

**EDUCATION OF PATIENTS WITH DIABETES IN THE COMMUNITY  
PHARMACIES (PILOT PROJECT IN BULGARIA)**

SERBEST ECZANEDE DİYABET HASTALARININ EĞİTİMİ  
(BULGARİSTAN PİLOT PROJESİ)

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**ABSTRACT**

*The objective of this study is to adapt and test a community pharmacy educational program for diabetes patients. In the study; The sample consisted of 24 type 2 and 14 type 1 diabetes patients on monotherapy, without severe complications. A patient satisfaction questionnaire (WHO five wellbeing index) was applied in the beginning and at the end of the survey. A five-month education was conducted on common problems and complications of diabetes. The whole program costs were calculated per patient and cost-effectiveness ratio was presented. Improvement was observed in patients' diabetes knowledge in both groups, decrease in the frequency of minor hypoglycemic incidents (about 60% less for type 2 and 5% less in type 1 diabetes group) and the blood glucose level (statistically significantly in type 2 diabetes patients). The total quality of life according to WHO index increased significantly from 29 to 44% and from 58.57 to 70.28% in diabetes type 2 and 1 patients respectively. The cost-effectiveness ratio calculated on the basis of the intermediate result that is decrease in the blood glucose level per patient is 7.5€ and for type 2 and 42,86 € for type 1 diabetic patients. Introduction of the education program has the potential to decrease the minor diabetes complications and from there - the economic cost of the diabetes as well to improve patient satisfaction and will promote the pharmacies as a source of health education and should be encouraged through the general reimbursement system.*

**Key words:** Community pharmacies, Diabetes, Patients education program, Pharmaceutical care, Pharmaceutical education.

**ÖZET**

*Bu çalışmanın amacı Diyabet hastalarının serbest eczanede eğitim programının adapte edilmesi ve denenmesidir. Çalışmalarda; deneme grubu, tip 1 monoterapili ağır komplikasyonları olmayan tip 2 ve tip 14 diyabet hastalarından oluşmuştur. Hastanın memnuniyetini yansıtmak üzere araştırmanın başlangıcı ve sonunda (DSÖ'nin refah endeksinin 5 belirtisini içeren) bir anket uygulanmıştır. Diyabet ile ilgili genel sorun ve komplikasyon konusunda 5 aylık eğitim düzenlenmiştir. Programa ilişkin bütün giderler hasta başına hesaplanmış olup gelir-sonuç oranı gösterilmiştir. İki gruptan hastaların diyabet konusundaki bilgilerinde gelişme, hafif hipoglisemi olaylarının sıklığında azalma (örneğin, tip 2 diyabet hastalarında yaklaşık % 60 oranında, tip 1 diyabet hastalarında ise % 5 oranında azalma) ve kan şekeri değerlerinin (tip 2 diyabet hastalarında istatistik açıdan önemli olan) azalması izlenmektedir. DSÖ'nin endeksine göre tip 2 diyabet hastalarının genel yaşam kalitesi % 29' dan % 44' e, tip 1 diyabet hastalarının yaşam kalitesi ise % 58.57'den % 70.28' e yükseldi. Kan şekeri değerindeki azalmanın ara sonucu bazında hesaplanan gider-sonuç oranı tip 2 diyabet hastalarında 7.5€, tip 1 diyabet hastalarında ise 42,86 € oldu.*

*Eğitim programı uygulanmasının diyabet hastalığının hafif komplikasyonlarını azaltma potansiyeli ile diyabet ile ilgili giderleri indirebilir, ayrıca hastanın memnuniyetini yükselterek eczaneleri sağlık eğitimi kaynağı olarak tanıyacak ve programın sağlık giderlerini geri ödeme sistemi tarafından teşvik olunmasına yol açacaktır.*

***Anahtar kelimeleri:** Serbest eczane, Diyabet, Hastaların Eğitim Programı, Farmasötik bakım, Farmasötik eğitim.*

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**INTRODUCTION**

Diabetes is a rapidly growing disease whose impact is felt clinically, socially and economically (1). It has reached epidemic proportions worldwide (2). Recent studies thought that diabetes type 2 affects, 3-5 per cent of the population in some countries and type 1 moves towards the younger ages (3).

Rates of diabetes have been rising around the world. The increase in prevalence has accelerated due to the aging population structures in the developed countries and to the globally increasing obesity, as well stressing life style. Poverty has been under recognized as a contributor to prevalence of diabetes but it is strongly connected with the unhealthy alimentary habits (4, 5). In the last decade, the overall incidence of diabetes has risen due to factors that are strongly related to the life style as is inactivity and population aging (6, 7). Diabetes is the sixth leading cause of death from disease in the world (1). In some transitional countries the adult morbidity data collected after 1950 demonstrate constantly rising increase from 150,000 to 230,000 and nowadays diabetes

affects more than 2% of the population. The number of patients with type 1 diabetes almost doubled at the same time due to their irrational therapy (8, 9). This chronic condition that presents a substantial socio-economic and quality-of-life burden, (10) drains the limited health care financial sources, tests the boundaries of clinical resources and decreases the quality of life of the patients and also of their families. The profile of patients with diabetes has evolved to include people of all ages and socioeconomic backgrounds, with varying medical histories and health behaviors whose approach to the disease should be facilitated by the health professionals (1, 11).

In 1989, in St. Vincent, Italy was signed the St. Vincent declaration, a joint initiative of the International Diabetes Federation European Region and the WHO European Regional Office. It is a program for strategic action to reduce the human and economic burden of diabetes in Europe and has been adopted by most of the European governments. The St. Vincent initiative has few target areas, which seek to improve the quality of life of people with diabetes and to promote education of patients so to prevent diabetes complications. In this project are involved all healthcare givers, including the pharmacists (12). Recent clinical outcome studies have made diabetic patients a target for primary care and pharmacist initiatives, so to be improved their quality of life (3, 13, 14, 15). Diabetes is now the subject of specific guidelines for the community pharmacists in the different countries that highlight measures and steps for including these healthcare specialists in the primary care diabetic team (13).

The community pharmacists are in fact in the unique position to improve the care of people with diabetes by collecting patient information, conducting drug regimen reviews, counseling patients, providing consultations with doctors regarding the prescribed drug therapy and by monitoring patients' treatment process (16, 17, 18). It was proven that in the community pharmacy the patient has an easy access to the pharmacist and the consultation is free of charge (18, 19).

However, in some countries, the community pharmacies are still not considered as a proper place for patient education (11, 20). The reason is that the preparation of educational programs requires time, specific training, and communication skills from the healthcare providers.

This problem stimulated us to adapt an educational program, suitable for implementation in the community pharmacies that will enable the pharmacists to apply it easily after a short training period; and to evaluate the effect of this program on the clinical, therapeutic and economic outcomes.

The **goal** of this pilot study was to test the adapted educational program for its applicability in the community pharmacy area for consultation of diabetes patients.

Two **study hypotheses** have been tested:

Hypothesis 1. Is it possible to organize a patient education program in the community pharmacies and what will be the major limits?

Hypothesis 2. What will be and how can be measured the results of the introduction of the educational program for diabetes patients both for the pharmacists and the patients.

### **Research Design and methods**

The educational program continued 6 months. The course was presented to 24 ambulatory patients with type 2 and 17 with type 1 diabetes that agree to participate. The program was completed by 14 diabetes type 1 patients. After the search among the internet and officially published local sources an educational program was chosen, promoted by Novo Nordisk for physicians and nurses that have been implemented successfully in several Central and Eastern European countries, like Poland, Czech Republic, Russia, Hungary, Slovak Republic and Slovenia, because of its proven local applicability. The educational units were selected on the basis of expert opinion of 10 pharmacy managers for the most often discussed questions with diabetes patients.

#### ***The educational units' content***

The course included five teaching units and preliminary introductory patient evaluation module.

**The first unit** acquainted each of the patients with the aim of the educational program, provided general concept about diabetes and about self-monitoring and emphasized on the active patient participation in the treatment. The personal information of each of the patients was collected, concerning the duration of the disease, the prescribed drug treatment, the approximate monthly frequency of the minor hypoglycaemic incidents. Each of the patients was instructed about the symptoms of minor hypoglycaemia and how to manage with it. Symptoms of minor hypoglycaemia include trembling, sweating, anxiety, blurred vision, tingling lips, paleness, mood change or confusion. As a practicum every patient was shown how to perform and record glucosuria self-monitoring in an individual notebook. At the end of the first unit, each of the patients was supplied with written materials on hypoglycaemia and risks of hyperglycaemia. They were asked to monitor glucosuria twice daily (2 hours after the main meals). The goal was to learn how to cope with the incidents of hypoglycaemia and hyperglycaemia.

During the **second teaching unit** it was discussed with every patient the effect of obesity on insulin sensitivity and the advantages of weight reduction. The meaning of the term “bread unit”

was clarified. An easy approach for meal selection based on “bread units” was structured. It was emphasized that the regular physical activity helps controlling the weight and may help to manage diabetes high blood pressure and cholesterol, heart disease, osteoporosis, arthritis, and other chronic diseases. Each of the patients was supplied with written materials on proper nourishing for diabetic patients and physical activity.

The **third teaching unit** focus on foot care. The educator explains foot examination and seriousness of the lesion (sore or ulcer) development on the plantar (bottom) of the patient’s foot if the sugars is not controlled. The patients were taught that neuropathy is the loss of sensation, and the patient is not aware that he/she is developing sores on the bottom of his/her foot.

During the **fourth meeting** the educator discussed with every patient the essence of the diabetic eye diseases that include: diabetic retinopathy, cataract and glaucoma. It was explained that diabetic retinopathy is a leading cause of blindness among the adults with diabetes and was cleared that diabetic retinopathy cannot be completely avoided, but the risk can be greatly reduced by better control of the blood sugar level that can slow the onset and progression.

The **fifth educational unit** diabetes patients was based on the possible adverse drug reactions that can arise during the drug treatment as well on possible problems during injecting insulin and using injection facilities. It was cleared that a person with diabetes may develop weakness, sweating, nausea, and palpitations if an antidiabetic drug reduces the blood sugar level too much. This type of adverse drug reaction that is usually predictable but sometimes unavoidable may occur if a drug dose is too high, if the person is unusually sensitive to the drug or if another drug slows the metabolism of the first drug and thus increases its level in the blood. That is why the patients were told to be strict to the prescribed dose and ask for advice when such a reactions appear.

***The educational materials*** used during the program included:

- a set of one-page written materials that illustrate the most important aspects of every educational lecture, provided to the patient after every module;
- questionnaire cards for distribution among the participants as a standardized procedure for assessment of their knowledge acquired in the previous educational units;
- individual notebooks for recording the self-monitored data (glucosuria and body weight);
- patient’s satisfaction questionnaires for evaluation patient’s quality of life;

- instruction files for the educator as a structured guideline on how to perform each session, what kind of information to supply to the patients, what questions to ask in the beginning of each module to evaluate patients' level of knowledge.

Preliminary trained pharmacy students at the latest course of their study were used as educators.

***Patient selection and study design.*** The inclusion criteria for the participants in the pilot study were patients with type 2 or type 1 diabetes, without severe complications of diabetes such as retinopathy or nephropathy. It was preferred patients on mono therapy either one per oral antidiabetic drug or insulin. Exclusion criteria were other severe life-limiting illness, inability or unwillingness to participate in the diabetes education program. The individuals who covered the inclusion criteria and agreed to participate were included in the study after providing an informed consent.

#### ***Measuring the results***

At the beginning and at the end of the program were evaluated: the clinical data (medical history, duration of the diabetes, body weight, annual hospitalisation rate, and glucosuria), the recorded metabolic control, recorded minor hypoglycemic incidents and the regularity of drug intake (used to control diabetes and other risk factors).

In the beginning and at the end of the fifth session to the patient was given questionnaire in order to be assessed the changes in the patient's quality of life after the education. The WHO (five wellbeing index (1998 version) was used as it is proposed by the St. Vincent initiative (12). The questionnaire measures the quality of life during the last two weeks (QL) in 5 scales – feeling in good spirit; calm and relaxed; active and vigorous; wakening up fresh and rested; interesting daily life. The maximum score per item is 5 and per patient ranges from 0 to 25 representing worst possible and best possible scenarios respectively. A percentage score per patient or for all patients is achieved by multiplying total score per patient or all patients by 4.

#### ***Cost of the educational program***

All of the used health, patients and other society resources were properly recorded during the observation and summarized after the end of the programme. The cost of the prescribed medication was calculated for the trade name of the drugs. The peroral antidiabetics were classified later according to its chemical composition as Sulfonylurea Agents, Biguanides, Prandial glucose regulators, Alpha glucosidase inhibitors and Thiazolidinediones. The insulin therapy was separated according to type of dosage regime as intensified or classic. The average monthly cost of the

medication therapy was calculated based on market price of used medicines of every single patient. The cost of medication therapy of complications was calculated by the same approach in case if they appear (23, 24).

The cost of the materials, transport and phone calls is calculated on the basis of their market prices of units consumed during the programme.

Labour expenses are calculated on the basis of time spent by the pharmacists multiplied by the respective average wage. The time expenses of the patients are calculated on the basis of the time spent for participating in the project and the average income of the included patients.

It was used the statistical program Statistica, Ver. 6 to analyze the collected data.

## RESULTS

The characteristics of the patients who participated in the pilot project are shown on Table 1. All the 24 diabetes type 2 patients regularly participated till the end of the pilot program while 3 of patients with type 1 discontinued the program due to changes in their residence. The average duration of the diabetes, type 2 was 8.7 years ( $\pm 5.06$  SD). The average duration of diabetes type 1 was 7.64 years ( $\pm 5.01$  SD). The wide standard deviations are maybe due to the inclusion criteria of the participants - lack of severe complications and willingness to participate. The blood glucose levels, used as a control metabolic parameter, in the beginning of the project were found to be  $8 \pm 1.95$  SD on average in type 2 and  $8.02 \pm 1.55$  SD in type 1 diabetes patients. Although some other studies are focused on the HbA<sub>1c</sub> level as a measure of diabetes development and treatment progress we choose blood glucose level as suitable for easy self-measurement and widely used in local primary settings incl. pharmacies (24).

Prevailing part of the type 2 diabetes patients (72 per cents) included in the project were found to use sulfonylurea agents, 32 per cents are on glibenclamid therapy, 15 per cents on glipizid, 11 per cents on gliclazid and 7 per cents on glimepiride, while those with type 1 were all on intensified dosage regime (Table 1). This distribution of per oral antidiabetic medicines is mainly because of the higher reimbursement rate and lower price of glibenclamid. Biquanides were prescribed in 25 per cents of all cases and metformin was the only product from this therapeutic class. The prevalence of the intensified regime is due to the younger ages of included type 1 diabetes patients that correspond with the contemporary therapy standards established by the endocrinology society (12, 23).

**Table 1.** Characteristics of the patients and their therapy

Characteristic	Type 2 diabetes patients	Type 1 diabetes patients
Sex		
Female	71%	35%
Male	29%	65%
Age (years)	64.96 ± 10.18	26.76 ± 6.28
Duration of diabetes since diagnosis (years)	8.7 ± 5.06	7.64 ± 5.01
Medication therapy		
Sulfonylurea Agents	72%	
Biguanides	25%	
Prandial glucose regulators	4%	
Alpha glucosidase inhibitors	4%	
Thiazolidinediones	4%	
Intensified regime		100%
Blood glucose levels (mmol/l)	8 ± 1.95	8.02 ± 1.55

Data are % and means ±SD.

During the 6-months education and its end, the observed metabolic and behavioral parameters performed significant changes for type 2 diabetes patients as they are summarized in Table 2. The blood glucose levels reported for all patients decreased from  $8 \pm 1,95$  mmol/l to  $7,2 \pm 0,99$  mmol/l, thus performing a steady decrease with in the rate of 0.8 mmol/l per patient ( $p < 0.05$ ). Statistically significant differences were observed between the baseline values and the values recorded at each time point during the study that we consider due most probably to the educational process. Blood glucose levels had decreased at the end of the first month after the start of the educational project and this tendency is constant during the whole study (Table 2). The second control parameter - the number of the reported minor hypoglycemic incidents requiring urgent physician check up fold to 0 per cent according to the patients' records (Table 2). For type 1 diabetes patients the blood glucose levels vary among  $8.02 \pm 1.95$  mmol/l and  $7.88 \pm 0.95$  mmol/l and frequency of reported minor hypoglycemic incidents requiring urgent physician check up fold with 5% ( $p < 0.05$ ) (Table 3). These facts can be explained mainly with the improved self-monitoring of the glucose level by the included patients and appropriately taken measures to manage risk of its deepening.



**Table 2.** Changes in the diabetes 2 patients sample after the educational process

Variable	Time period			
	0	1 month	3 month	6 month
Blood glucose levels (mmol/l)	8 ± 1, 95	7, 91±1,44	7,52±1,19	7,2±0,99
Frequency of reported minor hypoglycaemic incidents requiring physician check up (%)	58%	25 %	12%	0%
		QL – average	score per	patient
QL- feeling cheerful and in good spirit	1,71	-	-	2,45
QL- feeling calm and relaxed	2,29	-	-	3,38
QL- feeling active and vigorous	1,13	-	-	1,46
QL- waking up feeling fresh and rested	0,96	-	-	1,58
QL- daily life is filled with interesting things	1,25	-	-	2,08

Data are % and means ±SD. QL – “quality of life”.

The results from the twice-applied questionnaire assessing the quality of life of the patients in the beginning and in the end of the educational programme show that the five main indices have been improved with on the average of 0,58 for type 1 and 0,722 points for type 2 average diabetic patient included in the study (Tables 2, 3). The greater increases is observed in the sense of calmness and relax (1.09), followed by fulfilling days with interesting activities (0.83) and feeling in good spirit (0.74) for type 2 diabetics while type 1 improved with greater score their ability to wake up fresh and rested (1.74) and feeling in good spirit (0.93). It could be considered that the educational process affects both the physical and the psychological well-being and thus it is beneficial for the global patient's quality of life. The small sample size of observed patient did not allow to find factors affecting the well being but we can assume that those could be the patient age and type of diabetes together because the type 2 diabetic patients that are older possess lower quality of life.

The total quality of life measured as percentage according to WHO methodology increase from 29% to 44% (with 15%) in type 2 diabetic patients and from 58.57% to 70.28% (with 11.7%) in type 1 group of patients. Both groups perform a statistically significant improvement in the wellbeing index matching the methodology limit of 12%. We can consider the improvement in the quality of life as a result of the educational process but it is also evident that the results are more

appreciable in the diabetes type 2 group probably because of the lack of education in this group at national level in general.

**Table 3. Changes in the diabetes 1 patients sample after the educational process**

Variable	Time period			
	0	1 month	3 month	6 month
Blood glucose levels (mmol/l)	8.02 ± 1.95	8.01±1,35	7.95±1,45	7,88±0.95
Frequency of reported minor hypoglycaemic incidents requiring physician check up (%)	70%	65 %	62%	65%
		QL – average	score per	Patient
QL- feeling cheerful and in good spirit	2,92	-	-	3,85
QL- feeling calm and relaxed	3,36	-	-	3,71
QL- feeling active and vigorous	3,36	-	-	3,57
QL- waking up feeling fresh and rested	1,5	-	-	2,57
QL- daily life is filled with interesting things	3,5	-	-	3,85

Data are % and means ±SD. QL – “quality of life”.

Variable	for 1 person on average	for the type 2 diabetes project	for the type 1 diabetes project
Materials	0.50€	12€	7€
Time and labor expenses			
for the patient	0,12€	2,88€	1,80€
for the pharmacist	2,25€	54,00€	31,50€
Transport	3,00€	72,00€	42€
Phone calls	0,08€	1,92€	1,12€
Total	5,95€	142,8€	83,30€

Totally the cost for 6-month education of a patient is 6€ that is the minimal possible cost of such a programme and the whole project cost is € 226,30 (143€ for type 1 and 83,30€ for type 2 patients). The cost-effectiveness ratio calculated on the basis of the decrease in the blood glucose level per patient is 7.5€ for achieving one intermediate clinical outcome (6€:0.8mmol/l) for type 2 and 42,86€ (6€ : 0.14 mmol/l) for type 1 patients. The long term clinical outcomes could not be

observed during the six months project period but the steady decrease of blood glucose level, decrease in reported hypoglycemic incidents and increase in overall positive self-perception are serious prerequisites for achieving such improvements. Some preliminary savings due to the educational programme could be calculated on the basis of the decrease in the reported incidents requiring check up with physician. At the end of the programme no incidents were matched that save 10€ per patient which is the cost paid by the National health insurance fund for consultation of a patient with specialists. For 58% of the observed patients that report about having such incidents at the beginning, such savings are 140€ and thus benefit to cost ratio is at least about 1:1 (140€: 142, 8€) if there are no additional expenses. In type 1 diabetic group was observed 5% decrease in hypoglycemic incidence that save 10 € and do not lead to real savings or beneficial results.

### **Discussion and Conclusions**

Diabetes and its complications are responsible for the tremendous individual and public health burden of suffering at present time, and the epidemic is projected to continue into the future (25). The advanced pharmacy practice in diabetes management is a relatively new approach. The role of the pharmacist in it, integrates drug management, patients' compliance assessment, blood glucose monitoring, skills training, prospective and retrospective drug utilization review, adverse drug reaction and toxicity screening and education of the patients (26). These skills in fact are not new for the pharmacist but their introduction, as systematized approach in everyday practice should correspond to the local circumstances. To match the context of the pharmaceutical care, defined by the APA as "Patient-centered, outcomes-oriented pharmacy practice that requires the pharmacist to work in concert with the patient to promote health, to prevent disease and to assess, monitor, initiate and modify medication use", is a real challenge for the management of diabetes (27). In the beginning of 1990s, the community pharmacies in the transition countries were mostly oriented to cover the market driven parameters and less to the humanistic outcomes of their profession (28). It was necessary to initiate extending services provided by the pharmacies including patient education programs (29, 30, 31). In this sense this pilot study shows that it is possible to organize a patient education program in the community pharmacies in transition countries. The major limits for the qualitative development of such programs are the preparation of a short educational materials and time limits for the pharmacy staff and patients. At the same time the implementation of such an educational approach in the community pharmacy practice will help the pharmacists to gain their place as a competent and qualified healthcare provider, performing pharmaceutical care.

The results from our study confirm the literature evidences that education of patients with diabetes can be cost-effective and in some extend cost- beneficial (16, 18, 32). If the money that has to be spent for the patient's education is discounted, the possible savings for the patients from avoidable risks and further complications are obvious.

Having in mind the encouraging results, we can conclude that the pharmacy is a suitable place and pharmacists can cope with the challenge to participate in the education programs of people with diabetes. (26). The obtained results confirm the need for constant patients' education, using variety of educational models, as an essential part of the diabetes care that will result in decrease of the chronic complications of diabetes. The results show that such an approach has the potential to decrease the socioeconomic costs of diabetes and to improve the quality of life of patients with diabetes reported elsewhere (20). On the other hand, if there is no such an education, there are great possibilities for appearance of many serious complications such as eye disease, nerve damage, foot and leg ulcers and many others among the patients.

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