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**ORGANIZATIONAL AND LEGAL RESEARCH OF
INDICATORS OF INCIDENCE AND
PREVALENCE OF DIABETES MELLITUS IN
COUNTRYSIDE AREAS**

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The degree of orientation of the state on improving public health, organizational and legal improvement of healthcare is one of the key indicators of the state, its civilization and competitiveness. Meanwhile, indicators of health of Ukraine's population (according to national and international statistics) over the past decades have very serious negative trends: increased mortality (particularly among men of working age), morbidity, reduced life expectancy, etc. [1, 2]. The existing healthcare system have valid complaints from the public and the medical staff, it is still not able to adequately meet the needs of the population in health care, ensure the availability, quality and timeliness of health services, adequate prevention of morbidity and mortality etc. The financial and economic crisis has significantly exacerbated the problems associated with the provision of medical care in Ukraine, ensuring its availability and good quality. The need for reforming of the healthcare system highlights the inability, on the one hand, to ensure proper conditions of existing state funding, and the other – to introduce effective schemes for full competition in the health care and pharmaceutical provision in countryside areas [3-5]. Therefore, Ukraine implemented new organizational and legal approaches to the reform of healthcare system, which would make all processes transparent, will reduce unnecessary costs for public administration and improve accessibility in countryside areas with medicines of various clinical and pharmacological, classification, legal and nomenclature groups used in the pharmacotherapy of diabetes [6-8].

To the pharmaceutical provision for different groups of patients were dedicated publications of Ponomarenko M.S., Volokh D.S., Syatynya M.L., Gudzenko O.P., Mnushko Z.M., Tolochko V.M., Nemchenko A.S., but they did not review the problem of antidiabetic drugs for countryside areas based on the principles medical and pharmaceutical law (humanism, democracy, rule of the law, social justice, justice, scholarship, professionalism, efficiency, stability) [1, 9, 10].

Purpose of the study

To study the level of incidence and prevalence of diabetes mellitus in the Kharkiv region of Ukraine through organizational, legal, forensic and pharmaceutical research in the incidence of diabetes mellitus.

Materials and methods

The organizational, legal, forensic and pharmaceutical research conducted in countryside areas at the regional level on example of the Kharkiv region of Ukraine based on 62 public healthcare institutions, 16 public drugstores, healthcare institutions of other type of ownership. Materials of the research: legal framework for the organization of pharmaceutical healthcare system in countryside areas; forensic and pharmaceutical practice on complaints of the countryside population concerning the availability for them of the medicines for diabetes; regional statistics on incidence and prevalence of diabetes mellitus. In conducting the research used the following methods: legal, documentary, bibliography, comparative, forensic, pharmaceutical and graphical analysis.

Results and discussion

According to WHO, among the countries of the world there are 347000000 (as of 2010) people with diabetes mellitus, more than 80% of diabetes deaths occurred in low- and middle-income countries [11-15]. In conditions of limited funding of the healthcare system and low pharmaceutical provision for diabetic patients in countryside areas, the question of the optimal use of funds is very important to avoid negative consequences, as evidenced by the forensic and pharmaceutical practice (a typical example is shown below).

Example from the forensic and pharmaceutical practice. The hotline of the Department of Healthcare of Kharkiv Regional State Administration in December 2015 received a petition from Mr. V. (II disability group, patient with diabetes, living in countryside area) concerning the refusal to obtain anti-diabetic medicine diabeton and siofor, that he and his wife Mrs. T. (also patient with diabetes) can't obtain since August 2014, that is violation of their rights. According to the Constitution of Ukraine, regulations of medical and pharmaceutical law, decrees of the Cabinet of Ministers of Ukraine from 17.08.1998 N1303 "On regulation of free and concessional dispensing medicines prescribed by doctors in the case of outpatient treatment of certain groups and in certain categories of diseases" and from 05.09.1996 N1071 "On the procedure of procurement of medicines by healthcare institutions financed from the budget", and Article 7 of the Law of Ukraine "On citizens appeals" was introduced to address the Kharkiv district administration and the Kharkiv district Council, which in within the scope of authority and competence resolved the issue by providing them partially with needed medicines (Table. 1).

Table 1 – Analysis of the forensic and pharmaceutical example

Criteria	Story
Area	Countryside area
Affected individuals	2 persons: Mr. V., 2 nd group invalid, patient with diabetes; Mrs. T., patient with diabetes
Medicines, which delivery was blocked	Diabeton (60 mg of gliclazide) N. 30 (France)
	Siofor 850 (850 mg of metformin hydrochloride) N. 60 (Germany)
Legislative base	- decree of the Cabinet of Ministers of Ukraine from 17.08.1998 N1303 "On regulation of free and concessional dispensing medicines prescribed by doctors in the case of outpatient treatment of certain groups and in certain categories of diseases and for certain categories of diseases"; - decree of the Cabinet of Ministers of Ukraine from 05.09.1996 N1071 "On the procedure of procurement of medicines by healthcare institutions financed from the budget"
Local authority, that helped to restore patients' rights	Department of healthcare of Kharkiv Regional State Administration
Consideration and resolving of the issue	An issue resolved by providing partial provision with anti-diabetic medicines
The cost of the privileged pharmaceutical provision	272,03 UAH

This example shows that provision of the privileged categories of patients with diabetes mellitus isn't full. Among the possible reasons for such organization of the pharmaceutical provision for privileged categories of citizens we can point to the constant rise in prices for anti-diabetes medicines and delay of the registration of their wholesale prices.

diabetes at a rate of 100 thousand population) and prevalence (the number of reported cases of diabetes at a rate of 100 thousand population) with diabetes at the regional level by the example of Kharkiv region. The incidence and prevalence of diabetes in districts of Kharkiv region in 2012 and 2013 are presented in Table. 2 and 3.

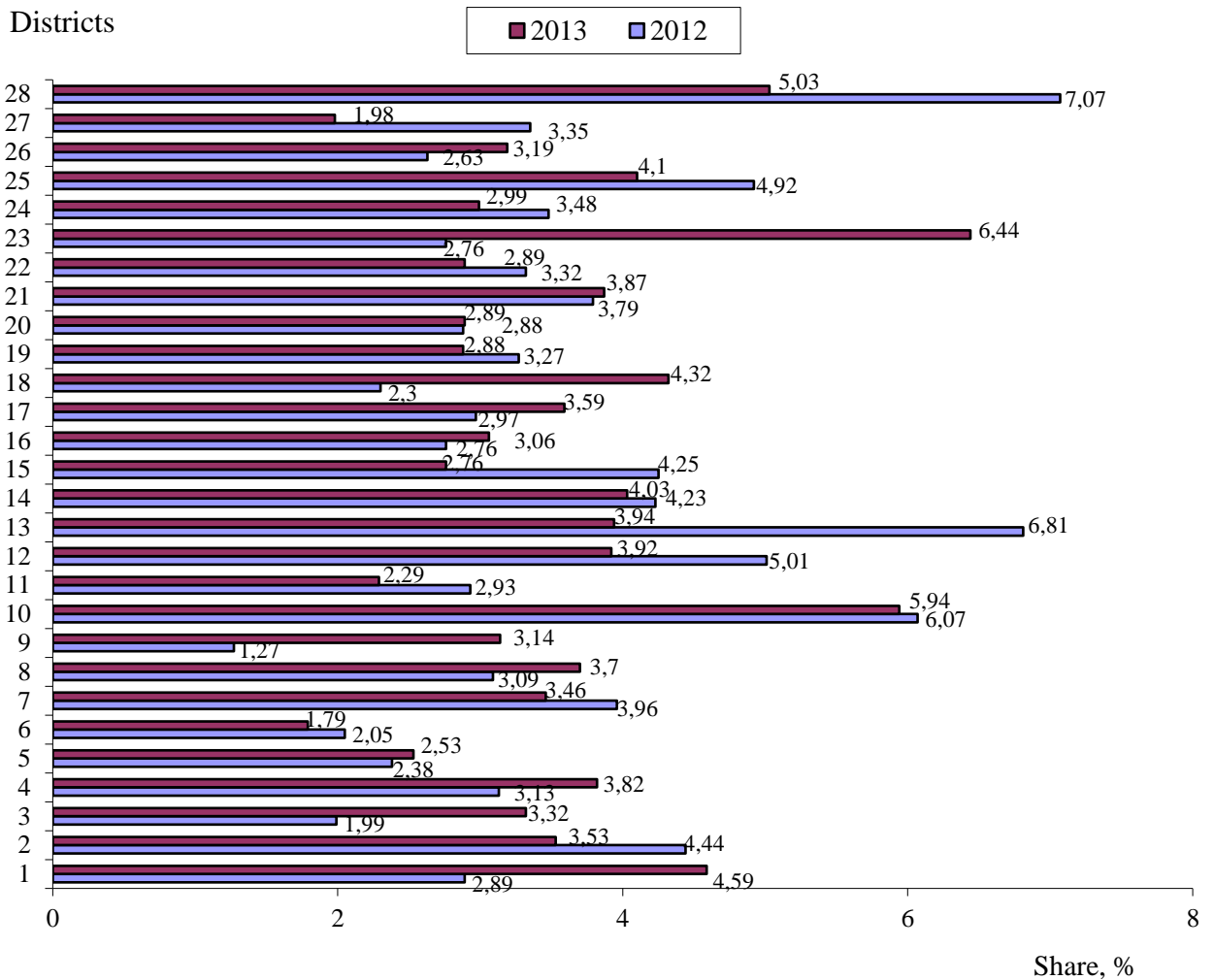
The next phase of the study was a comparative analysis of the incidence (number of new recorded cases of

Table 2 – Quantitative indicators of regional incidence on diabetes [16-18]

Kharkiv region's district	Incidence on diabetes at a rate of 100 thousand population					
	2012			2013		
	Quantitative value	Share, %	Ranking	Quantitative value	Share, %	Ranking
Balakliysky	219,48	2,89	10	362,84	4,59	25
Barvinkovsky	337,55	4,44	23	279,34	3,53	15
Blyznyukivsky	150,94	1,99	2	262,77	3,32	13
Bogodukhivsky	238,23	3,13	14	302,52	3,82	18
Borivsky	181,22	2,38	5	200,16	2,53	4
Valkivsky	156,17	2,05	3	141,88	1,79	1
Velykoburlutsky	300,95	3,96	20	273,89	3,46	14
Vovchansky	235,09	3,09	13	292,98	3,70	17
Dvorichansky	96,43	1,27	1	248,58	3,14	11
Dergachivsky	461,56	6,07	26	469,91	5,94	27
Zachepilivsky	222,52	2,93	11	181,20	2,29	3
Zmyivsky	380,61	5,01	25	310,14	3,92	20
Zolochivsky	517,24	6,81	27	311,90	3,94	21
Izyumsky	321,65	4,23	21	319,06	4,03	22
Kegichivsky	322,97	4,25	22	218,20	2,76	5
Kolomatsky	209,86	2,76	7	241,71	3,06	10

Krasnogradsky	225,74	2,97	12	283,98	3,59	16
Krasnokutsky	174,77	2,30	4	341,91	4,32	24
Kupyansky	248,51	3,27	15	227,67	2,88	6
Lozivsky	218,63	2,88	9	228,53	2,89	7
Novovodolazky	288,17	3,79	19	306,04	3,87	19
Pervomaysky	251,96	3,32	16	228,66	2,89	8
Pechenizhszky	209,88	2,76	8	509,22	6,44	28
Sakhnovschinsky	264,24	3,48	18	236,42	2,99	9
Kharkivsky	373,57	4,92	24	324,58	4,10	23
Chuguyivsky	200,17	2,63	6	252,15	3,19	12
Shevchenkivsky	254,55	3,35	17	156,81	1,98	2
Lyubotyn	537,52	7,07	28	398,31	5,03	26
All over the region	7600,18	100,00%		7911,36	100,00%	

Comparison of the incidence level on diabetes in the Kharkiv region in the ratio shown on Fig. 1.



- | | | |
|---------------------|--------------------|---------------------|
| 1 – Balakliysky | 10 – Dergachivsky | 19 – Kupyansky |
| 2 – Barvinkivsky | 11 – Zachepilivsky | 20 – Lozivsky |
| 3 – Blyznyukivsky | 12 – Zmyivsky | 21 – Novovodolazsky |
| 4 – Bogodukhivsky | 13 – Zolochivsky | 22 – Pervomaysky |
| 5 – Borivsky | 14 – Izyumsky | 23 – Pechenizhszky |
| 6 – Valkivsky | 15 – Kegichivsky | 24 – Sakhnovshynsky |
| 7 – Velykoburlutsky | 16 – Kolomatsky | 25 – Kharkivsky |
| 8 – Vovchansky | 17 – Krasnogradsky | 26 – Chuguyivsky |
| 9 – Dvorichansky | 18 – Krasnokutsky | 27 – Shevchenkivsky |
| | | 28 – Lyubotyn |

Figure 1 – Distribution of the incidence on diabetes by share

Fig. 1 shows that in 2013 increased the number of newly registered patients with diabetes by nearly 4%. The largest number of diabetic patients in Pecheniz'ke (6,44%) and Dergachi (5,94%) regions. The smallest number of

patients in Valky (1,79%) and Shevchenkovo (1,98%) districts. The discrepancy between these areas was 0,19%. For clarity, we compared the district level of the incidence of diabetes by rank (Fig. 2).

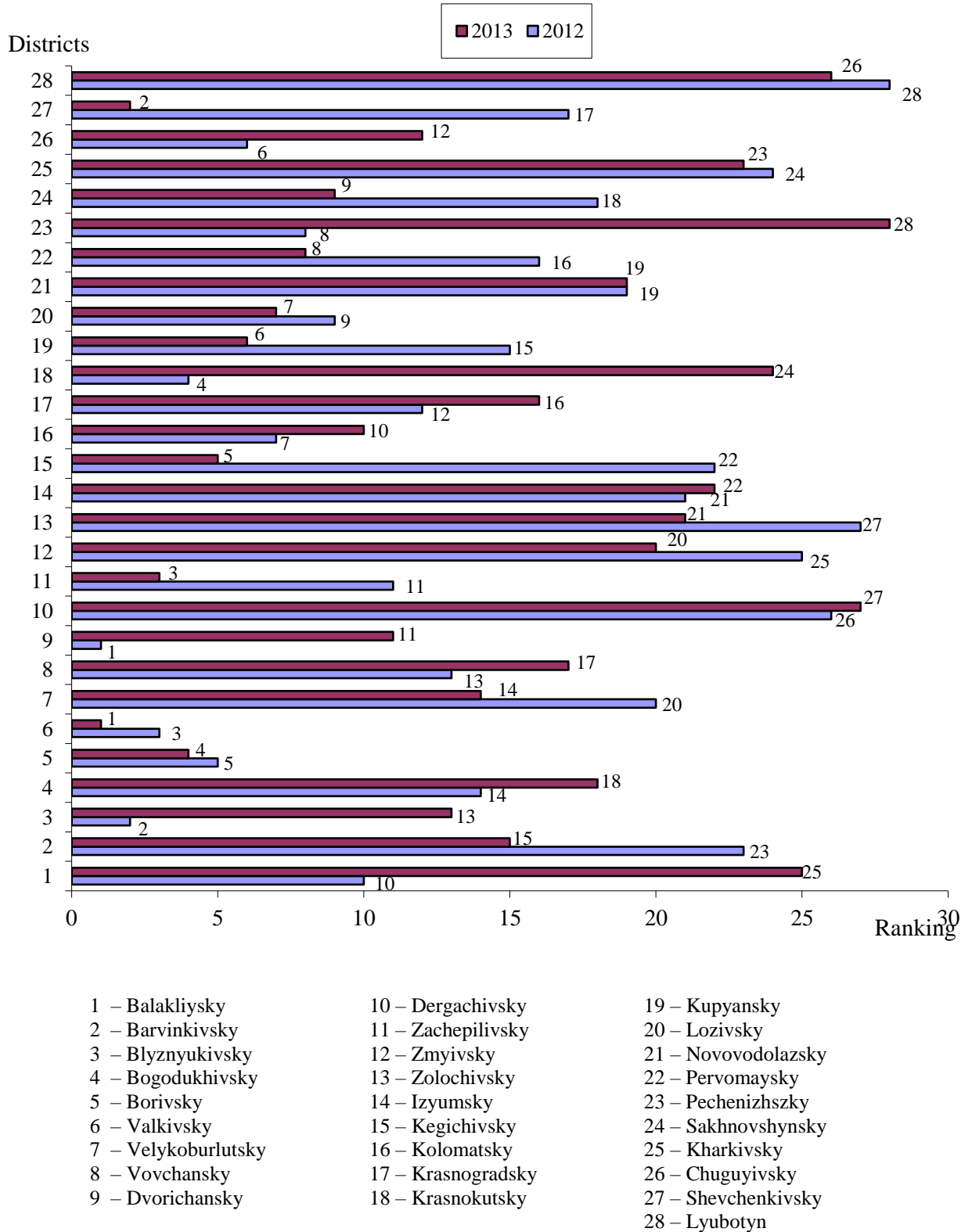


Figure 2 – Distribution of the incidence on diabetes by ranking

Fig. 2 shows that the region with the highest ranking (number 28) for 2012 was Lyubotin, and in 2013 became Pechenegi district, next-ranking Zolochivsky (2012) and Derhachevskiy (2013) areas, and with the lowest rank (№ 1) in 2012 was Dvurechansky area, and in 2013 was Valkovsky area.

The increase in the prevalence of diabetes is due to various factors, including stress, obesity, aging population, quality of food and life. That's why we presented a comparative analysis of the prevalence of diabetes in the Kharkiv region (tab. 3).

Table 3 – Quantitative indicators of regional level of the prevalence of diabetes [16-18]

District	Prevalence on diabetes at a rate of 100 thousand population					
	2012			2013		
	Quantitative value	Share, %	Ranking	Quantitative value	Share, %	Ranking
Balakliya	2503,23	3,11	5	2482,57	2,93	5
Barvinkovsky	3412,09	4,24	24	3556,39	4,2	24
Blyzniukivsky	2799,69	3,48	12	2964,8	3,5	14
Bogodukhivsky	2697,4	3,35	9	2897,72	3,42	11
Borivsky	3137,39	3,9	21	3276,91	3,87	21
Valkivsky	1929,14	2,4	1	2014,06	2,38	1
Velykoburlutsky	2255	2,8	2	2293,83	2,71	2
Vovchansky	2960,45	3,68	18	3103,48	3,66	18
Dvorichansky	2378,53	2,96	4	2475,01	2,92	4
Dergachivsky	3650,35	4,54	28	3795,01	4,48	27
Zachepilivsky	2738,29	3,41	10	2849,29	3,36	10
Zmyivsky	2514,5	3,13	7	2580,4	3,04	6
Zolochivsky	3639,03	4,53	27	3779,89	4,46	26
Iziumsky	2836,74	3,53	15	3114,81	3,67	19
Kegichivsky	3132,79	3,9	22	3407,61	4,02	22
Kolomatsky	2833,16	3,52	14	2725,93	3,22	9
Krasnogradsky	2507,23	3,12	6	2577,82	3,04	7
Krasnokutsky	2556,46	3,18	8	2680,02	3,16	8
Kupyansky	2353,79	2,93	3	2416,2	2,85	3
Lozivsky	2795,83	3,48	13	2921,16	3,45	12
Novovodolazky	2904,73	3,61	17	3037,1	3,58	17
Pervomaysky	3070,98	3,82	20	3276,03	3,86	20
Pechenizhszky	3510,78	4,37	26	4631,05	5,46	28
Sakhnovschinsky	2968,25	3,69	19	3006,51	3,55	16
Kharkivsky	3445,3	4,28	25	3423,42	4,04	23
Chuguyivsky	2868,72	3,56	16	2928	3,45	13
Shevchenkivsky	2752,9	3,42	11	2993,73	3,52	15
Lyubotyn	3265,87	4,06	23	3560,4	4,2	25
All over the region	80418,62	100%		84769,15	100%	

Comparison of the prevalence of diabetes by the ratio shown in Fig. 3.

Analysis of the prevalence of diabetes in countryside areas of the Kharkiv region showed that Valky and Velikoburlutsky districts have the smallest number of diabetic patients (2.38% and 2.71% respectively), and the largest in Pecheniz'ke and Dergachi districts (5.46% and 4.48% respectively). The increase in prevalence of diabetes may indicate a lack of funding for healthcare system, lack of qualified and trained medical personnel, large distance of the countryside areas from healthcare institutions and inappropriate organization of the pharmaceutical provision.

Comparison of prevalence per 100 thousand of population with diabetes by ranking shown in Fig. 4.

Thus, Fig. 4 shows that the highest rank (№28) on the prevalence of diabetes in 2012 was Dergachi district, and in 2013 it was replaced by Pechenegi and Derhachevskiy (rank 27) districts. In 2012 rank 27 took Zolochiv district, which in 2013 moved to 26, observed decrease trend in the prevalence of diabetes at the regional level.

Based on the analysis the Kharkiv region divided into 3 levels (Fig. 5):

- on the incidence of diabetes in the absolute index (index 2013), namely: 1 moderate level (200 patients); 2 average level (200 to 300); 3 high level (300 and above);
- the prevalence of diabetes in absolute terms at a rate of 100 thousand population (2013 data), namely: 1 moderate

level (0 to 2900 patients); 2 level average (from 2900 to 3200); 3 high level (from 3200 onwards).

The results of the graphical and comparative analyzes revealed following areas: - which have both a reasonable amount of morbidity and prevalence of diabetes (Valkovsky and Zachepilovsky districts); - having both the

average incidence and prevalence of diabetes (Bliznyukovsky, Volchansky, Lozova, Sahnovschinsky, Chuguyiv districts); - which are both quite high incidence and prevalence of diabetes (Derhachevskiy, Zolochiv, Pechenezhsky, Kharkiv city, Lyubotin districts).

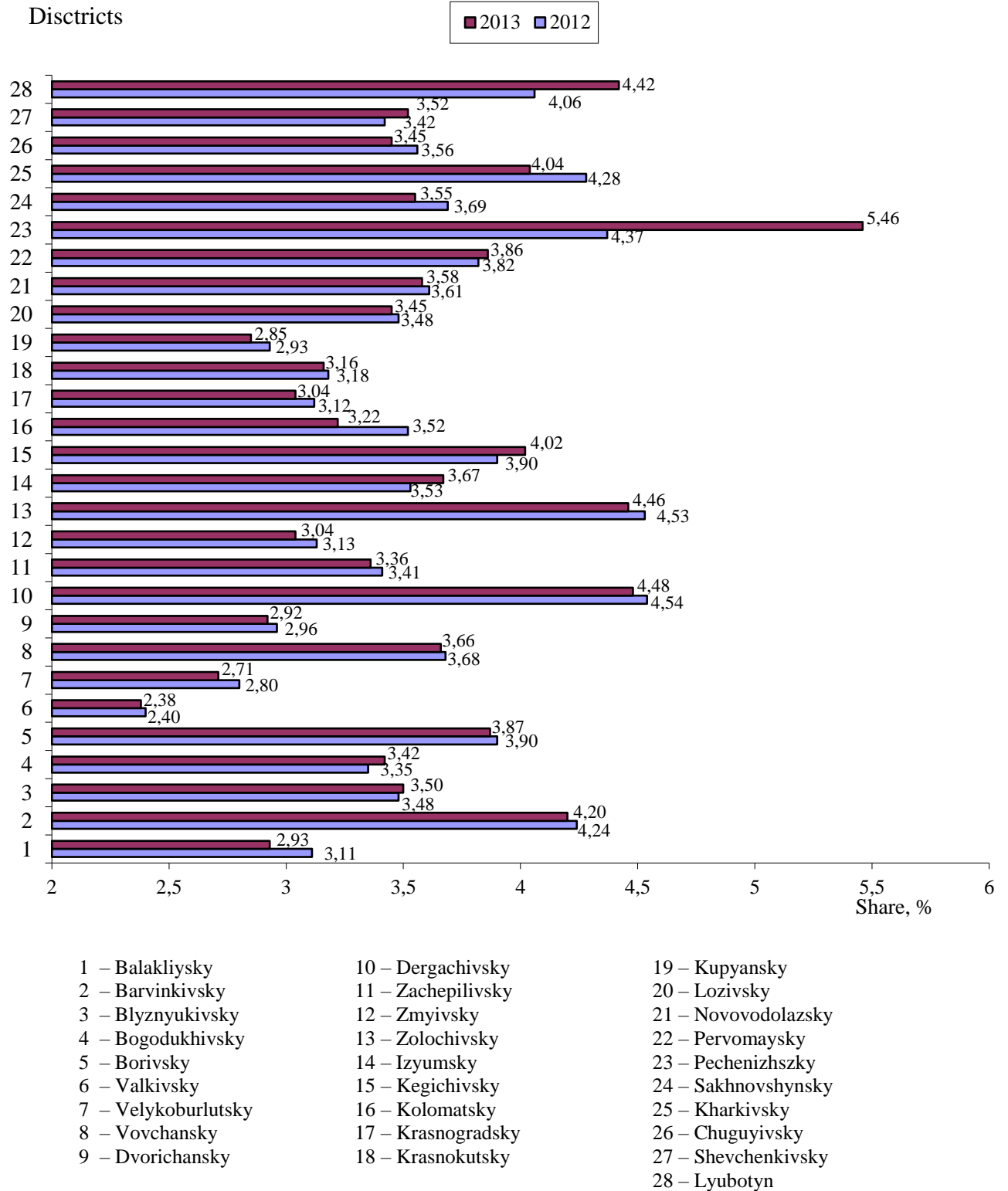


Figure 3 – Comparison of the prevalence of diabetes by share

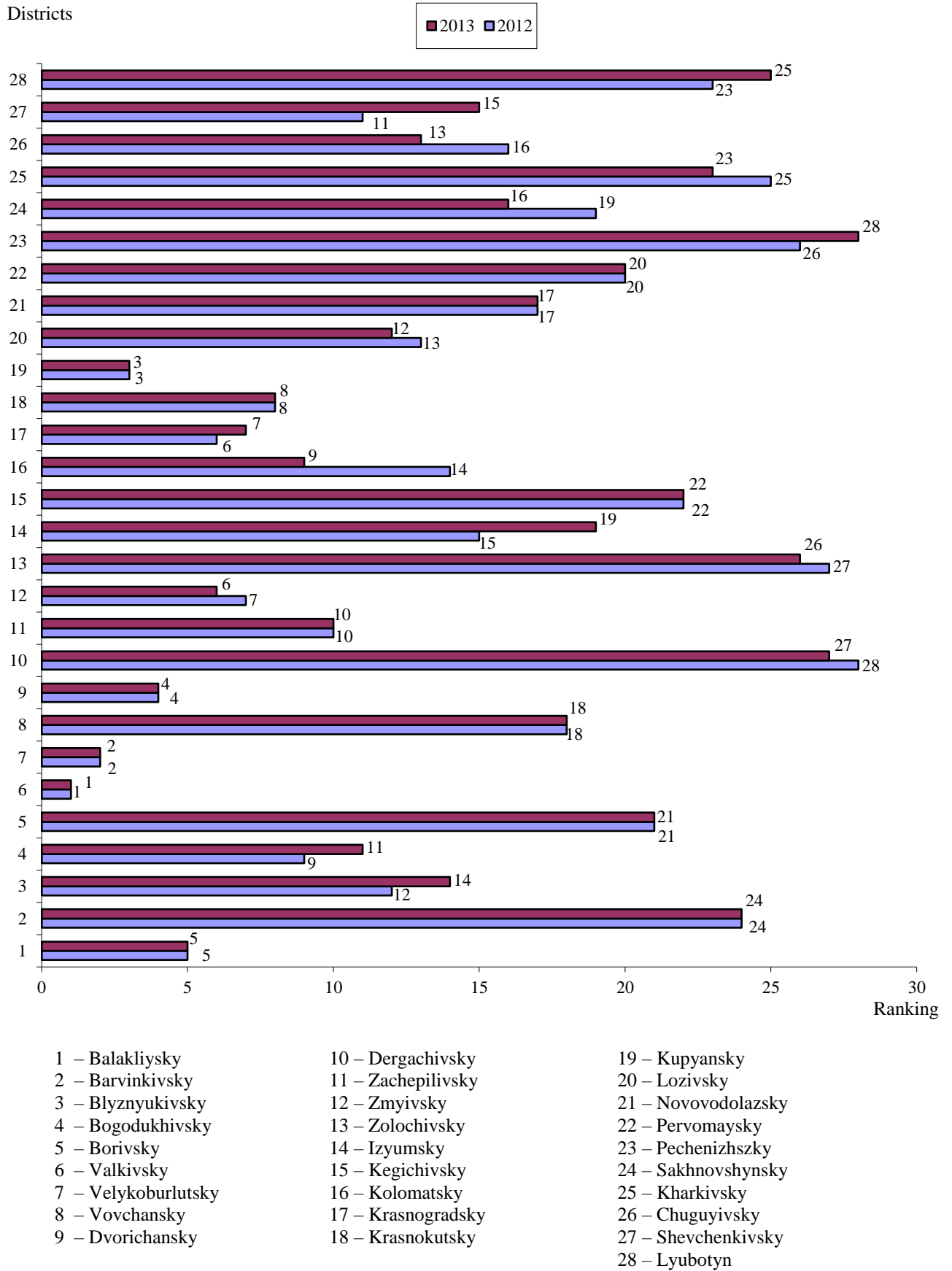


Figure 4 – Comparison of the prevalence of diabetes by ranking

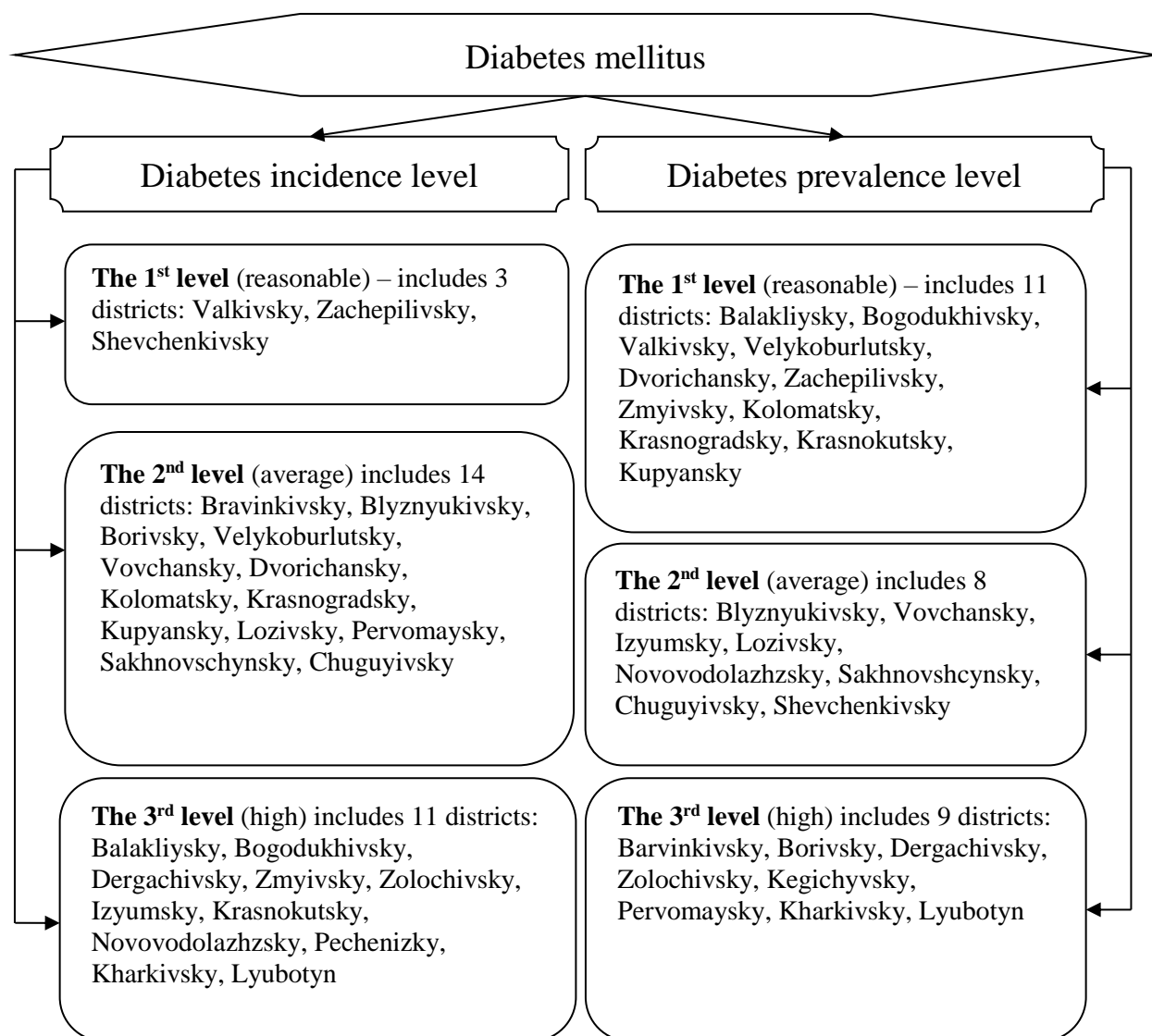


Figure 5 – Distribution of morbidity and prevalence of diabetes by Kharkiv region’s districts

Districts of the Kharkiv region, which became the third level have the highest number of patients with diabetes, this indicates a relatively passive behavior of the villagers to checkups, attitude towards their health, compliance with recommendations and a low level in the chain of relations "doctor - patient with diabetes - pharmacist".

Thus, we can conclude that the treatment of diabetes should be based on the principles of pharmaceutical law provided in the Article 4 of the Law of Ukraine "On the basis of legislation of Ukraine on healthcare" from the state budget. The experience of the European Union (France, Germany, etc.). [6, 19-21] suggests that the following is necessary: - the adoption of the Law of Ukraine "On the introduction of the insurance model of healthcare"; - development of the updated State program "Diabetes mellitus". Also, it is necessary to propose such changes to the legislation: - twice increased funding by providing targeted subsidies from the state budget (application distribution expenditures of the State Budget of Ukraine code program classification of expenditures and crediting the state budget 2311410, code

functional classification of expenditures and crediting budget 0180); - abolish decree of the Cabinet of Ministers of Ukraine from 02.07.2014 N240 "On reference pricing for medicines and medical supplies procured for the state and local budgets"; - make annual review, update and adjustment of the list of anti-diabetic medicines of domestic and foreign production which regional healthcare institutions can, fully or partially financed from state and local budgets approved by the decree of the Cabinet of Ministers of Ukraine dated 05.09.1996 N1071.

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Introduction. For recent decades in Ukraine populations' health indicators became quite serious negative trends: increased mortality rates among people of working age, morbidity, reduced life expectancy and more. It should also be noted that one of the main indicators of the state, its civilization and competitiveness is the degree of orientation of the state to improve the health of citizens, legal and organizational improvement of the healthcare sector. The financial and economic crisis has significantly exacerbated the problems associated with the provision of medical care in Ukraine, ensuring its availability and good quality. The current healthcare system is fair and complaints from the public, and the medical staff, it is still not able to adequately meet the needs of the population in

healthcare, to ensure the availability, quality and timeliness of health services, adequate prevention of morbidity, mortality and more. The need for healthcare reform emphasizes the failure to ensure the proper conditions existing in state funding and to implement effective schemes for full competition in the healthcare and pharmaceutical provision in countryside areas is therefore, in Ukraine implemented new organizational and legal approaches in reforming the health service. That is why in Ukraine implementing processes that are transparent, will reduce unnecessary costs for public administration and improve accessibility of the medications in countryside areas of different clinical and pharmacological, classification, nomenclature, legal and regulatory groups used in the pharmacotherapy of diabetes mellitus. **Materials and methods.** The organizational and legal, forensic and pharmaceutical researches were conducted in countryside areas at the regional level on example of the Kharkiv region on the basis of 62 public healthcare institutions, 16 public enterprises of healthcare and health companies of other ownership. Materials of the research were: the legal framework for the organization of pharmacy of the healthcare system in countryside areas; forensic and pharmaceutical practice concerning the complaints on countryside accessibility for their antidiabetic drugs; regional statistics of incidence and prevalence of diabetes mellitus. In conducting the research used the following methods: legal, documentary, bibliography, comparative, forensic and pharmaceutical, graphical analysis. **Results and discussion.** In the limited funding of the healthcare system and low pharmaceutical ensuring of patients with diabetes mellitus in countryside areas, the question of the optimal use of funds to avoid negative consequences, as evidenced presented in the article on an example of forensic and pharmaceutical practice. Among the possible reasons for such organizations to ensure pharmaceutical provision for privileged categories of citizens can point to the constant rise in prices for antidiabetic drugs and delay in timely registration of wholesale prices for these drugs. Also during the study was a comparative analysis of incidence and prevalence of diabetes at the regional level by the example of Kharkov region. The increase in the prevalence of diabetes is due to various factors, including stress, obesity, aging population, quality of food and life. The increase in the prevalence of the disease may indicate a lack of financing health systems, insufficient qualifications and training of medical personnel, the remoteness of rural health facilities and inadequate organization providing pharmaceutical rural antidiabetic drugs passivity farmers regarding preventive examinations, treatment their health, compliance with recommendations and a low level in the chain of relations "doctor - patient with diabetes mellitus - pharmacist." **Conclusions.** Diabetes mellitus treatment should be based on the principles of pharmaceutical law provided in Art. 4 of the Law of Ukraine "On the basis of legislation of Ukraine on healthcare" from the state budget. Also in reforming of the healthcare system must take into account the experience of the European Union, and the need to propose such changes to the legislation: - twice increased funding by providing targeted subsidies from the state

budget; - Statement of the Cabinet of Ministers of Ukraine of 02.07.2014 p. Number 240 "On reference of pricing for medicines and medical supplies procured for the state and local budgets"; - Annual review, update and adjust the list of antidiabetic drugs domestically who can buy HCF regional level in rural areas, fully or partially financed from state and local budgets approved by the Cabinet of Ministers of Ukraine dated 05.09.1996, number 1071 .

Keywords: diabetes mellitus, incidence, prevalence, circulation, antidiabetic medicines, pharmacy, forensic pharmacy, pharmaceutical law.