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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

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PHARMACOECONOMIC ANALYSIS OF MEDICAL CARE FOR CHRONIC RENAL DISEASE PATIENTS IN NEED OF RENAL REPLACEMENT THERAPY VIA PERITONEAL DIALYSIS AND HEMODIALYSIS IN THE RUSSIAN HEALTHCARE ENVIRONMENT

Abdrashitova G.T., Yagudina R.I., Serpik V.G.,

Laboratory of Pharmacoeconomic Research, I.M. Sechenov First Moscow State Medical University of the Ministry of Health of the Russian Federation

Abstract: *In the framework of the presented study, we have performed a pharmacoeconomic analysis of medical care for chronic kidney disease patients who need renal replacement therapy via peritoneal dialysis and hemodialysis. The study results demonstrates that the aggregate costs of peritoneal dialysis therapy, on the average, are lower than those of hemodialysis by 12 % due to the lower costs of treatment of the chronic kidney disease and renal replacement therapy related complications and lower indirect costs due to longer preservation of the capacity for work. Peritoneal dialysis demonstrated higher clinical effectiveness and lower aggregate costs and, as consequence, lower cost-utility ratio, i.e. demonstrated the advantages over hemodialysis.*

Key words: *chronic kidney disease, end-stage, renal replacement therapy, peritoneal dialysis, hemodialysis, pharmacoeconomic analysis, effectiveness, quality of life, cost-utility analysis, budget impact analysis, sensitivity analysis.*

Chronic kidney disease (CKD) is one of the most common conditions in the world among chronic noninfectious diseases from the incidence and cost of treatment point of view. CKD is a progressive loss in renal function over a period of three months and more [1]. CKD can progress to end-stage kidney failure that requires continuous renal replacement therapy or transplant. End-stage renal disease (ESRD) is characterized by breakdown in the quality of life, induces invalidization and disablement and requires high-cost renal replacement therapy (RRT) techniques.

There are three types of RRT:

1. Hemodialysis (HD) is a technique of extracorporeal blood refining by means of artificial filter (the dialyzer). When using the hemodialysis, also called "the artificial kidney", removal of waste products such as uremic toxins and free water from the blood is being maintained. Routine hemodialysis is conducted in a dialysis outpatient facility, either a purpose built room in a hospital or a dedicated, standalone clinic. The length of each exchange is 4-5 hours; treatment is given 3 times a week. Hemodialysis is an intermittent therapy; this results in accumulation of toxins and excess fluid in the body between dialysis sessions. Besides, a patient with end-stage renal failure cannot leave the place where his or her local dialysis facility is located.

2. Peritoneal dialysis (PD) is an RRT method based on principles of diffusion, filtration and convection transfer of toxins and liquids from blood to dialyzing solutions placed in patient's peritoneum. Process of blood refining is intracorporeal and continuous that is physiologically closer to normal kidney function. Despite HD, PD can be maintained in-home, that results in patients keeping ability of greater flexibility and preservation of employment.

3. Kidney transplantation (KT) is a radical RRT method that is the organ transplant of a donor kidney into a patient with end-stage renal disease. However, because of a shortage of organs available for donation, a long transplant waiting list and high cost technology, this RRT method is less available both in the Russian Federation (RF) and in other countries.

While debating the specifics of pathogenesis of the end-stage kidney disease and the specifics of treatment of patient with this disease, it is necessary to underline the importance of the quality of life. Patients with end-stage renal disease depend on the dialysis procedure, medical equipment, staff, nutritional and liquid requirements, and medicine, and suffer from disablement and restricted mobility. Further stresses associated with this method of treatment are a need in a vascular access which, in many cases, is visible for others, surgical implantation of a permanent catheter and need in its re-implantation in the event of complications [34].

It is important to realize that each of the RRT modalities described above has its indications and contraindications which should be taken into account when choosing the therapy method for a particular patient. Currently, so called an integrative approach to RRT is widely used in the international nephrological practice [4-8].

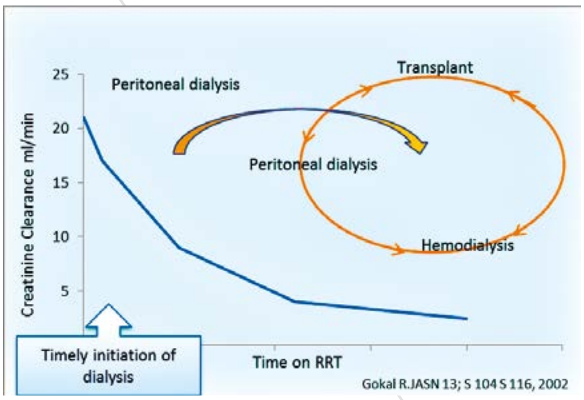


Figure 1 shows an integrative care approach for end-stage renal disease patients

suggested by Gokal R [9]. According to this concept if both PD and HD are available for patients, then PD should be considered as a first-choice treatment that allows maximum preservation of a residual kidney function. Usually, a patient is treated with PD for 3-4 years with the following transfer to HD or transplantation, if this method is available. The prime objective of the integrative care approach is to prolong, as much as possible, life and improve the quality of life in patients with end-stage renal failure that, according to the international retrospective data, is possible only when combining different RRT types [4-9]. Besides, in his study "An Evaluation of an Integrative Care Approach for End-Stage Renal Disease Patients" Wim Van Biesen et al. notes than PD is an optimal first-choice RRT modality for the significant population of end-stage renal disease patients, as PD treatment allows preserving the residual renal function for a longer time, that is, undoubtedly, one of the key advantages of this dialysis mode [10-14]. Accordingly, in the absence of absolute contraindications (abdominal adhesions, drainage, abdominal wall suppurative diseases, mental illnesses), PD should be regarded as the first-choice therapy.

It should be noted that end-stage renal disease morbidity is steadily increased all over the world. Thus, the study by Liyanage et al. testified that 2.6 million people are treated with RRT all over the world. However, the meta- analysis data and further extrapolation to the world-wide population demonstrates that the actual number of patients requiring RRT exceeds the current level of RRT availability in 2–3 times; about 2.3 million patients will die prematurely because of the lack of access to RRT. According to the forecasts by Liyanage, by 2030, the number of people treated with RRT all over the world will increase to 5.4 million [2]. According to the Russian Dialysis Society (RDS), the annual rates of patient's population increase in the RF equals 8.7% that also proves the increase in incidence rate and end-stage renal disease morbidity [3].

The PD to HD ratio varies in different countries. For example, PD is used with 75-78% of end-stage renal disease patients in Mexico and Hong-Kong, 22-25% - in South Korea and Great Britain and 30% - in Canada. In turn, the share of PD in the general dialysis population in the USA, Japan, Germany, France and Italy does not exceed 10% [15]. Such a difference is associated both with the historical practice and financing of the system of the Ministry of Health.

According to the RDS reports, the HD share in the RF dialysis therapy structure prevails and makes 91.5%, whilst the PD share is 8.5% only [3]. It should be noted that RRT belongs to the cost-consuming and hi-tech types of health care for which tariffs are established on the regional level. As the RF consists of 85 constituents varying in the level of development, uniform prices for HD and PD are absent; this makes significant differences in the quality and availability of treatment of patients in different regions.

The data for different RF regions, that as of the beginning of year 2015 had approved and officially published in government sources tariffs for both HD and PD exchanges, as shown in Fig 2, proves that the rates significantly vary by size and, as consequence, by the range and scope of services included. For example, the price for one 1 HD session varies from RUB 3,557 in Astrakhan Region to RUB 6,596 in Khabarovsk Territory. The median of the cost of one HD session in the RF amounts to RUB 5,000. The cost of one PD exchange varies from RUB 319 in Tula Region to RUB 812 in Chelyabinsk Region. The median of the cost of one PD exchange in the RF amounts to RUB 620. Thus, the prices for PD and HD significantly vary in different RF regions, sometimes, in several times.

Taking into account the current situation in the RF, when the healthcare resources are limited and the cost of RRT is relatively high, optimization of the health care of end-stage renal disease patients from the viewpoint of the health care system is a priority task for the health care policy makers [16]. Pharmacoeconomic analysis is one of the important tools in choosing more clinically and economically effective therapy. From the above reasoning, a pharmacoeconomic analysis of health care costs of patients with chronic kidney disease, who need renal replacement therapy via peritoneal dialysis and haemodialysis, is an urgent question for the Russian healthcare system.

Materials and Methods

The analytical decision making model has been developed for this pharmacoeconomic study. To build the model, retrospective data on the end-stage renal disease patient population, health care structure and effectiveness as well as direct and indirect costs of therapy were used. PD and HD were chosen as subjects of analysis, as these therapies are more common in the RF. The analytical decision making model allows performing a pharmacoeconomic analysis with regard to the health-care system budget in whole, including direct and indirect costs, or from the viewpoint of the budget of a medical and preventive treatment facility with a dialysis center, where direct costs are included only [17, 18]. In this article, we include the results of modeling with regard to the the health-care system budget in whole. The study was conducting using the following methods: effectiveness analysis, cost analysis, modeling, cost-utility analysis, budget impact analysis and sensitivity analysis.

The first stage of this pharmacoeconomic study included a retrospective analysis of clinical effectiveness which included of selection of criterion of effectiveness and search for effectiveness values relevant for the RRT types under study [19]. Relevant foreign publications were searched in the database PubMed, Medlink, Cochrane, and Russian-language publications – in the database "Russian Medicine" of the Central Medical Research Library of the I.M. Sechenov First Moscow State Medical University, elibrary.ru, free search engines (Yandex, Google).

The quality-adjusted life year (QALY) being a generic measure of disease burden, including both the quality and the quantity of life lived, was chosen as the effectiveness criteria. Nowadays QALY is widely used utility criteria showing qualitative and quantitative life estimation for patient's point of view. QALY is a significant criteria either for the researches in assessing the value for money of a medical intervention, or the decision makers [17-20].

The next stage of pharmacoeconomic study was the analysis of costs, both direct and indirect (Fig. 3).

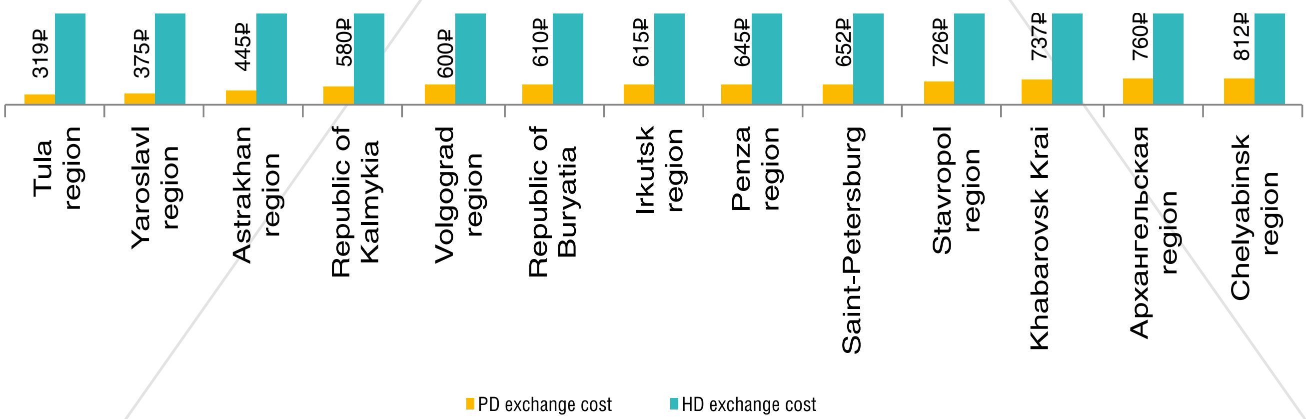


Figure 2 Fixed PD and HD exchange tariff rates in different regions of RF

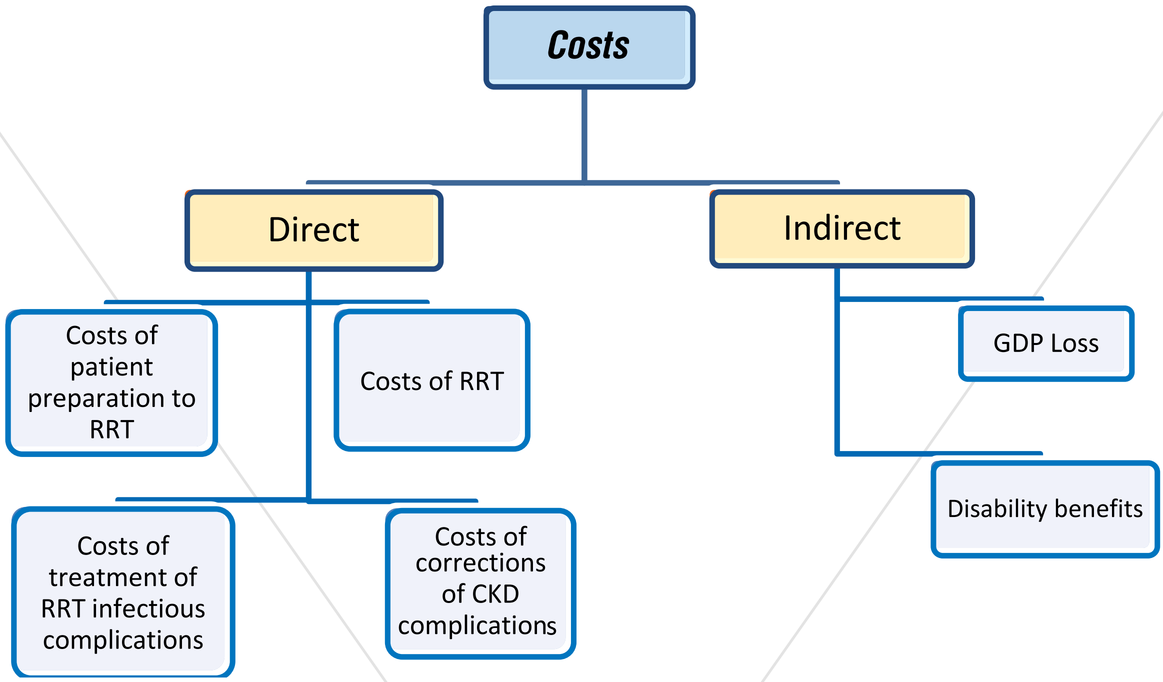


Figure 3 Structure of costs included in the presented study

Direct costs included the costs of patient preparation to RRT and the costs of RRT as such. Besides, both the costs of treatment for RRT infectious complications and CKD complications were included subject to the incidence thereof. Indirect costs included lump sum disability benefits, disability annuities (subject to the degree of disability) and GDP loss because of the disablement of patients of economically active age. In this study, as sources of prices for medical services and pharmacotherapy, we used the prices of the Compulsory Medical Insurance Fund, registered prices for the essential drug list (EDL) products and data from aptechka.ru for drugs not included in the EDL [21, 22].

The next step of the pharmacoeconomic study was the cost-utility analysis (CUA) on the basis of the costs of treatment of one patient with end-stage renal disease. CUA can be considered a special case of cost-effectiveness analysis (CEA), and the effectiveness is measured in the units of "utility" from the viewpoint of a health care consumer. The purpose of CUA is to estimate the ratio between the cost of a health-related intervention and the benefit it produces in terms of the number of years lived in full health by the beneficiaries. The results of cost–utility analysis are expressed as ratios to be calculated by the following formula:

CUR= Cost/QALY, where:
CUR – Cost-Utility Ratio
Cost - Total costs of the comparable treatment regimen (RUB);
QALY – Quality adjusted life year

The next step was the budget impact analysis that allows determining the amount of finance required to implement the health technology and comparing it to the available healthcare system budget [23, 24]. The budget impact analysis is conducted using the following formula:

BIA = Cost1 - Cost2 , where:
Cost1 - total costs of the first treatment regimen, RUB;
Cost2 - total costs of the second treatment regimen, RUB;
BIA - Budget Impact Analysis, RUB.

The pharmacoeconomic study included the sensitivity analysis of the degree of reliability of the study results [17].

It is important to note that, in this study, a cohort was represented by hypothetic population of end-stage renal disease patients without contraindication both to PD and HD and with dialysis being first prescribed. The time horizon was equal to one year. Because of the small time horizon and lack of relevant evidence, transferred between the RRT was not taken into account. Risks of complications were regarded as constant throughout the time horizon.

Results and Discussions

Analysis of Effectiveness

In the course of the cost-effectiveness analysis, we identified and compared different effectiveness criteria used in evaluation of dialysis modalities in clinical studies. Such criteria included the incidence of RRT complications, incidence of CKD complications, preservation of ability to work, risk of access failure and re-creation, and quality of life. All of the analyzed criteria for each of the technologies are summarized in Table 1.

We conducted search of information and found a unique direct comparative study by Sennfält K. et al. with the results of evaluation of the quality of life of PD and HD patients. To evaluate the quality of life of dialysis patients, we used EuroQol health questionnaire, a facility for the measurement of health-related quality of life. According to the study data, the utility of PD was 0.65 and the utility of HD was 0.44 [25].

The data on preservation of ability to work in dialysis patients were obtained from the study by Julius M. et al. The purpose of the study was to compare the preservation of ability to work by PD and HD patients. In this study, it was established that the rate of the preservation of ability to work by PD patients was 27.4%, while only 9.6% of all of the HD patients are able to work [26].

After the study of such literature as the National CKD Guide and clinical studies and expert interviewing, we identified a list of CKD and RRT complications to be included in our analysis [1]. The data from Table 1 show that the CKD complications included anemia and secondary hyperparathyroidism. The RRT complications included costs of PD peritonitis treatment and sepsis treatment in HD patients.

The data on incidence of anemia and secondary hyperparathyroidism in end-stage renal disease patients were taken from the reports of the Russian Dialysis Society [3]. As no data on incidence of RRT complications were identified in Russian sources, relevant information was obtained from the published work by Ai-Hua Zhang et al. [27, 28]. The data on access failure and re-creation in HD patients were obtained from the reports of the Russian Dialysis Society; however, because of lack of information on PD, the data on the average frequency of re-implantations was taken from several foreign studies [3, 29-33].

Table 1. **Effectiveness analysis results**

Utility Indicator	**PD**	**HD**	**Source**
QALY	0.65	0.44	[25]
Effectiveness criteria and safety	**PD**	**HD**	
Preservation of ability to work, %	27,4	9,6	[26]
Incidence of CKD complications, % - secondary hyperparathyroidism - anemia	 0,89 0,875	 0,95 0,915	 [3] [3]
RRT complications rate, % - sepsis - peritonitis	 - 14	 10 -	 [27, 28] [27, 28]
Risk of access failure and re-creation, %	14	40,2	[3, 29-33]

Incidence of CKD and RRT complications as well as risk of access failure and re-creation were used in the direct costs analysis, while preservation of ability to work was used in the analysis of indirect costs.

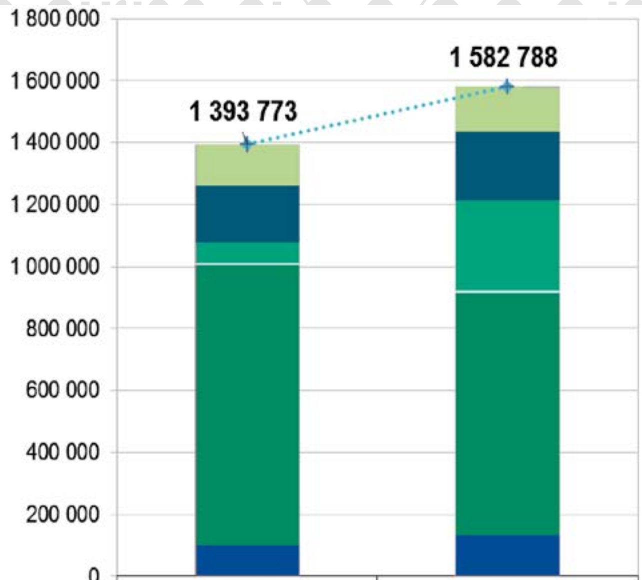
Cost Analysis

The nest step of the study was the estimation of direct costs of treatment of end-stage renal disease. The costs of preparation of end-stage renal disease patients for HD or PD were calculated on the basis of the Standard of Pre-Dialysis Special Medical Care in End-Stage Renal Disease in Hospitalization for the Purpose of Preparation to RRT considering the need in re-creation in PD and HD [35]. The standard covers diagnostics, medical attendance and follow-up by different medical specialists, laboratory and instrument tests and examinations, surgery, non-medicinal prophylaxis and pharmacotherapy. As is seen from Fig. 4, the costs of preparation of a patient for PD therapy are lower than HD due to cost of creation of a HD arteriovenous fistula making RUB 10,300, while the cost of PD catheter insertion makes RUB 2,400. It should also be noted that access re-implantation in HD occurs more frequently as compared to PD, 40.2% and 14% cases, respectively; this significantly increases the costs of preparation of a patient to HD.

The costs of RRT included the costs of HD and PD medical procedures only and were calculated exclusively on the basis of the price list of the Compulsory Medical Insurance Fund and RRT regimen data according to the international clinical recommendations (European guide on optimal hemodialysis practice 2002, NHS-NICE 2011, KDOQI 2009) and instructions of dialysis solutions use, according to which HD patients were given treatment 3 times a week and PD patients - 4 exchanges daily on average, that is 28 exchanges a week.

Then, we determined the costs of CKD- and treatment-related complications. The costs of correction of CKD-related complications were determined on the basis of the common scheme: PD "peroral ferrum + epoetin alpha", HD "iron sucrose injection + epoetin alpha", where the average dose of erythropoetin in HD and PD patients were taken from the annual report of the UK Renal Registry, taking into account that, on the average, the erythropoetin doses given to PD patients are three times as less [35, 36, 37].

The estimation of indirect costs included calculation of costs of disability benefits and monthly payment in cash that depend on the degree of disability patient [38]. In model-building, we admitted an assumption that a half of patients with end-stage renal disease were assigned Disability Class 1 and another half of patients were assigned Disability Class 2. On the basis of the data of CKD morbidity among the economically active population and average per capita gross domestic product (GDP), we assessed the GDP loss because of the disablement of patients with end-stage renal disease. As the mean age of CKD dialysis patients, according to the Russian Dialysis Society, was 47, every other patient was regarded as a patient of economically active age. Per capita GDP was taken from the data of the RF Federal State Statistics Service for 2014 [39].



	ПД	ГД
Disability benefits	133 480	145 582
GDP Loss	180 379	224 605
Costs of corrections of CKD complications	68 876	290 878
Costs of treatment of RRT infectious complications	6 466	7 263
Costs of RRT	905 200	782 143
Costs of patient preparation to RRT	99 371	132 318
Total costs	1 393 773	1 582 788

Figure 4 Cost analysis of annual costs per one typical patient

The data from the costs analysis demonstrates that the aggregates costs of treatment of ESRD patients consist mainly of RRT, for both PD and HD. The annual average costs of PD treatment of one typical patient are lower by 12 % as compared to HD treatment; this results from the lower costs of treatment of CKD- and RRT-related complications and lower indirect costs due to longer preservation ability to work.

Cost-Utility Analysis

According to the available data on the utility of technologies used, we performed modeling with the one year time horizon. In this study, cost-utility ratios for comparable regimens of treatment of end-stage renal disease patients were determined (Fig. 5).

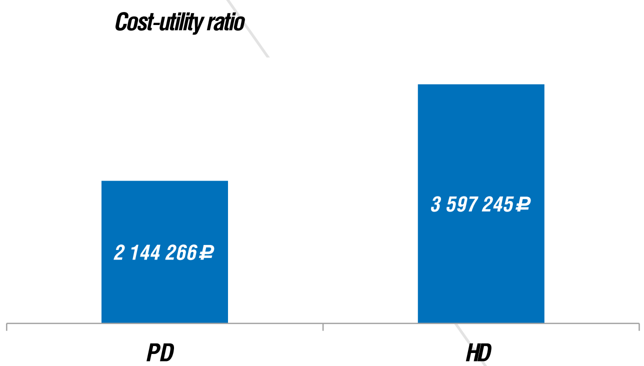


Figure 5 Annual cost-utility ratios per patient

The shown above, PD approach is a dominant technology characterized by lower costs and higher clinical effectiveness resulting in the lower cost-utility ratio.

Budget impact analysis

The budget impact analysis conducted as a part of the pharmacoeconomic study allowed forecasting change in the budget of treatment of end-stage renal disease patients provided with access to PD. In view of the above, we suggest that two scenarios should be discussed: current scenario when the PD and HD population corresponds to the RRT actual practice and taken from reports of the Russian Dialysis Society, and foreseeable scenario with the one-to-one PD to HD treatment ratio.

In this Article contains the budget impact analysis results for the Russian Federation in whole, and, for the purpose of illustration of adaptivity of the analysis results, the results for Tula Region and Chelyabinsk Region, where there is the greatest difference both on PD tariffs and the distribution of patients among the dialysis types. The budget impact analysis scenarios are presented in the table 2.

Table 2. **Budget impact analysis scenarios**

Regions	Share of Patients, %			
	Current Distribution		Predictive Distribution	
	PD	HD	PD	HD
Tula Region	14	86	50	50
Chelyabinsk Region	2	98	50	50
Russian Federation	8,5	91,5	50	50

Above figures 6, 7 and 8 demonstrate that the transfer of 50% of patients to PD therapy results both in savings of the RF budget in whole of RUB 1 752 738 457 that makes 5.2%, and budgets of the regions (in this particular case, the budget of Tula Region for RUB 20 069 046 (13.1%) and Chelyabinsk Region for RUB 19 061 779 (1.7%)). As a result of the budget impact analysis demonstrate that transfer of 50% of patients to PD therapy of end-stage renal disease patients allows budget savings up to 13%. It should be noted that, notwithstanding different prices in the regions, the results remain invariant for the significant amount of regions.

Sensitivity Analysis

Sensitivity analysis is a mandatory procedure in a pharmacoeconomic study and is used to evaluate the stability and adequacy of the conclusions made in the course of a study. This study was conducted using the two-factor sensitivity analysis in which two variables are changed simultaneously. This type of analysis is used when both selected variables are key ones and there is a definitely high of variation thereof. In the course of analysis, we have established that the prices for PD and HD are factors which influence the results of the pharmacoeconomic study most of all. Therefore, we studied the effects of change in the prices on the results of the pharmacoeconomic study when the price for HD was decreasing and the price for PD was increasing simultaneously.

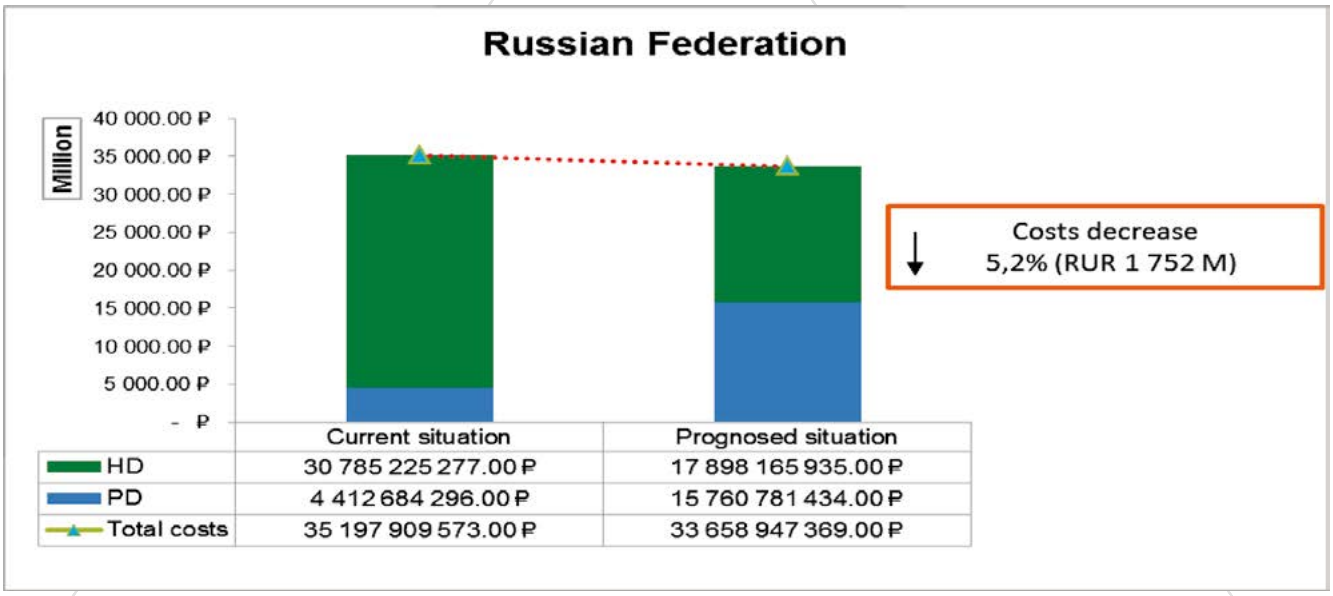


Figure 6 Budget impact analysis results as exemplified by the Russian Federation in whole

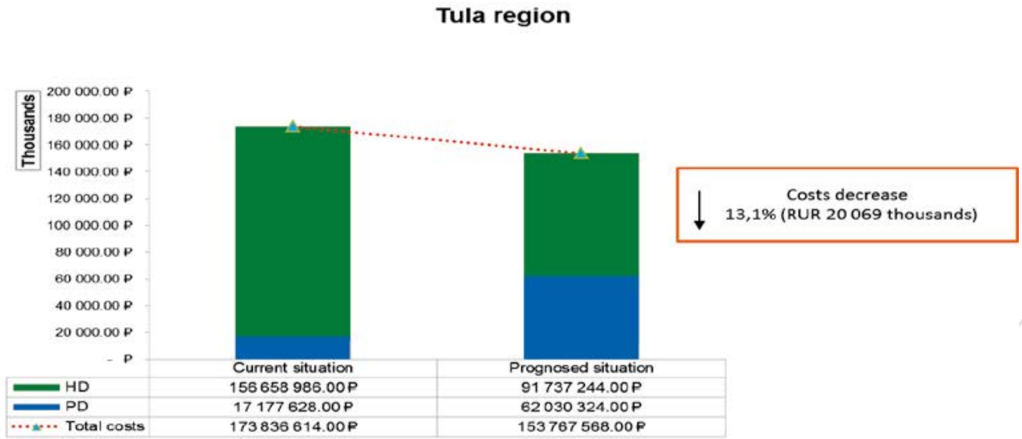


Figure 7 Budget impact analysis results as exemplified by the Tula Region

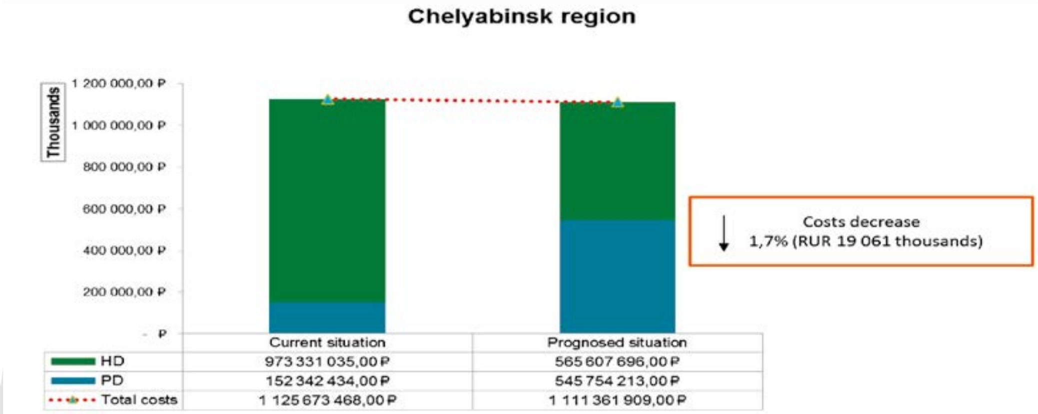


Figure 8 Budget impact analysis results as exemplified by the Chelyabinsk Region

Changing parameter	Type	8,5%	0%	-8,5%
Tariff	PD	RUB 672	RUB 620	RUB 567
	HD	RUB 5 425	RUB 5 000	RUB 4 575
Costs per patient per year	PD	RUB 1 290 335	RUB 1 393 772	RUB 1 136 451
	HD	RUB 1 424 665	RUB 1 582 787	RUB 1 291 701

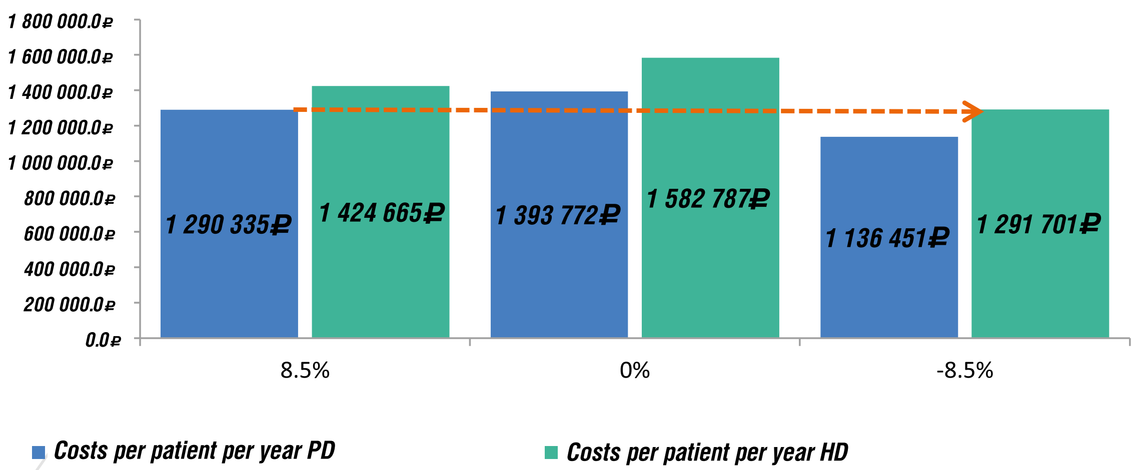


Figure 9. Sensitivity analysis data

The sensitivity analysis data demonstrate that the conducted pharmacoeconomic analysis is adequate and the data and the cost analysis data are stable. PD preserves an advantage over HD throughout the variation range of these two factors from +8.5% to -8.5%. (Fig. 9).

Conclusion

The cost analysis demonstrates that the aggregate annual costs of treatment of one typical PD patient are lower than those of HD treatment, on the average, by 12 % due to the lowers costs of treatment of CKD and RRT-related complications and lower indirect costs due to the longer preservation of ability to work. The cost–utility analysis data demonstrate that PD is a dominant modality with lower costs, higher clinical effectiveness and, as consequence, lower value of the cost–utility ratio. The budget impact analysis demonstrates that transfer of 50% of patients to PD allows saving up to 13% of healthcare budget with a view to the entire patient population annually. The sensitivity analysis proves the stability of the pharmacoeconomic study data.

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