SOCIAL AND ECONOMIC ASPECTS OF THE INCREASING INCIDENCE OF DIABETES IN VARNA AND BULGARIA

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ABSTRACT:

Objective: The impact of socio-economic factors on the increased incidence of chronic diseases requires changes in the policy of health authorities. In view of that, the study tried to investigate the role and consequences of those factors on T2DM and thus contribute to future development of comprehensive programmes for screening, diagnostics and treatment.

Methods and materials: Forecasting the incidence rates of diabetes on a national and regional scale using regression analysis of results from municipal programs between 2015 and 2019 in Varna. The following models were studied: linear, cubic, quadratic, exponential, logarithmic, power, growth and inversion. Data processing and analysis were performed with the software set SPSS Statistics and graphical analysis with Microsoft Excel.

Results: A constant rise in the number of diabetes cases was identified. At national level, mortality among females was higher than mortality in males, while at local level (Varna), such correlation was not established. Costs for the studied groups steadily increased during the studied period. Healthcare services for people with diabetes mellitus cost 2.5 times more than that of people without diabetes of the same age group.

Keywords: diabetes mellitus, antidiabetic agents, trends, NHIF, age, gender

INTRODUCTION:

Diabetes is a chronic metabolic disease characterized by elevated levels of blood glucose (or blood sugar), which accompany serious damage to the major vivacity of the heart, blood vessels, eyes, kidneys, and brain [1]. Diabetes was identified as the seventh leading cause of death globally in 2016 [2]. According to recent data published by the International Diabetes Federation, 463 million adults (aged 20-79 years) had diabetes in 2019. If not adequately controlled, global diabetes prevalence is expected to increase by approximately 51% in 2045 [3]. Factors contributing to the development of type 2 diabetes mellitus (T2DM) have long been established, yet this disease still poses a substantial global burden.

Prevalence of diabetes and comorbid brain disorders is increasing worldwide, particularly in low- and middle-income countries. Diabetes and its complications impose sub-

stantial economic costs on developing countries. Several comorbid conditions have been described for diabetes, including central nervous system (CNS) disorders [4].

Public health policies and plans for the provision of services all depend on the general population's state of health and comorbid diseases which change over time [5]. This will place a strain on healthcare costs and healthcare services as well as decreased work productivity and increased likelihood of early retirement or mortality. This will ultimately be a burden on the country's economy [6].

Among the main factors for the diabetes epidemic are increasing rates of obesity, sedentary lifestyle and population aging. The financial and economic crisis caused difficulties in treating diabetes. EU countries have been reducing their healthcare budgets as part of cost-cutting measures.

Patients with type 2 diabetes have concomitant metabolic abnormalities and a considerably higher risk of retinopathy, neuropathy and nephropathy, as well as ischemic heart disease and cerebrovascular accidents. This makes diabetes a chronic, progressive and costly disease.

The EU member states spend on average a staggering 10% of their healthcare expenditures on treating diabetes and related complications. In some countries, this number is as high as 20% [7]. Results from the *Cost of Diabetes in Europe - type 2 study (CODE-2)* indicate that microvascular and macrovascular complications increase costs by 3.5-fold over those without complications, the highest costs being those for hospitalization - 30 to 65% of total costs. According to data of the International Diabetes Federation in Bulgaria, public resources for the treatment of diabetes account for approximately BGN 550 million. 20% of these are spent for outpatient follow-up – check-ups, tests, blood-glucose test strips and insulin pumps, 20% for medicinal products, as all contemporary pharmacotherapies are reimbursed. The essential part of spending - 60% is for hospitalizations and treating diabetes complications [8].

National evidence-based diabetes standards and standard criteria for referral of patients from primary care to a higher level of care are available and fully implemented nowadays. However, there is no strategy to reduce overweight and obesity, no diabetes register and recent national risk factor survey measuring blood glucose. All medicines in primary care facilities – insulin, metformin and sulphonylurea are available in Bulgarian health services [9, 10].

Population-wide research in Bulgaria initiated by Sanofi-Bulgaria and implemented in September 2015 by MED Communications reported that 60% of Bulgarians recognize diabetes as a socially significant disease. Despite the recommendations for annual screening, 45% of them have never been tested for diabetes [11].

In 2015 the Ministry of Health entrusted the University Specialized Hospital for Active Treatment of Endocrinology 'Acad. Ivan Penchev' EAD (USHATE) with the task to keep a medical register, regularly collect, store, analyze, interpret and publish data for patients with diabetes and people with diabetes predisposition and to maintain a patient database. A key objective of that was promoting public health and improving the quality of healthcare of patients with diabetes mellitus. The analyzed information was anonymous. Data about diabetes mellitus was extracted from the text sections of patients' medical records using Natural Language Processing software. Problems with entering and coding data were due to the significant number of patients diagnosed with type 1 and type 2 diabetes mellitus within a year; some medical records had codes for both for type 1 and type 2 diabetes mellitus. Simultaneously assigning codes for two types of diabetes at one examination is inadmissible, and such medical records were not analyzed for the type of diabetes. Coding for type 1 and type 2 diabetes mellitus within a short span of time leads to an inaccurate identifying of the type of diabetes since there is a transition from type 2 diabetes to type 1 and from type 1 diabetes mellitus into type 1. From a clinical point of view, such patients should be isolated cases that were difficult to diagnose. If correctly diagnosed, change of type 1 diabetes into type 2 and vice versa is not very likely to occur. These diagnostic inaccuracies cause inaccuracies in the information and numbers of patients with diabetes in Bulgaria. Newly diagnosed patients with diabetes mellitus in the studied period were 80 530. The number of diseased patients with diabetes mellitus for that time was 16 782. Based on data from the register, the number of patients with complications of diabetes was 163 000, over 50% of patients had not achieved good control of the disease. The most affected group was that of women aged 60 to 74 [12]. The regions of Blagoevgrad, Kardzhali and Yambol had the lowest incidence rate of diabetes. At the opposite end were Vidin, Montana and Vratsa. The incidence rate in Varna Region was similar to that of Veliko Tarnovo, Targovishte and Razgrad regions which was above the national average. Overall, diabetes prevalence in Northern Bulgaria was higher compared to the southern part of the country [12].

The European chapter of the International Diabetes Federation (IDF Europe) has found huge differences in the access to quality medicines and medical devices for patients with diabetes in Europe. Insufficient measures for control of the disease lead to deterioration in the quality of life and spiralling increase of healthcare costs. Type 2 diabetes is a disease in which glucose levels rise over time, with or without treatment and irrespective of the type of treatment given. Such variability compromises glycaemic control and may lead to microvascular and macrovascular complications [13].

A worrying trend is young onset T2DM which was not typical in children. Nowadays, however, childhood obesity is not casuistry, and children also develop diabetes mellitus. On the other hand, obesity is also associated with type 1 diabetes. The use of fatty, sweet and junk foods disrupts the intestinal flora. This impairs the proper functioning of the immune system, which protects the body against diabetes type 1 [14].

Research into the Bulgarian regulatory framework did not find a specific government regulation on the prevention and treatment of diabetes. Such a document is neither available in the registers of Varna Municipality, which calls for changes in policies of the healthcare authorities and the development of a comprehensive programme for screening, diagnostics and treatment of patients with diabetes.

The healthcare and social activities of Varna Municipality are focused on ensuring equal rights and provision of equal access for children and adults from vulnerable groups to all areas of public life and health services through coordination and cooperation with local authorities, NGOs and civil society. Varna Municipality has adopted a vision that aims to provide social and healthcare services adequate to the needs of its citizens, to build sustainability, expand the network of social services and implement health-promotion activities. Three municipal programmes related to diabetes are active in the region: '*Care of children with diabetes and children with rare diseases*' - 2019, '*I succeed*' and '*Early detection, prevention and screening of complications of diabetes: diabetic foot*' - 2019.

RESULTS AND DISCUSSION:

The municipal programme '*Care of children with diabetes and children with rare diseases*' - 2019 was intended for medical professionals, educators and parents. Its purpose was to train and support them in the everyday care of children with diabetes and rare endocrine diseases in nurseries, kindergartens, schools and social services. The programme was implemented by *Varna Paediatric Endocrine Society*. Children with diabetes living in Varna Municipality were 90. As part of the programme, individual plans for each of the 90 children were developed covering the daily care and appropriate behaviour of medical professionals, school staff and parents in cases of hypoglycaemia/hyperglycaemia and the related risks. Four training workshops were held for medical professionals to update their knowledge and acquire confidence in their daily support for children with diabetes and rare endocrine diseases. In the long run, the programme will improve the care of children with diabetes in childcare, schools and social services on the territory of Varna Municipality. Thus parents will not leave their jobs in order to measure blood glucose levels and to administer insulin while their children are in the nursery, kindergarten, school or social service. All of the above will lead to promoting health, quality of life and self-confidence in children with diabetes and rare diseases and help them feel equal to their peers.

To address overweight and obesity in children and adolescents, Varna Municipality launched the screening programme '*I succeed*' in 2007. So far 4 500 children have been

screened. Outcomes of the programme between 2015 and 2019 were studied and analyzed in an attempt to update available data. During that period, 1935 overweight children and school students from Varna were identified. Their blood glucose, cholesterol and triglycerides levels were tested. Chil-

dren with abnormal lab tests were consulted by a paediatric endocrinologist, and treatment plans were prescribed. The screening was consistent with WHO guidelines and adapted to the current regional context. Screening findings on the degrees of obesity are presented in Figure 1.

Fig. 1. Distribution by gender and degree of obesity among the 30% obese children (I –the lowest, V – the highest).

An estimated 30% of the 1935 overweight children and adolescents had varying degrees of obesity and metabolic issues. Of the 30%, children with a second degree of obesity held the highest percentage (27.5%+7.2%), followed by third degree (14%+13.5%), while (9.5%+2.7%) were in the highest fifth degree. Based on gender, obesity was predominant in boys. After the lab tests, 6% of children had elevated cholesterol levels and 94% abnormal triglycerides levels. The highest percentage of obesity was observed in children in the age group 7-13.

Fig. 2. Number of abnormal lab tests

Weight measuring and BMI in %, at the beginning and end of the screening, showed improved BMIs (BMI is

used to indicate the transition from overweight to obesity and a high degree of obesity). Unfortunately, childhood obesity trends in Varna follow the global trend. Subsequently, overweight and obesity lead to metabolic syndrome and increased incidence rate of T2D among young people, along with other factors such as family history, lower social status and the impact of the family context. Obesity and T2D among young people is a significant problem associated with substantial public and personal costs. Patients living with diabetes mellitus need specific care, and the lack thereof can cause physical and psychological issues, socio-economic problems (for the families as well) and even lead to social exclusion. Therefore, urgent prevention among adolescents is needed.

'Early detection, prevention and screening of complications of diabetes: diabetic foot' - 2019, started in response to the National Strategy 2020 focusing on prevention. The purpose of the programme was to stop the trend for late diagnosis of diabetes-related complications and the risk of disability for patients; to create a space for educating and helping patients without referrals with physical activities, nutritional and hygiene advice, i.e. to fill in the gaps in the system. Regarding legislation – the regulation on assistive devices allows the prescription of diabetic insoles only and not shoes and other footwear. People are entitled to special footwear in the cases of missing toes or partial foot amputation. The National Health Insurance Fund reimburses two or three medical appointments a year for patients with a registered work disability, depending on the type of diabetes. This is very restrictive since they are not entitled to tests and consultation, although consultations with neurologists, vascular surgeons and orthopaedists are needed. It is important to build a register of patients because lack of statistics hampers work and planning future prevention

steps, rehabilitation and treatment. In 2019 the programme covered 200 people with diabetes, and 120 with complications were registered. 'Diabetic foot' was predominant, accounting for 70% and neurological complications - 30%. Patients with diabetic foot problems were filed in the programme, and the rest were referred to specialists for consultation and treatment.

More than 15 000 Bulgarian diabetic patients have been diagnosed with diabetic neuropathy. Patients who develop diabetic foot ulcers are an estimated 5% of all people with diabetes or approximately 28 000 Bulgarians [15].

Table 1 shows diabetes incidence in Bulgaria between 2012 and 2018.

Table 1. Diabetes incidence between 2012 and 2018, by ICD code [16]

Bulgaria	E10	E11	E12	E13	E14	Secondary diagnosis	Total
2012	29 650	396 119	33	101	4 776	518	431 197
2013	28 736	412 764	40	93	4 776	472	446 881
2014	30 767	425 235	41	85	4 952	560	461 640
2015	26 188	441 140	27	73	5 215	549	473 192
2016	25 525	451 892	24	96	5 638	661	483 836
2017	24 823	461 269	22	92	5 975	758	492 939
2018	24 282	471 878	18	38	6 640	825	503 752

In the reviewed period, patients with non-insulin dependent diabetes mellitus accounted for the largest share (ICD E11). The second position was held by those with insulin dependent diabetes mellitus (ICD E10).

Fig. 3. Distribution of patients with diabetes by type of the disease

At a national level, a consistent trend was observed where cases of non-insulin dependent diabetes mellitus had a 19.4-fold predominance during the studied period.

Table 2. Diabetes incidence between 2012 and 2018 in the region of Varna, ICD code [17]

Varna	E10	E11	E12	E13	E14	Secondary diagnosis	Total
2012	1563	27177	8	21	682	20	29 471
2013	1500	28153	11	0	536	29	30 232
2014	1668	28641	12	0	474	23	30 821
2015	1428	29637	0	0	504	30	31 607
2016	1444	30249	0	0	579	40	32 322
2017	1416	30536	0	0	547	45	32 549
2018	1385	30979	9	0	618	55	33 047

The situation with incidence rates in the Region of Varna was similar to that in the country – the share of patients with non-insulin dependent diabetes mellitus (ICD

E11) dominated, followed by patients with type 1 diabetes mellitus (ICD E10). At the regional level, T2D was 22.36 times more common than T1D.

Fig. 4. Distribution of patients with type 1 and type 2 diabetes in Varna Region

Diabetes prevalence (% of population ages 20 to 79) in Bulgaria was reported at 6 % in 2019, according to the World Bank collection of indicators [18]. There was a steady upward trend in the number of new diabetes cases and younger age of onset. At national level, mortality among females was higher than mortality in males. At local level (Varna), such correlation was not established. A retrospective study of the national diabetes register investigated the quality of diabetes control and its economic implications in Bulgaria for the years 2012–2016. Patients were categorized according to type of diabetes, gender, newly diagnosed cases per year, body-mass index (BMI) and achieved disease control. According to the study, the total saved costs for all

diabetes-related complications in the whole population amounted to BGN 20 million. Results for the period 2012–2016 showed improved control of diabetes. The share of patients who achieved control increased during the studied period reaching over 40% of the afflicted population [16].

Healthcare services for people with diabetes mellitus cost 2.5 times more than those provided to non-diabetic people of the same age. Currently, diabetes ranks third in costs following cancer and cardiovascular diseases.

Between 2018 and 2020, costs of diagnosis and treatment of decompensated diabetes mellitus in persons younger than 18 increased from BGN 610 to BGN 779, in adults over 18 from BGN 660 to BGN 702. Table 3.

Table 3. Volumes and prices of clinical pathway activities purchased by NHIF, National Framework Agreement 2020 – differences compared to 2018 and 2019.

Code	Clinical pathway	Price 2018 (BGN)	Price 2019 (BGN)	Price 2020 (BGN)	Volume 2020 (numbers)
78	Diagnosis and treatment of decompensated diabetes mellitus				
78.1	ICD E11 for persons over 18 years of age	660	660	702	41 644
78.2	ICD E11 persons under 18 years of age	610	732	779	1 112

Table 4. ANOVA analysis

		Sum of Squares	df	Mean Square	F	Sig.
Mortality	between groups	47,531	1	47,531	14,316	0,002
Bulgaria	within groups	53,124	16	3,32		
	Total	100,655	17			
Mortality	between groups	35,532	1	35,532	0,619	0,443
Varna	within groups	918,734	16	57,421		
	Total	954,267	17			

Costs for the studied period steadily increased in both age groups with T2D, which was more expressed in persons younger than 18. For persons over 18, a mean rate of 1.03 was reported, and for those under 18, the rate was 1.13.

In total, for patients with diabetes, the NHIF paid BGN 135 430 500, of which BGN 127 474 996 for medicinal products and BGN 7.9 million for medical devices [19].

A study of the impact of gender on diabetes mortality rates at national and regional levels was performed using the Analysis of Variance (ANOVA). Results are shown in Table 4.

At the national level, a statistically significant gender-based difference was found in mortality rates (higher mortality in women). In the Region of Varna, such a difference was not observed.

Forecasting the national and regional prevalence of diabetes in its various forms was made using regression analysis. The following models were studied: linear, cubic, quadratic, exponential, logarithmic, power, growth and inversion.

Regression and correlation coefficient, coefficient of determination and standard error of the forecast were calculated for each model (Figure 5).

Fig. 5. Graphs of the studied models (total for diabetes)

A summary of models is shown in Table 5.

Table 5. Summary of the models

	R	R ²	Std. Error	P
Linear model	0.995	0.990	2 805.565	<0.000
Logarithmic model	0.984	0.968	5 015.842	<0.000
Inversion model	0.902	0.813	12 196.228	0.006
Quadratic model	0.999	0.999	0.002	<0.000
Cubic model	0.991	0.982	0.006	0.054
Power model	0.988	0.976	0.009	<0.000
Growth model	0.993	0.985	0.007	<0.000
Exponential model	0.993	0.985	0.007	<0.000

Data is best described by the quadratic model. It provides the highest correlation and determination values and the lowest forecasting error. Coefficients are statistically significant.

The forecasting estimates of incidence rates of diabetes in Bulgaria, calculated with the constructed model, are presented in Table 6.

Table 6. Forecasting estimates for incidence rates of diabetes in Bulgaria

Time	Incidence rate
2019	510 137.6
2020	516 159.9
2021	520 885.7
2022	524 315.1
2023	526 448
2024	527 284.5

A forecasting model of incidence rates of diabetes both for Bulgaria and for the Region of Varna was constructed. The coefficients of the model are statistically significant, and the correlation between values is very high, which gives grounds for the model to be accepted. The forecast for 2024 is that nationally the cases of diabetes will reach 527 284.5, which is an increase of 17 146.9 compared to 2019. Forecasts for the Region of Varna are similar.

CONCLUSION:

Managing the increasing incidence rates of diabetes in Bulgaria will be one of the main clinical challenges of the 21st century. The results of this study indicate the need for the identification and development of strategies and different programmes to improve lifestyles with a focus on diabetes prevention. It is necessary to create registers with epidemiologic databases by disease type (morbidity, mortality, life expectancy, etc.).

Diabetes mellitus, also known as adult-onset diabetes, is gaining even greater significance in the context of increasing life expectancy and population aging. The rapid

growth of incidence rates of diabetes mellitus, along with increasing costs of diagnosis and treatment, call for policy changes by health authorities. One of the key issues remains unresolved - regular monitoring and registration of the population health status.

The national government has not targeted diabetes through a special prevention and treatment strategy. The Ministry of Health does not have a specific national pro-

gramme to curb diabetes because diabetes is included in an ongoing programme that includes modern healthcare policies for diabetic patients, in compliance with the requirements of both the United Nations and European Parliament. The document, *National program for prevention of chronic non-communicable diseases 2014-2020*, was adopted with Decision No. 538 of the Council of Ministers of September 12, 2013, 2014-2020 [20].

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