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- ОПРЕДЕЛЕНИЕ ПОРОГА «ГОТОВНОСТИ ПЛАТИТЬ» ПРИ ОДОБРЕНИИ МЕДИЦИНСКИХ ТЕХНОЛОГИЙ В УСЛОВИЯХ РОССИЙСКОГО ЗДРАВООХРАНЕНИЯ, РАССЧИТАННОГО НА ОСНОВЕ ПАРИТЕТА ПОКУПАТЕЛЬНОЙ СПОСОБНОСТИ
- ОРИГИНАЛЬНЫЕ РОССИЙСКИЕ ФАРМАКОЭКОНОМИЧЕСКИЕ ИССЛЕДОВАНИЯ

ASSESSING WILLINGNESS-TO-PAY THRESHOLD FOR HEALTH TECHNOLOGIES IN THE RUSSIAN FEDERATION ON THE BASIS OF PURCHASING POWER PARITY

Yagudina R.I., Kulikov A.Yu., Ugrekhelidze D.T.

Department of organization of medicinal provision and pharmacoeconomics, I.M. Sechenov First Moscow State Medical University of the Ministry of Health of the Russian Federation

Abstract: In this paper, the main methodological aspects of the willingness-to-pay analysis are highlighted. The values of the willingness-to-pay threshold according to the methodology of the World Health Organization are calculated, the ones of the Russian Federation and the countries of the Group of Twenty and the Commonwealth of Independent States were compared. The international experience of the calculation of willingness-to-pay threshold is covered. Advantages and disadvantages of various methods of calculation of the willingness-to-pay threshold are presented.

Key words: willingness-to-pay analysis, willingness-to-pay threshold, pharmacoeconomics, QALY, health economics, WHO, GDP, ICER, contingent valuation, welfare economics.

Relevance

Willingness-to-pay analysis is a universal tool for decision making in the healthcare. The peculiarity of this method is providing the results of the use of certain medical technologies in monetary terms. [1] Willingness-to-pay threshold (WTP) may vary depending on the country's economy, methods for the determination of the threshold and the nosology.[10] In addition, at present it is not clear which WTP is optimal for such indicators as LYG, QALY and DALY.[8]

This article will present all methods for the determination of the willingness-to-pay threshold, given their methodological justification and differences in the application. Definition of a WTP for the Russian Federation and comparison of this indicator with the WTPs of other countries according to WHO recommendations is currently important.

Willingness-to-pay analysis

The methodological basis of the willingness-to-pay analysis is the welfare economics - economic theory that studies how should be organized economic activity in order to maximize economic welfare of society. The theory uses value judgments to determine which goods to produce, how should be organized the production of how to distribute income and wealth in the present moment and in the future. [2] An important concept of this theory is the willingness-to-pay threshold, i.e. the amount (in national currency units of the country) that society is willing to spend to achieve a certain therapeutic effect or a surrogate endpoints for this category of patients.

Methods for the determination of the willingness-to-pay threshold.

There are several methods of the willingness-to-pay threshold determination: a survey (contingent valuation method, conjoint analysis), comparison with the results of the health technologies inclusion in a reimbursement lists and the method of determining WTPs according to the recommendations of the WHO's Commission on macroeconomics and Health

Economics, who later became widespread in all WHO's economic programs, in particular in the WHO-CHOICE. [3] In accordance with this procedure WTP is calculated by multiplying by three of the country's GDP calculated per capita.

Contingent valuation

In health economics, contingent valuation (CV) is a method of monetary valuation of health programs or health conditions, which gives the answer to the question what amount of money the respondents are willing to pay for gaining access to any program or achieve health. The purpose is to determine an individual's maximum willingness-to-pay for a certain condition or health programme, which usually does not have a market price through hypothetical questions. Another possible type of study is to determine willingness to accept (WTA), when compensation for the reduced state of health or lack of change is determined. Contingent valuation can be aimed to the following population groups: patient organizations, non-patients, decision-makers in healthcare and insurance companies.

Techniques to determine individuals maximum WTP include open-ended questions (in which the respondents are asked to directly state their maximum WTP), the so-called "bidding-game" (where respondents are given a first price for the good that is either accepted or rejected, and then the price is raised or lowered until the maximum WTP is reached), and the payment-card technique (where individuals choose a WTP amount from a range of suggested amounts on a card). With dichotomous questions each respondent accepts or rejects only one price for the good. Thus, the mean WTP can then be calculated as the area under the aggregate demand curve, and the median WTP is the WTP in which the probability of "yes" answer is 50 %. [9]

Dichotomous questions approach has the important advantage: it fully reflects daily process of decision-making during goods buying. During the payment-card technique the risk of systematic bias is much higher, and bidding-game is associated with starting point bias.

As an example of contingent valuation study authors choose the study of Hideo Yasunaga devoted to the willingness-to-pay estimation for mass screening for prostate cancer.[14]

In this study internet questionnaire survey in 400 men aged 50–59 from Japan was conducted. The questionnaire items included age, subjective assessment of health (five grades: very good/good/average/below average/bad). In the present survey, we added the items of family history of cancer, and history of receiving PSA screening questions. Despite this information questionnaire included two types of information sheets (A and B, describing the following evidence-based, objective facts):

1. Prostate cancer morbidity increases after age 50.
2. Biopsy is a standard method of close examination, which may entail hemorrhage or infections in a small percentage of participants.



3. The detection rate of prostate cancer screening is 0.93% in Japan.
4. In the PSA test, 10–20% of all negative results are proven false and 30–40% of all positive results are proven truly positive.
5. Approximately 20% of older Japanese males have latent cancer (i.e. cancer that is biologically insignificant).
6. The mortality-reducing effect of prostate cancer screening has not been clearly proven.

The respondents were randomly split into two groups and were provided with either Sheet A (facts 1-3) or Sheet B (facts 4-6), respectively. Each group was subdivided in relation with the first proposed price – X ¥ (X = 550, 1100, 3300, or 5500). A double-bound dichotomous choice approach was employed as the WTP elicitation method.

This survey aims to study academically the economic viability of cancer screening. There are no correct or wrong answers to the survey. Please answer the question with due consideration to the fact that paying for the screening will result in a reduction in the amount of money which can be used for other goods or services.

Assume that you can get a PSA screening for prostate cancer once a year on a chargeable basis. Would you be willing to pay ¥X for the screening? Select one of the following five choices:

- Yes, definitely;
- Yes, probably;
- I am not sure;
- No, probably not
- No, definitely not.

Only who chose «Yes, definitely» were meant to be agreed to pay the proposed price for the screening, other answers meant to be negative. It's important that «Yes, probably» was not included in results of WTP for reduction of «yea-saying bias». In case of price approval it was proposed to choose 1 level higher price, in case of decline – 1 level lower. Consequently, variants of prices in yens were the following: X = 220, 550, 1100, 3300, 5500 или 7700). As a result, data on the willingness to pay for the prostate screening was compared in group with positive and negative information in this procedure. The average willingness-to-pay for screening was 1670 ¥ (15,2\$). The difference between groups was not statistically significant. [14]

It should be noted that contingent valuation is still in the stage of usability assessment, as this method is rather subjective and often the healthcare decision-makers suppose incorrect to take decisions based on the opinion of limited population of patients and healthy people because of the differences in social status, illness severity and other factors.

Comparison with the results of the health technologies inclusion in a reimbursement lists

This method is used by the National Institute of Clinical Excellence (NICE). It represents the inclusion of drugs in the National healthcare system on the basis of retrospective analysis of own experience. To justify the introduction of medical technologies the quality-adjusted life-year (QALY) is used, which is considered as a universal indicator of the different interventions use for health in certain subgroups of patients. Currently NICE uses WTP threshold from 20,000 to 30,000 pounds per QALY, [4,5] however, the organization may include health technologies with higher thresholds in condition of getting additional data about its innovativeness and the need for its use. For example, there are the cases of inclusion of technologies for rare diseases (incidence of 1 case per 50,000 people and less NICE classification), cases with WTP equaling 200 000-300 000 £ per 1 QALY and of medical technologies that require lifetime use of 40 000 £ per 1 QALY. [6].

Australia

In Australia, the WTP threshold is used in the following way. The Ministry of health receives requests on the inclusion of drugs in the reimbursement list of the State program of pharmaceutical benefits. Pharmaceutical Benefits Advisory Committee conducts pharmacoeconomic evaluation of health technology, during the decision-making the therapeutic value of health technology, safety, budget impact analysis results are considered. Despite the fact that legally the value of willingness-to-pay threshold is not stated, retrospective analysis of the adoption of new health technologies from 1993 to 2004, conducted by scientists Henry and colleagues showed that the mean value of the WTP in Australia is 69 900 AU\$/QALY. [15]

Canada

Despite the fact that official data on the cost-effectiveness ratio is required during making decisions about new health technologies since

1996, the information about the approved values of the willingness-to-pay threshold are not detected on the official website of the Canadian Agency for drugs technology and health (CADTH) and in the recommendations of this organization.

During information retrieval the authors drew attention to the research of Canadian scientist Laupacis and his colleagues who calculated that health technologies with a value of 20 000 ICER below CAN\$/QALY will be reimbursed in the healthcare system of Canada, and a technology with an ICER of 100 000 CAN\$/QALY will be rejected by healthcare of Canada. [16]

In the 2008 study Rocchi and colleagues conducted a review of all decisions on reimbursement of drugs taken by the Advisory Committee of the Common Drug Review from 2003 to 2007 to assess the role of threshold willingness-to-pay decisions. From 62 applications, the ICER threshold was used in 25 cases, including 12 negative recommendations and 13 positive ones. Approved drugs had ICER equal to 80 000 CAN\$/QALY. In the rejected applications threshold ranged from CAN\$32 000/QALY up to CAN\$137 000/QALY. Based on these data the authors stated that the ICER threshold value is not an absolute criterion during making decisions in the Canadian health care system. However, the authors suggested that the discrepancy in values may be caused by increased importance of other criteria when considering drugs, received a positive recommendation.[17]

USA

For the first time in the USA., the willingness-to-pay threshold was calculated in 1982 for drugs for the treatment of renal failure under Medicare programme. This value was 50 000 US\$/QALY. Scientists King and Roberts supposed that noting the inflation currently this amount equals 95 000 US\$/QALY, however, some experts continue erroneously to use a figure of 50 000 US\$/QALY in their calculations. [19]

Recently scientist Braithwaite and colleagues published an article in which they considered the applicability of value US\$50,000/QALY in the current environment of health. The lower threshold of social WTP for life year gained (LYG) was estimated by calculating the incremental value of the use of medical technology (has been calculated the amount of incremental costs and the rate of decrease in mortality). They performed a simulation of costs and clinical outcomes for the entire population of the United States. The upper limit of social WTP for 1 year of extended life (LYG) were calculated as the unwillingness of the interviewed people to pay for insurance. The approach implies that the unwillingness of the individual to pay for insurance (even at high income) is a social WTP threshold. Costs and economic benefits associated with insurance were simulated to obtain the values of ICER. According to Braithwaite and colleagues the lowest WTP is \$183 000/LYG, and the upper value of the WTP is \$264 000/LYG. When account is taken of indicator of the quality of life the following results were obtained: the lower the value of WTP was \$109 000/QALY, and the upper limit is \$297 000/QALY.[19]

Despite the presence of several large studies on the calculation of the WTP for the USA, the Centers of insurance programmes Medicare and Medicaid refrain from using the united threshold willingness-to-pay when making decisions about reimbursement of health technologies.

Determination of WTP for Russia and other countries using 3 GDP method of World Health Organization

This method was the Commission on macroeconomics and Economics of health of WHO in 2002. This technique was used in the WHO report dedicated to the health status of the population (The World Health Report) and became the basis of the WHO program - WHO-CHOICE. In accordance with this procedure GDP is calculated by multiplying by three of the country's GDP, calculated per capita. It should be noted that although this method of calculation uses the calculation of DALYs (years of life, adjusted for disability) and not QALY, which is more typical of the world practice for pharmacoeconomic studies, the method of determining the willingness-to-pay threshold for a long time is indicative for healthcare decision-making in different countries. [1]

WTP for Group of Twenty countries and Commonwealth of Independent countries ones was calculated using 3 GDP method of World Health Organization.

According to Rosstat, the population of the Russian Federation is 146 267 288 people [11], while the GDP at the beginning of 2015 amounted to 71 406 billion (1 073 128 million \$ at the exchange rate on 26.09.2015). Dividing GDP by the population and multiplying by 3 we get that the willingness-to-pay threshold for Russia at the beginning of 2015 is 1 464 565 rubles (\$22 010 in terms of the dollar from 26.09.2015). Data on GDP of other countries are taken from the official site of the International monetary Fund [12], the data on

population was obtained from the statistical databases of the studied countries [13]. The results of this analysis are shown in tables 1 and 2. Exchange rate at the beginning of 2015 was 1\$ = 66 RUR.

During information retrieval it is found that in majority studies of the willingness-to-pay threshold analysis are most commonly used GDP calculations using gross domestic product valued at purchasing power parity. This method of calculation helps to get more unbiased data during GDP comparison. The purchasing power parity means the ratio of the two or more currency units, currencies of different countries, mounted on their purchasing power for a given basket of goods and services. According to the theory of purchasing power parity, for the same amount of money, converted at the current exchange rate of the national currency, in different countries you can buy the same amount of goods and services in the absence of transport costs and restrictions on the transport. It should be noted that in the report of the WHO Commission on macroeconomics and health Economics from 2001 («Macroeconomics and Health: Investing in Health for Economic Development») values of willingness to pay are calculated using GDP at PPP.

This study shows the WTP values calculated using the two types of GDP, however, the authors believe that the willingness-to-pay threshold, expressed through PPP is more objective decision-making tool.

Table 1. WTP of the Group of Twenty countries according to the GDP International Monetary Fund

| | Country | GDP (millions \$) | Population (people) | GDP per capita (\$) | WTP (3*GDP), \$ |
|----|----------------|-------------------|---------------------|---------------------|-----------------|
| 1 | Australia | 1 453 770 | 23 785 000 | 61 134 | 183 402 |
| 2 | USA | 17 419 000 | 320 668 000 | 54 324 | 162 972 |
| 3 | Canada | 1 786 655 | 35 702 707 | 50 043 | 150 128 |
| 4 | Germany | 3 852 556 | 80 925 000 | 47 607 | 142 820 |
| 5 | United Kingdom | 2 941 885 | 64 800 000 | 45 399 | 136 198 |
| 6 | France | 2 829 192 | 66 109 000 | 42 796 | 128 388 |
| 7 | Japan | 4 769 804 | 126 910 000 | 37 584 | 112 752 |
| 8 | European Union | 18 460 645 | 506 998 000 | 36 412 | 109 235 |
| 9 | Italy | 2 144 338 | 60 788 845 | 35 275 | 105 826 |
| 10 | South Korea | 1 410 382 | 51 342 881 | 27 470 | 82 410 |
| 11 | Saudi Arabia | 746 248 | 31 521 418 | 23 674 | 71 023 |
| 12 | Argentina | 540 197 | 43 131 966 | 12 524 | 37 573 |
| 13 | Brazil | 2 346 118 | 204 148 000 | 11 493 | 34 479 |
| 14 | Mexico | 1 282 719 | 121 005 815 | 10 600 | 31 801 |
| 15 | Turkey | 799 534 | 77 695 904 | 10 291 | 30 872 |
| 16 | China | 10 360 105 | 1 369 210 000 | 7 567 | 22 700 |
| 17 | Russia | 1 073 128 | 146 267 288 | 7 337 | 22 010 |
| 18 | South Africa | 349 817 | 54 002 000 | 6 478 | 19 434 |
| 19 | Indonesia | 888 538 | 255 461 700 | 3 478 | 10 434 |
| 20 | India | 2 066 902 | 1 269 735 000 | 1 628 | 4 884 |

Table 2. WTP of the Group of Twenty countries calculated according to GDP of World Bank valued at PPP (April 2015) and data on population (2015).

| | Country | GDP (millions \$) | Population (people) | GDP per capita (\$) | WTP (3*GDP), \$ |
|----|--------------------|-------------------|---------------------|---------------------|-----------------|
| 1 | USA | 17 419 000 | 320 668 000 | 54 321 | 162 963 |
| 2 | Saudi Arabia | 1 606 000 | 31 521 418 | 50 949 | 152 848 |
| 3 | Australia | 1 095 000 | 23 785 000 | 46 037 | 138 112 |
| 4 | Germany | 3 722 000 | 80 925 000 | 45 993 | 137 980 |
| 5 | Canada | 1 592 000 | 35 702 707 | 44 590 | 133 771 |
| 6 | Great Britain | 2 549 000 | 64 800 000 | 39 336 | 118 009 |
| 7 | France | 2 581 000 | 66 109 000 | 39 042 | 117 125 |
| 8 | Japan | 4 751 000 | 126 910 000 | 37 436 | 112 308 |
| 9 | European Union | 18 526 000 | 506 998 000 | 36 541 | 109 622 |
| 10 | Italy | 2 128 000 | 60 788 845 | 35 006 | 105 019 |
| 11 | South Korea | 1 779 000 | 51 342 881 | 34 649 | 103 948 |
| 12 | Russian Federation | 3 749 561 | 146 267 288 | 25 635 | 76 905 |
| 13 | Argentina | 948 000 | 43 131 966 | 21 979 | 65 937 |
| 14 | Turkey | 1 508 000 | 77 695 904 | 19 409 | 58 227 |
| 15 | Mexico | 2 141 000 | 121 005 815 | 17 693 | 53 080 |
| 16 | Brazil | 3 264 000 | 204 148 000 | 15 988 | 47 965 |
| 17 | South Africa | 705 000 | 54 002 000 | 13 055 | 39 165 |
| 18 | China | 17 617 000 | 1 369 210 000 | 12 867 | 38 600 |
| 19 | Indonesia | 2 676 000 | 255 461 700 | 10 475 | 31 425 |
| 20 | India | 7 376 000 | 1 269 735 000 | 5 809 | 17 427 |

Purchasing power parity conversion factor is the number of units of a country's currency required to buy the same amount of goods and services in the domestic market as a U.S. dollar would buy in the United States. The ratio of PPP conversion factor to market exchange rate is the result obtained by dividing the PPP conversion factor by the market exchange rate. The ratio, also referred to as the national price level, makes it possible to compare the cost of the bundle of goods that make up gross domestic product (GDP) across countries. It tells how many dollars are needed to buy a dollar's worth of goods in the country as compared to the United States.

According to the latest data issued by the World Bank, the purchasing power of the Russian ruble for 1 U.S. dollar is 19,95 rubles. [20] The Latest data of Rosstat in 2013 represented a value of 18,4 rubles. [21] The world famous journal the Economist estimated the value of the Russian currency in 22 rubles per dollar, using «Big Mac index». [22] In this study authors used the values of the World Bank, as the reported values of GDP are taken from the database of this organization.

In the calculations according to the GDP by PPP for 2015 (purchasing power parity) World Bank of the Russian Federation WTP is 76 905 \$.

Comparative analysis of the WTP indicators for the CIS countries was also performed. During the calculation of WTPs for CIS countries data from the local ministries of Finance and statistical databases was used to obtain more accurate data for the simulation of the current economic situation in the region. Method of WTP calculation remained unchanged. As a result, the first place of the willingness-to-pay threshold in dollar values is in Republic of Kazakhstan (\$24 099), followed by the Russian Federation (\$22 010), and the lowest WTP value was observed in Tajikistan (\$2 694). Despite the fact that Russia has the highest GDP compared to most of the countries, due to

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the large population (9th in the world) Russia lags behind most developed countries in WTP which is less than in Australia in 8 times, but more than WTP India to 4.5 times.

During the calculation of WTP per 2015 World Bank data was used (PPP) and in this figures Russia has for 2015 year a 76905 \$ threshold being ahead of Kazakhstan (71 827 \$) and Belarus (54 425 \$). Noting the unstable economic situation, high speculative trends, and using international experience of WTP calculation we can say that WTP calculation using PPP is more appropriate.

Table 3. Willingness-to-pay threshold of the CIS countries using nominal GDP

| | Country | GDP (millions \$) | Population (people) | GDP per capita (\$) | WTP (3*GDP), \$ |
|----|--------------------|-------------------|---------------------|---------------------|-----------------|
| 1 | Kazakhstan | 141 263 | 17 585 500 | 8 033 | 24 099 |
| 2 | Russian Federation | 1 073 128 | 146 267 288 | 7 337 | 22 010 |
| 3 | Azerbaijan | 62 081 | 9 593 000 | 6 472 | 19 415 |
| 4 | Belarus | 43 955 | 9 481 000 | 4 636 | 13 909 |
| 5 | Armenia | 9 506 | 3 013 900 | 3 154 | 9 462 |
| 6 | Ukraine | 72 938 | 42 910 885 | 1 710 | 5 131 |
| 7 | Moldova | 5 535 | 3 557 600 | 1 556 | 4 668 |
| 8 | Uzbekistan | 55 293 | 31 025 500 | 1 782 | 5 347 |
| 9 | Kyrgyzstan | 5 737 | 5 895 100 | 973 | 2 920 |
| 10 | Tajikistan | 7 102 | 7 910 041 | 898 | 2 694 |

Table 4. Willingness-to-pay threshold of the CIS countries using GDP valued at PPP

| Country | GDP (millions \$) | Population (people) | GDP per capita (\$) | WTP (3*GDP), \$ |
|--------------------|-------------------|---------------------|---------------------|-----------------|
| Russian Federation | 3 749 561 | 146 267 288 | 25 635 | 76 905 |
| Kazakhstan | 418 000 | 17 458 500 | 23 942 | 71 827 |
| Belarus | 172 000 | 9 481 000 | 18 142 | 54 425 |
| Azerbaijan | 165 000 | 9 593 000 | 17 200 | 51 600 |
| Ukraine | 371 000 | 42 910 885 | 8 646 | 25 937 |
| Armenia | 24 300 | 3 013 900 | 8 063 | 24 188 |
| Uzbekistan | 172 000 | 31 025 500 | 5 544 | 16 631 |
| Moldova | 17 700 | 3 557 600 | 4 975 | 14 926 |
| Kyrgyzstan | 19 200 | 5 895 100 | 3 257 | 9 771 |
| Tajikistan | 22 300 | 7 910 041 | 2 819 | 8 458 |

Evaluation of the results of pharmacoeconomic analysis based on the willingness-to-pay threshold

Based on the threshold willingness-to-pay obtained above, the results of pharmacoeconomic analysis are estimated as follows: if incremental costs do not exceed the WTP as a new health technology can be considered cost-effective for widespread implementation. Therefore, these drugs may be automatically included in the list of the Essential Drug Coverage, Vital and essential medicines and «7 nosologies». New health technology will be considered acceptable if the incremental costs exceeds the WTP, but do not exceed twice the WTP. Borderline is acceptable if WTP is exceeded twice, but not exceeded three times the WTP, and unacceptable for the application, if incremental costs are exceed three times the WTP.

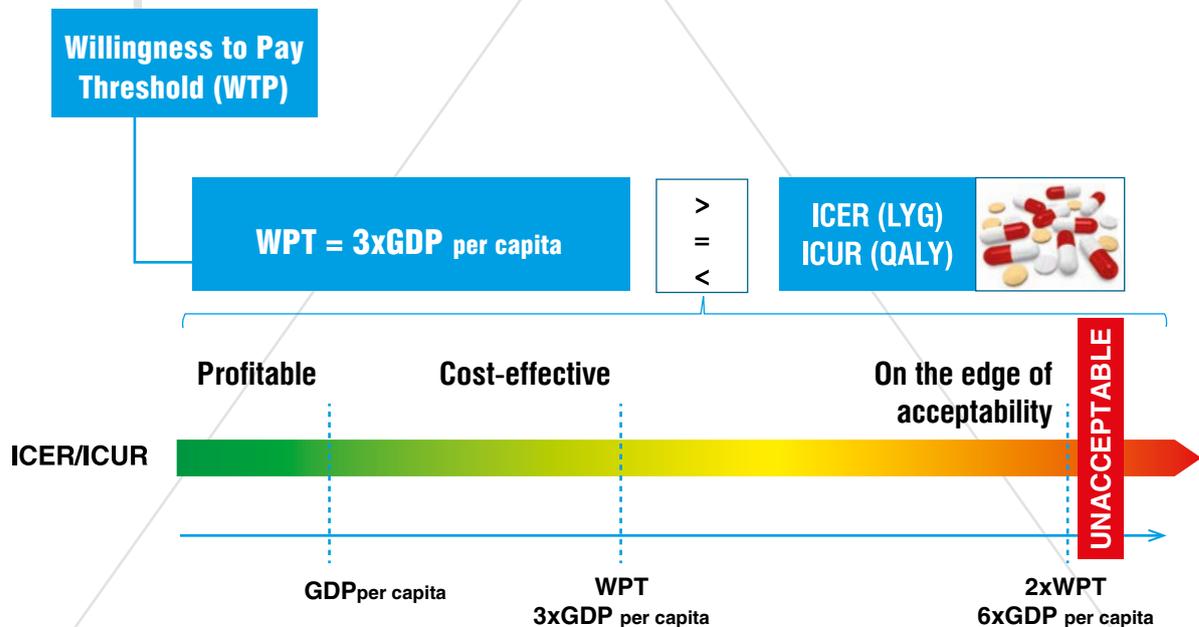


Figure 1. Evaluation of the results of pharmacoeconomic analysis based on the willingness-to-pay threshold

Conclusion

The analysis revealed main ways of calculating the WTP threshold used in decision making in the healthcare systems of different countries. Willingness to pay analysis for the Russian Federation in accordance with the methodology of the World Health Organization according to the results of the comparative analysis revealed that the willingness-to-pay threshold for the Russian Federation is 22 010 \$ (1 452 660 rubles according to the current rate 1\$ = 66 rubles). In the calculations using GDP at purchasing power parity WTP is 76 905 \$ (1 531 178 on the basis of purchasing power parity or ruble to dollar - 19,96 according to World Bank). This study shows the WTP values calculated using the two types of GDP, however, the authors believe that the willingness-to-pay threshold, expressed through PPP is more unbiased decision-making tool. Due to the small WTP in Russia, to increase pharmacoeconomic efficiency of foreign drugs are offered three ways: reducing the cost of the drug, the approval of drugs in certain categories of patients and the distribution of risks.

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