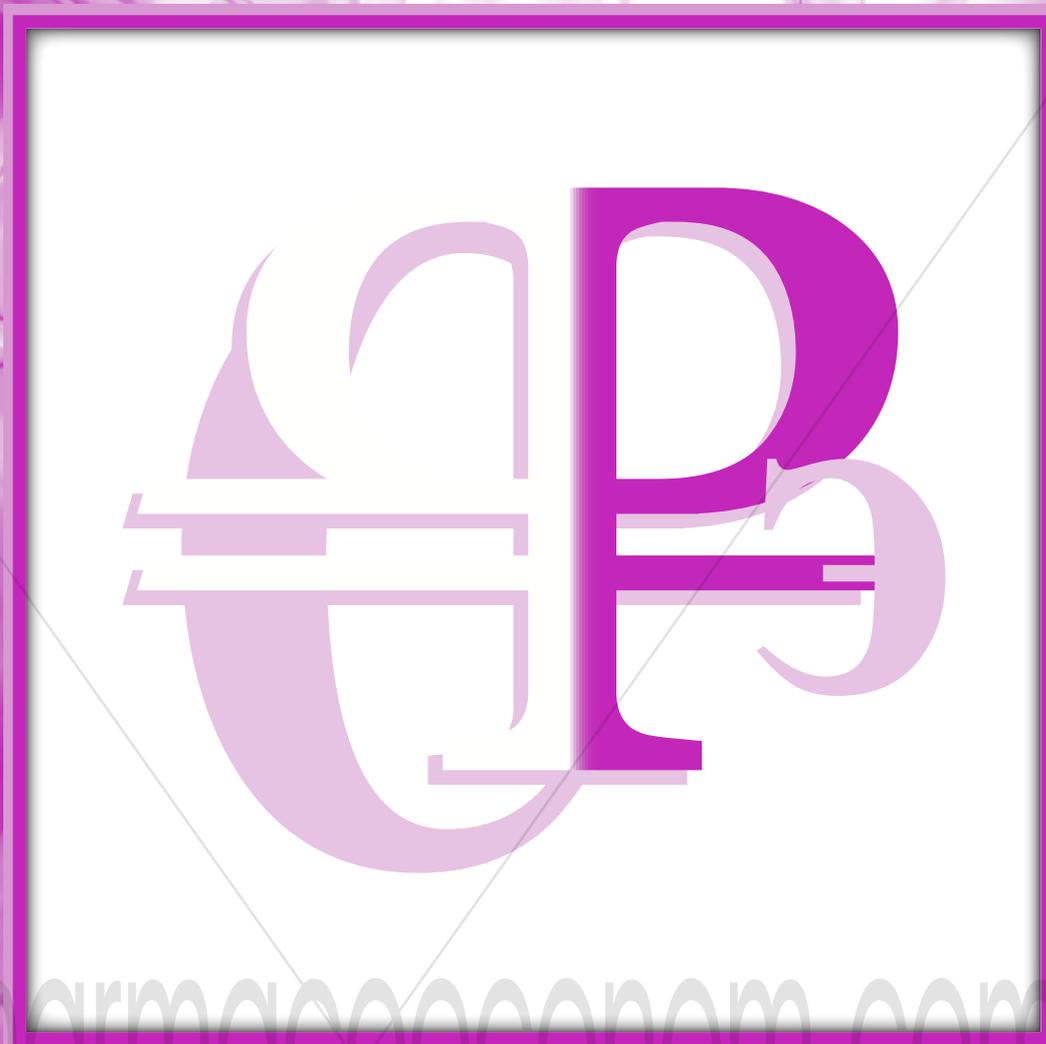


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- **IX НАЦИОНАЛЬНЫЙ КОНГРЕСС С МЕЖДУНАРОДНЫМ УЧАСТИЕМ «РАЗВИТИЕ ФАРМАКОЭКОНОМИКИ И ФАРМАКОЭПИДЕМИОЛОГИИ В РОССИЙСКОЙ ФЕДЕРАЦИИ»**
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- **ОРИГИНАЛЬНЫЕ РОССИЙСКИЕ ФАРМАКОЭКОНОМИЧЕСКИЕ ИССЛЕДОВАНИЯ**

ECONOMIC BURDEN OF MULTIPLE SCLEROSIS IN THE REPUBLIC OF BELARUS

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Abstract: In this article the economic burden of multiple sclerosis in the Republic of Belarus is presented. Analysis is performed using calculation direct and indirect costs.

Key words: Republic of Belarus, multiple sclerosis, economic burden, economic impact, cost analysis, direct costs, indirect costs, first call, specification of costs.

Multiple sclerosis (MS) is a disease of the central nervous system, affecting the brain and spinal cord during inflammatory demyelinating process, i.e. the process of destruction of the myelin sheaths that insulate nerve fibers. As a result of demyelination and scarring of damaged tissue conduction of impulses from the brain and back to him largely deteriorates, leading to the development of various symptoms depending on the localization of these lesions. The disease is characterized by the manifestation of a multitude of randomly distributed foci, which differ in the degree of aggravation. There is the standard of medical care to patients with MS in the Republic of Belarus, approved by the order of Ministry of health of the Republic of Belarus dated 19.05.2005, No. 274 allocate 2 to the degree of manifestation of the disease: multiple sclerosis debut (first appeal) and for remitting (exacerbation of multiple sclerosis 2 severity) [10].

Multiple sclerosis is a disease of young people, which develops, as a rule, in women of 25-35 years and in men of 35 to 40. MS half to two times more often affects women. The disease is accompanied with frequent hospitalizations and disability of patients [10]. In the Republic of Belarus the overall incidence is about 41 cases per 100 000 population [2].

This article provides an assessment of the economic burden in the Republic of Belarus in connection with the conduct of MS patients. Direct and indirect costs were taken into account.

Analysis of the economic burden was conducted on the basis of standards of medical care to patients with MS in the Republic of Belarus, official statistical publications. The proportion of patients with the first treatment and remitting course (2 degrees) and degree of disability were taken from the publication, describing the analysis of cost of illness of multiple sclerosis in real clinical practice in the Russian Federation. To convert the results obtained in foreign currency is used exchange rates as of 01/12/2014 [1,3,4,5,11,12]. To select a source of data on the cost of medical services were analyzed rates 3 health institutions, namely: 5 city clinical polyclinic Minsk, Mogilev regional hospital,

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and Children's polyclinic №1 of Grodno. The prices were comparable, but in the end it was decided to use data Mogilev regional hospital, due to the fact that in their price list (price list refers to the tariffs for the provision of health services in a health facility) presents all the necessary services for managing patients with MS [8].

Brief description of the health system of the Republic of Belarus

After obtaining an independence by the Republic of Belarus, the healthcare system has maintained a state structure, which allows to realize every citizen the right to health protection and free medical care.

The main source of financing of the health system in the Republic of Belarus are state funds generated from tax revenue. Amount of funding available depends on the economic situation in the country and also on the amount of funds received in the form of taxes. Every year, there is a tendency to increase budget spending on health care.

In this industry there is a system of financing expenditures per capita, this policy has been used to reduce disparities in the distribution of funds through the territories of the Republic.

Total expenditure on health care of the Republic of Belarus for all sources of financing in 2012 is about 6% of GDP, the share of public spending is about 4% of GDP [7].

Methodology of cost analysis

From the perspective of pharmacoeconomic analysis of the «disease burden». Cost is the monetary value spent on therapy resources in monetary terms. There are several types of classification included in pharmacoeconomic costs, but most often is used the division of costs into direct and indirect

Direct costs (DC) are charges directly related to disease or therapy. It resources it resources that are used only in the event of a disease and nothing else. Direct costs are divided into medical (direct medical costs) and non-medical (overhead).

Thus, the direct medical costs include:

- ✓ costs for diagnostic, therapeutic, rehabilitative and preventive health services, procedures and treatments;
- ✓ the costs of essential drugs and medicines required for the correction of side effects of the therapy;
- ✓ costs for the maintenance of the patient in hospital;
- ✓ fee for the use of medical equipment, space and resources (allocation of fixed costs of budget items), etc



Direct non-medical costs include:

- ✓ the cost of non-medical services provided to patients at home (e.g., services social services)

Indirect costs (IC) - are costs that are indirectly associated with the disease or intervention, most often due to temporary or permanent disabilities of the patient. Also in some sources referred to as «indirect costs.»

Indirect costs include:

- ✓ costs for temporary disability leave, , benefits and employment disability pension and other social benefits to the patient, provided by the law;
- ✓ social payments to the relatives of the patient who needs constant care due to temporary incapacity for work;
- ✓ loss of gross domestic product associated with the disease (economic losses from reduced productivity in the workplace)

Indirect costs associated with lost resources that were not incurred in connection with the disease of the patient, most often evaluated through the loss of gross domestic product, and directly through welfare payments.

Based on the classifications of costs were assessed the economic burden of the Republic of Belarus on the conduct of MS patients. The stages of the assessment are presented in figure 1.

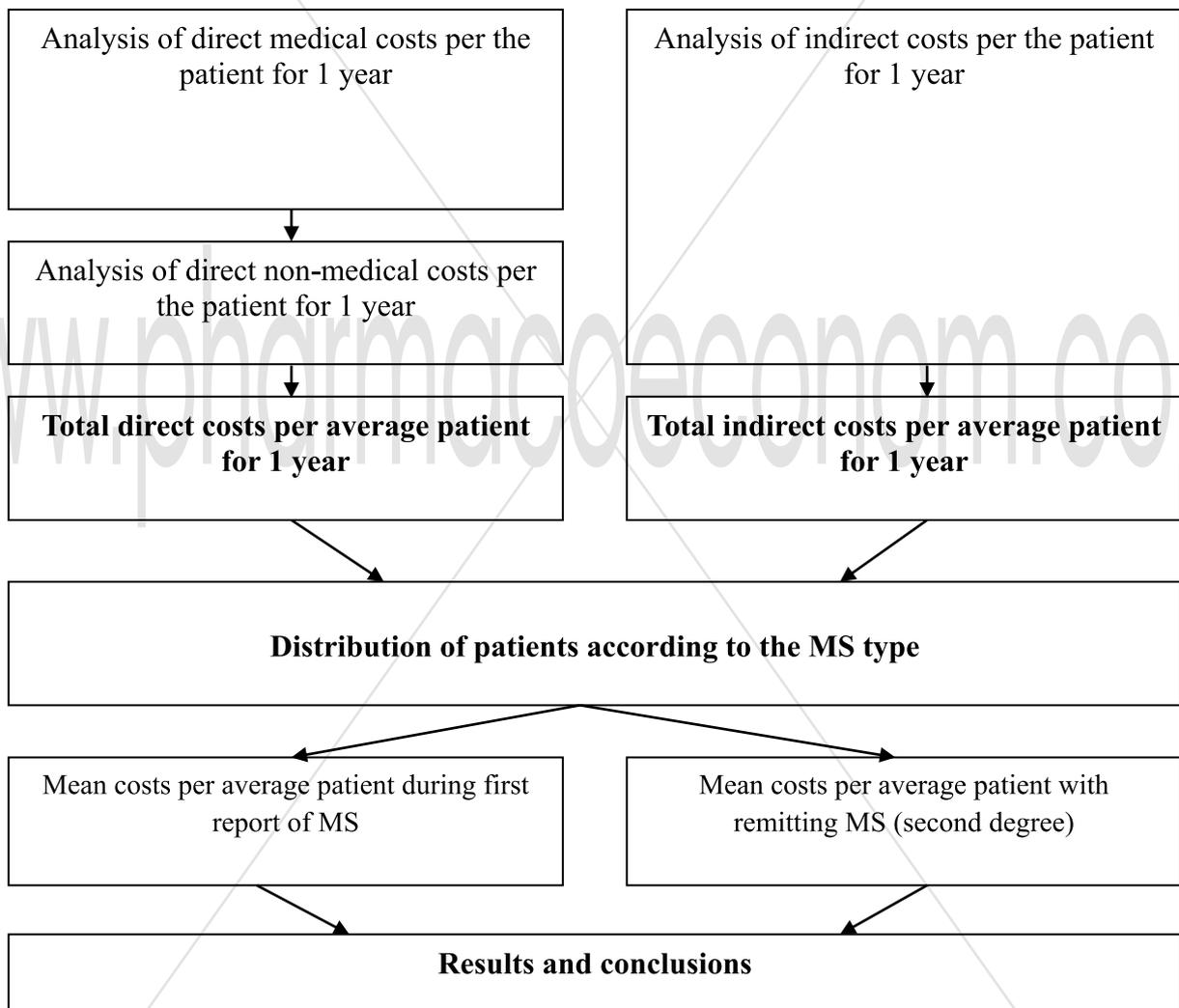


Figure 1. Scheme of cost analysis during estimation of burden of disease of multiple sclerosis in the Republic of Belarus

The analysis was conducted based on the standard of medical care to patients with MS in the Republic of Belarus. The standard has a division of medical services for a functional purpose (diagnosis, treatment and pharmacotherapy). In the case of diagnosis and therapy specify type of service, frequency and average number of service delivery. The frequency and average amount of service is determined by the expert developers taking into account evidence of effectiveness, safety and economic viability, as well as practical experience.

Frequency assignment services reflects the average number of its destination. Frequency can take values from 0 to 1, where 1 means that all 100% of patients it is necessary to provide this service.

Data on the size and structure of medical services, including diagnostic procedures, presented in the manner described in the standard are allowed to conduct their economic evaluation. To estimate the cost of such medical services, including diagnostic and medical procedures that were applied to the following formula:

$$C = \text{Price}(C) * P(S) * n(S)$$

$$\text{Cost}(S) = \sum \text{Price}(S) * P(S) * n(S)$$

Cost(S) – the cost of medical treatments, RUB.

Price (S) - the cost of medical treatments, RUB.

P(S) – the rate of medical procedure prescriptions;

n(S) – the number of units of provided medical procedures.

Using up to date at the time of the study the pricelist of services of the Mogilev regional hospital, costs were calculated on a separate diagnostic procedure.

The total cost of the examination of the patient was estimated as the sum of costs for all diagnostic procedures

$$\text{Cost}(S) = \sum \text{Price}(S) * P(S) * n(S) = \text{Cost}1 + \text{Cost}2 + \dots + \text{Cost}n$$

Then similarly evaluated therapy patients including medical and drug therapy, according to the type of flow RS that are contained in the standard. Regimen, documented in the standard, were calculated for a specific time period that is specified in the standard. In the same way the costs of hospitalization at the hospital for 20 days and the continuation of the course of outpatient treatment is 28 days. The method of estimation of costs for medical services in the treatment of patients in outpatient and inpatient units similar to the assessment of costs for diagnostic procedures and meant the same approaches and formulas.

The duration of the courses of medications and frequency of side effects was determined on the basis of their instructions for use. The calculation of the cost of pharmacotherapy was conducted as the product of the price of the drug on the course dose, as reflected in the number of packages of medicinal products.

The total cost of drug therapy was estimated as the sum of costs for all drugs specified in the standard of medical care.

$$\text{Cost}(S) = \text{Cost}(\text{Drug}1) + \text{Cost}(\text{Drug}2) + \dots + \text{Cost}(\text{Drug}n)$$

After completing the evaluation of all functional groups of the medical services included in the standard for estimating the total cost of the disease as the sum of all costs.

$$C(\text{total}) = C(\text{diagnostics}) + C(\text{medical service}) + C(\text{drug therapy})$$

Indirect costs were defined as the sum of indirect costs and lost revenues. In the first place was estimated lost GDP from temporary disability. The calculation was made as follows:

$$C(\text{GDP}) = (\text{GDP}/\text{EAP})/\text{WD} * \text{MDD}$$

C(GDP) - GDP loss per one person

GDP – total GDP per year

EAP - economically active population

MDD - mean days of disability

WD - amount of working days per year

GDP losses due to the forced withdrawal of labour was calculated

as follows:

$$C(\text{GDP}/\text{year}) = \text{GDP}/\text{EAP}$$

Loss due to lost GDP, because of the refusal of the patient's relatives to care for the sick was considered similarly.

Expenses for the payment of disability benefits per person are considered as the product of the sum of monthly allowance for 12 months. Similarly, costs were calculated in the payment of benefits to relatives caring for patients.

Payments for temporary disability were calculated as the product of average payout in one day by the number of days in sick leave.

The costs of services of a social worker was determined based on the average annual income of a social worker.

In total the sum of all the above parameters forms the «burden of disease»[10].

1. Direct medical costs

In the first place were estimated direct costs direct management of patients in health care institutions (HCI), including the costs of diagnosis and treatment of patients, as well as the stay of patients in hospital or rehabilitation Department.

1.1 Diagnosis outpatient

Diagnosis at the stage of admission in LPU included the inspection specialists (therapist, optometrist), laboratory tests (General analysis blood and urine, ALT+AST+bilirubin+urea+total protein) and analysis using instrumental techniques (electrocardiography and radiography of the chest).

It was further estimated the total cost of all diagnostic procedures for each patient as the sum of costs for all diagnostic procedures.

The average cost of diagnosis in primary care depending on the type were as follows (in year):

- The first treatment for multiple sclerosis - 209 200 rubles.
- Remitting (2nd stage aggravation) - 209 200 rubles.

1.2 Diagnostics at the stationary stage

In a similar way to estimate the cost of diagnosis of patients at the outpatient stage. It included the same diagnostic procedures as outpatient and analysis to determine creatine serum, albumin, immunological blood tests, MRI of brain and spine with contrast enhancement. Some of the procedures of diagnosis are assigned according to the testimony, such as: counseling therapist, gynecologist, otolaryngologist, echoencephalography, evoked potentials of the brain of one modality [1].

The average cost of diagnostics during inpatient treatment depending on the type of flow in the year amounted (in case of the frequency assignment of additional procedures and the existence of complications equals 15%):

- First call for medical service for multiple sclerosis - 971 684 rubles.
- Remitting duration (2nd stage aggravation) - 711 009 rubles. [11].

Excess almost 37% of the cost of diagnosis of the patient's inpatient treatment compared to outpatient during the first call due to the fact that to establish a correct diagnosis must undergo a greater range of treatments.

1.3 Staying in MPI

The cost of stay was calculated as the product of the value of one day of detention in accordance with the Pricelist of me «Mogilev regional hospital» and length of stay in days according to the register of patients.

The average length of stay of patients in hospitals was 20 days, the price of a bed-day - 92 200 rubles.

The average cost of a stay in the center depending on the type of flow in MS per year

- First call for medical service for multiple sclerosis - 1 844 000 rubles.
- Remitting duration (2nd stage aggravation) - 1 844 000 rubles.

1.4 Therapeutic services

Therapeutic treatments consisted of intravenous laser irradiation of blood, hyperbaric oxygenation (HBO), therapeutic plasmapheresis. these procedures were prescribed only in the direction of the patient in the Republican center for complex diagnostic cases[1].

The average cost of therapy (provided that a part of difficult diagnostic cases makes up 15%) stationary phase per patient depending on the type of flow in the year

- First call for medical service for multiple sclerosis - 480 300 rubles
- Remitting duration (2nd stage aggravation) - 480 300 rubles. [11].

1.5 Pharmacotherapy at inpatient therapy stage

Pharmacotherapy includes more than 15 drugs, the main ones were glucocorticoids - such as methylprednisolone, prednisone, dexamethasone, and other drugs were used as collateral for the relief of side effects, including: reversal of neurological disorders, the manifestation of hyperimmune status, poor coordination, tremor, dizziness, increased muscle tone and dizziness [1].

Source of data on the cost of drugs was the retail selling prices for the



medicines (database of electronic resource www.tabletki.by), because the database of tenders for the procurement of the Republic of Belarus had limited access [6].

The average cost of pharmacotherapy on the stationary phase depending on the type of flow in year is as follows:

- First call for medical service for multiple sclerosis - 457 663 rubles.
- Remitting duration (2nd stage aggravation) - 461 187 rubles.

1.6 Pharmacotherapy at the outpatient stage

At this stage, we calculated the annual cost of drug therapy received by the patient on an outpatient basis.

Pharmacotherapy outside the hospital was estimated in a similar way as pharmacotherapy in stationary conditions using the same calculation formulas. At this stage, was used similar products, the difference is in the duration of the course, since the average duration of treatment inpatient treatment lasted for 20 days, and outpatient treatment lasts for 28 days, this leads to differences of effective indicators.

The average cost of drug therapy outside of a hospital setting depending on the type of flow in year is as follows:

- First call for medical service for multiple sclerosis - 1 153 323 rubles.
- Remitting duration (2nd stage aggravation) - 1 451 643 rubles.

Pharmacotherapy during exacerbation of second-degree requires nearly 26% higher than at the onset of multiple sclerosis due to the increase in the number and extent of side effects that are specified in the standard, thus, it entails an increase in the spectrum of drugs used.

1.7 Direct non-medical costs

It was further evaluated by direct non-medical costs in the form of expenses for services of a social worker. The average cost for the services of a social worker for one patient (based on electronic resource www.belstat.gov.by provided that the proportion of patients who are forced to seek the services of a social worker is 6%) was equal to 4 219 804 rubles [5,11].

Table 1. Direct costs for patients with multiple sclerosis maintenance in the Republic of Belarus

| Type of costs | Belorussian rubles (p.) | US Dollars (\$) |
|------------------------------------|-------------------------|-----------------|
| Diagnostics (outpatient) | 209 200 | 19 |
| Diagnostics (inpatient) | 867 414 | 80 |
| Maintenance of patients in MPI | 1 844 000 | 169 |
| Pharmacotherapy (stationary) | 459 073 | 42 |
| Pharmacotherapy (afterwards) | 1 272 651 | 117 |
| Therapy | 480 300 | 44 |
| Payment for social worker services | 4 219 804 | 388 |
| Total: | 9 352 442 | 860 |

As can be seen from data presented in the table, the average cost of conducting one patient at level 9 352 442 rubles (\$860 USD (provided that the proportion of patients with the second degree of aggravation is 40%) [11].

The visual structure of direct costs is presented in figure 2.

You should pay attention to the fact that the largest share of expenditures goes to pay for the services of a social worker and is 45% of the direct costs, and pharmacotherapy for inpatient and outpatient - 19%, respectively.

2. Indirect costs

For the analysis of indirect costs for the management of patients with multiple sclerosis the following parameters were set:

- the proportion of patients who received 3 disability degree, 39%;
- the proportion of patients who received 2 degree of disability - 21%;
- the proportion of patients who received 1 the degree of disability is 10%;
- the proportion of patients who were forced to abandon the work - 39%;
- the proportion of patients whose relatives were forced to abandon the work, with the aim of wooing patients - 14% [11];
- average number of days of disability due to illness - 20 [1].

2.1 Costs for disability benefits

Source of data on the average size of pension disability was the electronic

database of the site www.minsk.gov.by. Depending on the degree of disability the average pension was expressed in the following amounts:

- 1) III stage - 785 648 rubles per month
- 2) II stage - 890 401 rubles per month
- 3) I stage - 1 152 283 rubles per month

Also included allowances to relatives caring for patients. The average benefit for the care of the disabled of the 1st group was 1 047 530 rubles [4].

The average cost for the payment of disability benefits and benefits to care for a sick family member per year is \$ 7 303 383 rubles, or \$671, in turn, the average payoffs to care for a sick relative - 1 759 850 rubles, or \$162, respectively.

2.2 GDP loss due to temporary disability

To analyze the economic burden of the loss of incapacity, refusal to work and the office assessed the value of GDP per person in a year and a day on the 2013 figures. According to the Federal service of state statistics of the Republic of Belarus, the total GDP in 2013 equals 636784 billion; the number of economically active population of the Republic of Belarus - 4,569 million. Using these data, were defined as GDP per capita per year, as the annual GDP of the number of the economically active population. Annual GDP per capita is at the level of 139 541 370 rubles, or \$12 810[5].

Average GDP losses in connection with temporary disability of patients with multiple sclerosis a year is estimated at 11 061 154 rubles, or \$1 017 per person.

2.3 GDP losses due to the forced cancellation from work

The magnitude of the economic burden of forced refusal to work in the year of the MS patients was defined as GDP per capita per year.

Average GDP losses due to forced failure patients from work is \$ 54 354 . In turn, the average GDP losses due to the forced giving up of relatives with the purpose of caring for a year at level 19 511 876 rubles, or \$1 793 per person.

Thus, the total indirect costs per patient of multiple sclerosis patients in the year amounted to 122 429 409 rubles, or \$11 253 (table 2).

Table 2. Mean indirect costs per 1 patient with multiple sclerosis for 1 year

| | Belorussian rubles (rubles) | US Dollars (\$) |
|--|-----------------------------|-----------------|
| Average GDP losses due to the failure of the sick from work | 54 354 511 | 4 995,82 |
| Average GDP losses due to the refusal of relatives of patients, for the purpose of caring for a sick | 19 511 876 | 1 793 |
| GDP loss due to temporary disability | 11 061 154 | 1 017 |
| Average expenses associated with payments of disability benefits | 7 303 383 | 671 |
| Average cost, associated with benefits to care for sick relatives | 1 759 850 | 162 |
| GDP losses due to the forced cancellation from work | 28 438 635 | 2 614 |
| Mean indirect costs per 1 patient | 122 429 409 | 11 253 |

Visual structure of indirect costs is presented on the figure 3.

These charts show that the largest part of indirect costs (over 60%) in GDP losses due to the refusal to work of patients and relatives for the purpose of patient care.

Summary

Total costs (direct and indirect) to conduct one patient with multiple sclerosis was 131 781 rubles or \$12 112. Based on an estimate of total morbidity in the Republic of Belarus (about 41 cases per 100 000 people) and population, it was calculated the value of the total incidence of multiple sclerosis than 3900 cases. Thus, the total expenditures of the state for the conduct of all MS patients 514 871 691 279 rubles, or \$47 322 744 (0.08% of GDP). Share

of direct and indirect costs is 7% and 93%, respectively. This suggests that a major economic burden falls on indirect costs. And the total GDP losses (for temporary disability, patients' refusal to work, refusal of relatives from working for the purpose of caring for the sick) is equal to 64% of total costs.

You should also pay attention to the fact that medicines account for just over 1% (1,3%) of the economic burden. In Russia this figure exceeds 40% of total costs, due to the inclusion of Multiple sclerosis disease modifying drugs (MSDMD) in clinical practice. In Republic of Belarus this group of drugs is not included in the standard.

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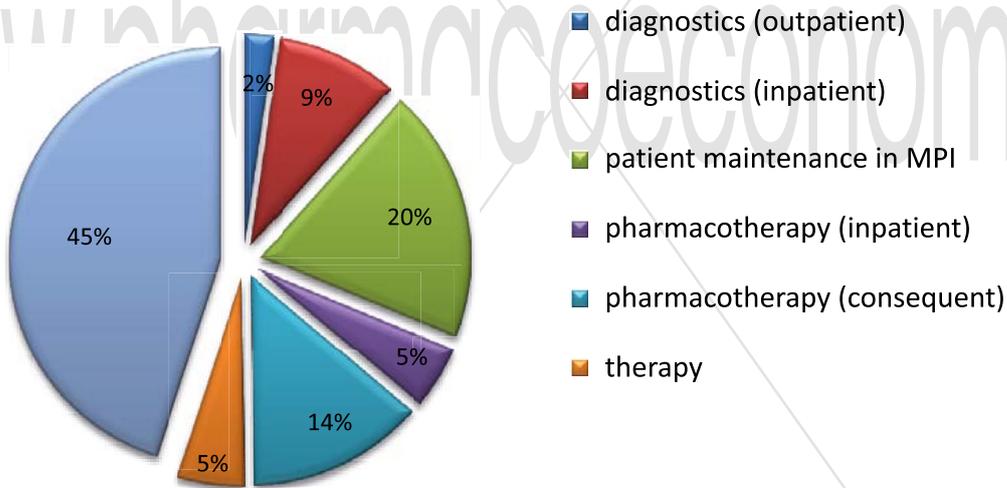


Figure 2. Structure of direct costs for patients with MS per year

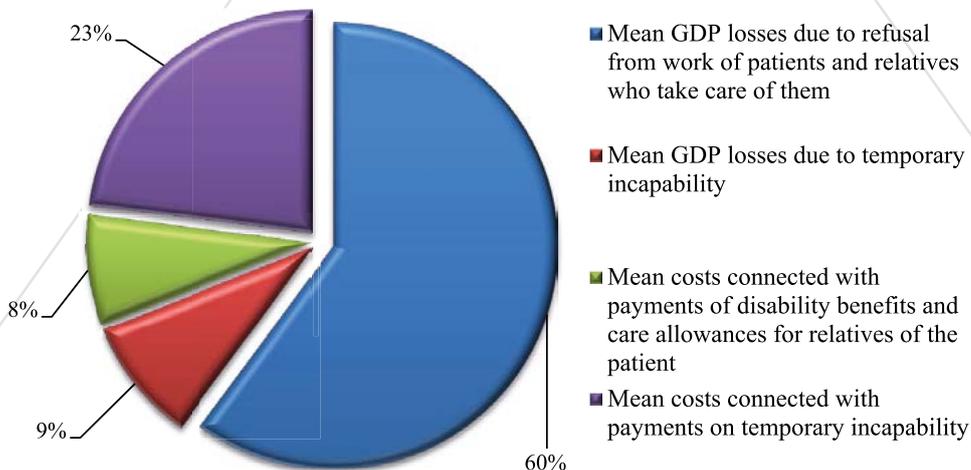


Figure 3. Structure of indirect costs per 1 patient with multiple sclerosis for 1 year