. Experience from different jurisdictions reveals that it is difficult to find evidence for the use of explicit thresholds in reimbursement decision making process (3). According to various experts, collection of evidence has to be initiated first to provide the necessary empirical argumentation for or against adaptation of such an explicit threshold. In addition, an explicit single threshold denies the possibility of incorporating into Pricing & Reimbursement (P&R) decision making other dimensions such as societal preferences and distributional equity (4). A P&R process based solely on the results of cost-effectiveness analysis (CEA) suggests that health

outcomes maximization should be the single criteria in the allocation of healthcare resources (5). This maximization principle of CEA has been criticized on many occasions (6), in particular due to the assumption of linearity, which does not distinguish between health gains to two different individuals *i* and *j*. (7).

The underlying hypothesis of this study was that the general public may demand incorporation of additional criteria in the Polish P&R decision making process, such as equity and/or severity of disease, beyond the explicit CE threshold. This is particularly important as the healthcare system serves the people of Poland and their preferences should be considered when decision making criteria are used.

The hypothesis is grounded on a substantial body of literature. Available theoretical models suggest that the value of a statistical life will vary over the spectrum of altruistic concerns whereby safety-focused altruism is identified as special case (8). The empirical research indicates that equity and disease severity plays an important role in the decision making process in the healthcare public sector (9;10). For example, a recently published research among Hungarian GP's found that high mortality as well as a capacity to benefit was distinguished as key criteria for distributional preferences (11).

OBJECTIVE OF THE STUDY

The objective of this study was to explore the attitudes of the general public toward the key decision criteria that should be used in the pricing and reimbursement decision making process in Poland. The research aimed to better understand the supplementary arguments that the general public believe should be taken into consideration alongside the explicit acceptability threshold. The following research questions were addressed: (i) Does the general public consider the need to value disease severity in the P&R decision making process? (ii) Should life-threatening therapies receive more funding even if it means limiting the public budget for those that impact quality of life only? (iii) Does the general public prefer to achieve more equitable distribution of health benefits instead of health outcomes' maximization?

To our knowledge, there have been no attempts to study societal preferences toward reimbursement criteria in Poland so far. Consequently, an extensive literature search was performed to identify relevant examples from other jurisdictions. Given that the allocation of scarce public resources involves balancing the needs of different groups, the public in helping to define the criteria for allocation is important. Incorporating the views of the public allows for the defensibility of decisions, an important consideration for decision makers.

METHODS

Literature Review

The literature review was performed using the PubMed database. The objective was to seek studies that investigate societal preferences with respect to allocation criteria in the healthcare sector. The following keywords were used alone or in combination: equity-efficiency trade off, reimbursement criteria, societal preferences, health maximization principle. In addition, expert input was sought to prepare a final version of the study questionnaire.

Two publications retrieved from the literature review were particularly impactful on the questionnaire design. These were the study by Desser and colleagues (2010) (10), where respondents were asked to trade-off between fatal and nonfatal disease, and Johannesson and Gerdtham (12).

Study Design

The study was conducted by a professional survey firm TNS PENTOR as a part of a multi-topic, quantitative omnibus face-to-face study on a representative sample of 1,000 residents of Poland aged 15 years and over. The general characteristics of the survey population are presented in Table 1. The survey sample was representative of the Polish population regarding region and the size of the place of residence. Once the results had been weighted, the sample was also representative with regard to the gender, age, and education level.

The study consisted of two phases: *Phase A*: pilot study. In depth interviews with 10 responders aged 55+ with primary and/or secondary education, conducted on 10 March 2011. *Phase B*: a cross-sectional observational study, conducted between 23 March and 15 April 2011.

Setting. The objective of phase A was the pretesting of the questionnaire. The pilot study was performed to evaluate understanding of research questions, detect problems with processes to derive responses and other issues with the questionnaire. The inclusion criteria of age above 55 years with a lower education level were therefore chosen on purpose for the pilot study. The pretesting did not indicate any problems with understanding of the questions. However, the instructions to questions were revised in accordance with the comments received.

Table 1. General Characteristics of Survey Population

	Total (n = 1011)
Men	47%
Mean age (years)	41
Married	57%
Highest level education	
< Secondary grade	50%
Secondary school	33%
University	17%
Gross personal income ^a PLN (EUR)	
> = 2,000 (481)	79%
< 2,000 & > 10,000 (2,406)	20%
< = 10,000(2,406)	1%

^aExchange rate 1 PLN = 0.24 EUR.

Questionnaire

The questionnaire consisted of several parts. In the first part respondents were asked to rate statements about equity and efficient use of resources on a four point Likert scale (1 = completely disagree, 4 = completely agree).

The second part of the questionnaire consisted of two experiments presenting hypothetical trade-offs that may be faced by a decision maker in a hypothetical jurisdiction. A binary choice question was administered to elicit responder's altruistic preferences; this approach was used as it is considered as easier to answer and also avoids the starting point bias which may occur if more than one bid level is introduced.

In each experiment, a society consisted of two homogeneous groups of patients that shared the same characteristics except for their current health state. Diseases in the question were specified in terms of functional level only and not in terms of diagnosis. The health problems were defined with the use of EQ-5D domains. The utility associated with the baseline health states for both groups in both experiments (1 and 2) was 0.50.

In the first experiment, a responder had to allocate a given limited budget either to 400 patients with a nonfatal disease A, 100 patients with fatal disease B, or a combination of patients with A and B. The treatment effect for both groups was defined so that the expected QALY gain per patient for improvement of quality of life in the first group was equal to the expected QALY gain for survival benefit in the second group.

In the second experiment, a responder had to prioritize a given treatment either to a group X with a baseline life expectancy of 2 years or a group Y with a baseline life expectancy of 8 years. The survival gain per patient was eight years for the first group and randomly varied from 2 to 8 years for the second group. It was assumed that the treatment affected survival only and did not affect the quality of life of patients. The costs of

treatment were assumed the same for X and Y. Both groups consisted of 100 patients.

Statistical Analysis

Experiment 1. The first experiment was similar in nature to the one proposed by Dessler and colleagues (2010) (10). The responder made a trade-off between spending additional budget on treatment for patients with impaired quality of life (disease A) versus four times more expensive treatment for patients with fatal disease (disease B). There were five different scenarios, each with a different allocation of additional funds between both groups, available for choice. Descriptive statistics were presented to describe the distribution of responses. For exploratory analyses, the dependent categorical variable with five levels, for each scenario, was composed to test the probability of allocation of additional budget for treatment of patients with disease B. Income, age, education, and gender were chosen as independent variables.

Experiment 2. Following the approach proposed by Johannesson and Gerdtham (12), logistic regression was used to estimate the mean marginal trade-off between survival gain in groups with more and less QALYs. The following regression model was chosen:

$$\ln(P/(1 - P)) = \alpha + \beta_1 x_1 \quad (1)$$

The null-hypothesis stated that there is no difference in the impact of marginal trade off on the probability of choosing patients with more QALYs across different i categories of x_j

Further details about both experiments and the logistic regression are presented in the appendix.

RESULTS

In total, 1,011 responders participated in face-to-face interviews. The response rate was 100 percent. The sociodemographic characteristics of study population are presented in Table 1.

Rankings on attitude to equity using a four-point Likert scale indicated strong support for the following statements:

“Everyone should have equal use of healthcare for equal needs always free of charge regardless of the cost” (mean score 3.4, SD 0.77),

“A lifesaving treatment should be covered by public resources regardless of costs” (mean score 3.4, SD 0.69); and

“The health budget should be used so that patients with the most serious illnesses receive treatment even if they don’t experience the largest health improvements” (mean score 3.0, SD 0.83).

At the same time, the Polish population indicated lesser support for the following statement “Health authorities should use resources to achieve the largest health benefits even if it that means some benefitting more than others” (mean score 2.5, SD 0.94).

Table 2. Preferences of Respondents for Allocating Resources between Groups A and B (Experiment 1)

Scenario (no. of patients A and B)	No. of responders		
	No	%	95% CI
1 A0; B100	108	10.7	8.2 11.9
2 A100; B75	239	23.6	22.0 27.3
3 A200; B50	382	37.8	33.4 39.4
4 A300; B25	136	13.5	12.2 16.5
5 A400; B0	146	14.5	12.3 16.6
Total	1,011		

A, patients with impaired quality of life; B, patients with fatal disease; CI, confidence interval.

General preferences are presented in the Supplementary Table 1, which can be viewed online at <http://dx.doi.org/10.1017/S0266462313000482>.

Experiment 1. A summary of results for experiment 1 is presented in Table 2. In total, 75 percent of responders recommended to treat both groups of patients to at least some extent. Half of those who recommended treating both groups preferred an equal distribution of funds between groups A and B; of the other half, slightly more preferred to distribute a greater proportion of funds to group B, indicating a trend to support greater treatment for patients with a fatal disease. The remaining 25 percent of responders favored treatment of only one group of patients. There were 11 percent and 15 percent of responders that recommended only life extending treatment for group B or only quality of life improvement for group A respectively. Multinomial regression revealed that there were no significant differences across sociodemographic groups (Table 3). The descriptive analysis confirmed that results do not vary across different subpopulation defined by education, income nor by gender and age of responders (Supplementary Table 2, which can be viewed online <http://dx.doi.org/10.1017/S0266462313000482>).

Experiment 2. The percentage of responders choosing patients’ group Y for the three different marginal trade-offs decreased from 51 percent to 43 percent. When the difference in treatment effects was largest (the lowest marginal trade-off) 51 percent of responders were in favor of group Y. At the same time, 43 percent of responders chose group Y if treatment effect was the same for both groups (the biggest marginal trade-off).

The results of the logistic regression analysis are shown in Table 4. The marginal tradeoff has the expected negative sign and is statistically significant. According to the estimation based on the logistic regression equation, an average responder is willing to forgo one QALY in health improvement for patients

Table 3. Odds Ratio from Multinomial Logistic Regressions, Dependent Variable: Which Scenario Do You Recommend for Allocation of Extra Funds between Patients with Disease A (Common Disease) and Patients with Disease B (Life-Threatening Disease)? (Experiment 1)

Independent variable	Odds ratio	<i>p</i> value
Gender		
Male	1.00	.99
Age		
<25 and >65	0.61	.01
< 65	0.69	.11
Income		
<2,000 & >10,000	1.40	.08
< = 10,000	0.81	.78
Education		
Secondary school	1.08	.63
University	0.70	.12

Table 4. Coefficients of the Logistic Regression Analysis of the Probability of Choosing Patient with Longer Life Expectancy at Baseline

	Coefficients	<i>p</i> values
Marginal trade-off of life-years	−0.643	.040
Intercept	0.415	.085
LogL	−69.813	

Note. No discounting of QALYs (experiment 2).

Y to reduce the difference between both groups X and Y with 0.64 year (i.e., 7.7 months).

The differences in pattern of responses were also studied (Supplementary Table 3, which can be viewed online at <http://dx.doi.org/10.1017/S0266462313000482>). The inclusion of composite variables, that is, marginal trade off with gender as independent variables in the logistic regression revealed that no significant differences were observed between male and female responders in the probability of choice patients group Y. In a similar manner, the stratification by education, income and age did not provide any evidence for a different response patterns by different subpopulations.

DISCUSSION

The study provides support for the thesis that Polish society does not consider that maximization of health outcomes should be

the sole criteria when making decisions concerning allocation of healthcare resources. All research questions were answered positively.

Strong support for the statements about equity (42 percent agreed and 44 percent strongly agreed) was confirmed by results of the trade-off experiments.

In the first experiment only 14.5 percent of responders preferred to maximize QALY gains (scenario 5), while a majority chose to distribute the available budget to both groups of patients irrespective of health benefits achieved. As many as 38 percent responders recommended that funds should be divided equally to all patients. Not only does experiment 1 support equal distribution of health outcomes instead of health maximization, but it also indicates that the Polish society is willing to limit public funding for therapies that improve quality of life to ensure available funding for therapies that treat life-threatening diseases. In total, 85.5 percent responders chose to treat fatal disease at the expense of nonfatal disease, with more than 30 percent of all answers supporting larger expenses for group B than group A (scenario 1 and 2), despite the larger size of group A. Of interest, there were no differences in response patterns across various socio demographic groups in experiment 1. A possible explanation is that a strong cultural identity has influenced Polish national preferences across sociodemographic characteristics.

The second experiment further demonstrates that Polish society altruistically supports more equitable distribution of health benefits instead of pure health outcomes' maximization. Even if treatment of group Y translated into patient Y living for 12 years longer compared with patient X, only 48 percent of responders prioritized treatment of patient Y. This indicates a preference for resources to be provided in areas where baseline outcomes are worse and supports the need to include disease severity in the P&R decision making process. The logistic regression revealed that an average responder is altruistically willing to lose one QALY for patient Y in the treatment effect to minimize the difference between both X and Y only with 7.7 months.

Of interest, there were no differences in response to trade off across various socio demographic groups. The results of the second experiment are in line with available empirical evidence that suggests that CEA's principle to maximize health gains contradicts with general public recommendations to treat severely ill patients ahead of others. For example, in a study by Cookson and Dolan (1999) public support in the UK was found for the "rule of rescue," which gives priority to those facing an immediate threat to life (13). The priority toward targeting the most disadvantaged rather than adopting the maximization principle was revealed in other studies (14–16). To address the importance of the severity of the initial condition, Nord developed a mathematical model that allows a trade-off between severity and treatment effect to be expressed in terms of equivalence of numbers for different outcomes (17). Similar modeling attempts by Dolan revealed that respondents equally valued a

health gain (measured on a utility scale) from 0.2 to 0.4 as a move from 0.4 to 0.8 (18).

Additional empirical research also suggests that other populations do not follow the health maximization principle of cost-effectiveness analysis. Dolan's review of published research indicated that people are willing to sacrifice quality of life gains to give priority to the most severely ill (9). In addition to that, Ubel found that majority of prospective jurors in Philadelphia chose to distribute funds equally between moderately and severely ill patients (19).

Published revealed preference studies further confirm these findings. In revealed preference studies, the observed decisions by decision makers, and the determinants of these decisions are studied. In a study on NICE recommendations and the determinants of these recommendations, Devlin and Parkin (2004) found that beyond efficacy and cost-effectiveness, uncertainty and the burden of disease are also predictive of rejection (20). In another revealed preference study based on 103 submissions to the PBAC in Australia, Harris et al. (2008) found that, for equal cost-effectiveness ratios, treatments for life-threatening diseases were more likely to obtain reimbursement than treatments for non-life-threatening diseases (21).

Our results reinforce the emerging interest in multi criteria decision analysis (MCDA) for pricing and reimbursement purposes. MCDA is commonly used to support decision making in many fields but has only recently being formally introduced to support consistent and transparent decision making in health care. It is considered as a potential powerful approach to better reflect societal values in decision making. Baeten et al. (2010) explored the use of different approaches, among which MCDA to better address the equity-efficiency trade-off in decision making and found MCDA to be a workable approach (22). The Australian effectiveness and equity framework (EEF) for evaluating health interventions summarizes relevant information about candidate intervention programs within a multi-criteria performance matrix for presentation to decision makers (23).

MCDA facilitates an important dialog and forces decision makers to think hard about what they value, why they value it, and in what context they value it. Yet, MCDA struggles itself with practical issues, not the least some misconceptions such as that the criteria and values have objective existence and that MCDA will help to solve the problem. It needs to be acknowledged that it remains in the first place a process that can help to better structure and explore decisions.

In the Belgian setting, the law prescribes that any decision on the reimbursement of a new drug for which added value (and a price premium) is claimed must be based on the cost-effectiveness, the budget impact, the size of the therapeutic added value and the social/therapeutic need (the latter including aspects such as burden of disease, and the life-threatening character). It is also in line with ongoing discussion about value based pricing for drug technologies in the United Kingdom as well. In the consultation document that was made public, it

was suggested that higher cost-effectiveness thresholds should be envisaged for greater burden of illness, severity and unmet need, for significant improvement versus current treatments, for health gain not captured by current evaluations because of measurement difficulties, and for wider societal benefits. In addition to that, a plethora of qualitative and quantitative methods are being widely discussed to allow for incorporation of value judgments in P&R decision making process. In the end, whatever approach is used, it will need to be in line with the "accountability for reasonableness" framework, which has been for years considered as a leading framework for fair priority setting (24).

Our study is not free of limitations. The framing of the questions may have had an impact on results (framing effect) (25). The results concerned hypothetical examples. Responders may behave differently in real life settings. There might be a risk that responders answered not according to their own beliefs but as they thought they should. However, even if respondents answered in this way, it could be argued that it still reflects a preference for how the healthcare system should act in a situation of difficult trade-offs. As the study captured a representative sample of Polish society, the results can be interpreted as a representative view of how Polish society believes that healthcare funding should be allocated in Poland.

There might be a reference point bias which makes people behavior dependent on settings in which a particular question is posed. Even if the questionnaire was tested in a pilot study, there might be a risk of heavy cognitive overload affecting the results as well. This particular issue is often discussed with regard to person trade off experiments. We do not know how carefully the respondents have considered the issues addressed by questionnaire. The opportunities to reflect at length or discuss the raised topics were also limited. It should be noted, however, that responses to the initial preference questions are consistent with the responses to the choice experiments and to previously published choice experiments. This indicates that the respondents understood the experiments and that the potential drawbacks listed are unlikely to affect the results of the analysis.

Nevertheless, it should be underlined that the approach adopted in this study does not allow for a full insight into public preferences and as such to inform P&R decision making process to a full extent. To accomplish such an objective, a follow up study with more in-depth qualitative interviews should be considered.

CONCLUSIONS

The study was designed to test the strength of the commitment of the Polish population to the QALY maximizing principle. To our knowledge, this study is a first attempt to classify other aspects that need to be taken into consideration during the decision making process concerning allocation of healthcare resources in Poland. It is in line with recommendations for research proposed by those experts who advocate for multicriteria models based

on social value judgments. They introduce a broader scope of criteria in decision-making process such as characteristics of patients and factors related to the characteristics of the treatment effect on patients' health. The authors hope that thanks to this study a similar public debate about social criteria to be used in pricing and reimbursement decision making process on a healthcare market may be initiated in Poland as well. It is envisaged that the result of the above study could be used a starting point for this discussion. Even if it does not provide enough evidence for any change in the P&R law, it should be regarded as sufficient materials for policy makers to initiate a process that will lead to better adjustment of the legal regulations to the revealed societal preferences.

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SUPPLEMENTARY MATERIAL

Supplementary Tables 1, 2, and 3 can be found online at: <http://dx.doi.org/10.1017/S0266462313000482>

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CONFLICTS OF INTEREST

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APPENDIX

Experiment 1

A responder could choose a total gain of 400 QALY gain for the cohort of patients with disease A and 0 QALY gain for the cohort of patients with disease B (scenario 5) or a total gain of 100 QALY gain for the cohort with disease B and 0 QALY gain for the cohort with disease A (scenario 1), or any combination of QALY gains for both groups with the total number of QALY gained between 100 and 400 (scenario 2 or 3 or 4). While scenario 5 provided the highest number of total QALYs gain, scenario 1 gave the lowest

number of QALYs. The results from this experiment show to what extent a responder was willing to forgo health maximization in order to achieve a more equitable distribution of health outcomes (research question 3). At the same time, the experiment tested whether a responder was willing to replace treatment improving quality of life by a four times more expensive life extending therapy (research question 2).

Experiment 2

The question was framed to assess responder's preferences for a choice between disease severity (a health status of group X in comparison with group Y) and health maximization (an available health improvement of group Y) (research question 1). At the same time, the experiment assessed the trade-off between equity (the more equal distribution of QALY's between patients' groups at baseline) and efficiency (the total number of QALY's achieved after treatment) (research question 3).

The following regression model was chosen:

$$\ln(P/(1 - P)) = \alpha + \beta_1 x_1 \quad (1)$$

In equation (1), P is the probability of choosing the group with longer life expectancy and x_1 is a marginal trade-off. The marginal trade-off was defined as the difference in QALYs between each group before treatment divided by the difference in QALYs between each group after treatment. This value will demonstrate the extent to which a responder is willing to forgo a QALY of health improvement for group Y in order to obtain any reduction in the QALY difference between group X and group Y before the treatment.

The probability that respondents would choose to allocate treatment to patients' group Y was expected to decrease with increase of marginal trade-off. Therefore x_1 was hypothesized to have a negative sign.

The median marginal trade-off is achieved when the probability of choosing Y is equal to 0.5 (i.e., 50% of the individuals would choose patients X and 50% would choose patients Y at that trade-off). Since the marginal trade-off variable was entered as a linear variable, the median marginal trade-off equals the mean marginal trade-off. Consequently, by setting the probability of choosing Y to 0.5 in Equation (1) it was possible to estimate the mean marginal trade-off:

$$x_1 = -\alpha/\beta_1 \quad (2)$$

The logistic regressions were estimated by the maximum likelihood method. In the previous studies performed by Johannesson and Gerdtham (20), marginal trade off turned out to be an influential, and statistically significant, factor in the choices made by respondents. Hence, tests were performed to assess whether the age, gender, education and income of responders differentiated the impact of marginal trade off on the choices made. Each sociodemographic variable x_j with pre-defined categories was combined separately with the marginal trade-off x_1 in a composite variable x_{ji} . Different regression models were developed for every x_j with separate composite items for each category of x_j entered as an explanatory variable. Each regression model was followed by specific significance tests for composite variables x_{ji} .

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