ORIGINAL ARTICLE

Economic analysis of the implementation of guidelines for type 2 diabetes control developed by Diabetes Poland

What increase in costs is justified by clinical results?

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KEY WORDS

cost-effectiveness, diabetes, guidelines

ABSTRACT

INTRODUCTION Diabetes Poland has recently published guidelines for the treatment of type 2 diabetes. Treatment according to these guidelines is more expensive and requires more involvement of the patient than is the case in current clinical practice.

OBJECTIVES The aim of the study was to assess to what extent the cost of type 2 diabetes treatment according to the Diabetes Poland guidelines may be increased when compared with the cost of the current treatment, so that the introduction of the guidelines remains cost-effective in the Polish setting.

PATIENTS AND METHODS Two hypothetical patients were defined, John and Peter, representing the population of newly diagnosed type 2 diabetic patients. The disease progression was simulated assuming that John is treated according to the current practice and Peter is treated to achieve and maintain the goals defined by Diabetes Poland. The simulation was performed using the CORE model, which has been constructed based on the published scientific evidence and includes more than a dozen of diabetes complications. The model has been widely validated by numerous studies and is broadly used; it enables a reliable estimation of costs and clinical effects associated with diabetes. The parameters of the model were adapted to the Polish conditions. The analysis was conducted in a life-long perspective, discounting of costs/effects was included, and the acceptability threshold was set at 25,511 EUR per quality-adjusted life-year (QALY).

RESULTS The quality-adjusted life expectancy of John will be 0.3 QALY lower than the life expectancy of Peter. The treatment of diabetic complications will be 400 EUR more expensive in the case of John compared with that of Peter. Assuming the willingness to pay at the level of 7500 EUR/QALY, the cost of diabetes treatment of Peter may be 250 EUR higher than that of John's treatment. For the threshold level of 15,000 EUR/QALY, the difference in cost may be 450 EUR, and for the threshold level of 25,000 EUR/QALY – 725 EUR per year.

CONCLUSIONS Treatment according to the guidelines of Diabetes Poland may be cost-effective provided that the additional costs associated with intensification of therapy will not exceed 725 EUR per year.

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INTRODUCTION Diabetes is a metabolic disorder. It is characterized by hyperglycemia (increased blood glucose levels) and involves disturbances in insulin secretion and a decrease in tissue sensitivity to insulin.[1,2] Hyperglycemia that persists over a period of time may cause chronic complications,

including damage to the blood vessels, heart, kidneys, eyes, or nerves. In the long-term, hyperglycemia may lead to severe consequences such as myocardial infarction, stroke, amputation, and blindness.[1,2] The most common form of the disease is type 2 diabetes. It constitutes about 90% of all diagnosed cases. In the early stage of type 2 diabetes, treatment may be limited to appropriate diet and the proper level of physical activity. In subsequent stages, oral antidiabetic agents are added (monotherapy or combined treatment). If the above therapeutic options are not effective, insulin therapy has to be introduced. Because diabetes is a chronic disorder and failure to achieve normoglycemia is associated with the risk of late complications, it is important to diagnose the disease early and start effective treatment to delay vascular complications.

Currently, diabetes affects a few percent of the general population in the developed countries, and the epidemiological data indicate an ongoing rapid increase in the number of diabetics.[3-6] According to the International Diabetes Federation, there are 285 million adult patients with diabetes in the world.[7] In Poland, according to various estimations, there are about 2 to 2.5 million people with the disturbances of insulin absorption and production which allow to diagnose diabetes. Almost 1 million people in this group are not aware of their illness.[8,9]

Treatment of diabetes in Poland costs about 625 million EUR per year (9% of the health care budget). About 20% of the cost is associated with treatment of chronic complications.[10-13]

The most reliable marker of metabolic control is the level of hemoglobin A_{1c} (HbA_{1c}). For newly diagnosed patients with type 2 diabetes, the guidelines of Diabetes Poland[2] recommend the HbA_{1c} level of 7% or less. The recommended HbA_{1c} level is close to that observed in normoglycemia. This means that the metabolic control of a diabetic patient becomes similar to that of a healthy individual, and such level helps to reduce the risk of diabetic complications. HbA_{1c} of 7.0% or less is feasible for most patients and, at the same time, it is not associated with an unacceptable risk of hypoglycemia (sudden glucose deficiency in the blood that may lead to severe consequences).

Because patients with type 2 diabetes are at an increased risk of cardiovascular diseases (CVD), it is recommended to reduce additional risk factors associated with CVD, such as arterial hypertension and blood lipid disorders. The guidelines define therapeutic goals for blood pressure and lipid metabolism in the treatment of a diabetic patient.

The criteria for blood pressure control are:

1. systolic blood pressure <140 mmHg
2. diastolic blood pressure <90 mmHg;

and for lipid metabolism:

1. total cholesterol <4.5 mmol/l
2. low-density lipoprotein cholesterol <2.6 mmol/l (<1.9 mmol/l in ischemic heart disease)
3. high-density lipoprotein (HDL) cholesterol >1.0 mmol/l (>1.275 mmol/l for women)
4. non-HDL cholesterol <3.4 mmol/l
5. triglycerides <1.7 mmol/l.

The guidelines are updated every year to adjust them to the most clinically validated therapeutic management model based on the results of the published studies.

The aim of this study was to establish the additional cost associated with the optimization of type 2 diabetes treatment (the adjustment of the general standards of diabetes control to the therapeutic goals defined by Diabetes Poland) that would be affordable at a given level of willingness to pay for a unit of clinical effect (per quality-adjusted life-year – QALY).

PATIENTS AND METHODS The analysis involved a comparison between the hypothetical cases of 2 patients: John, whose therapy reflected the general treatment standards in Poland (clinical parameters at the mean levels observed in Poland), and Peter, whose therapy was intensified to achieve the therapeutic goals defined by Diabetes Poland. Simulation of the disease was performed using the CORE model.[14]

Because it was difficult to estimate the cost of Peter's therapy (treated according to the guidelines), we used a threshold analysis instead of a classic cost-effectiveness analysis. Thus, we assessed to what extent the cost of Peter's therapy could be higher compared with the cost of John's therapy, so that this treatment strategy remained cost-effective in the Polish setting.

QALY was the health effect evaluated in the analysis. The QALY is based on assigning "weight" values to the years of life reflecting life quality. The values are typically the numbers between 0 and 1 with 0 representing death and 1 representing full health. Two QALY may be equivalent to 4 years of life in a condition with the weight of 0.5 or to 2 years in full health. A cost-utility analysis was performed using the incremental cost-utility ratio (ICUR), i.e., additional costs that must be spent to achieve an additional unit of health effect. For example, ICUR at the level of 10,000 EUR means that in order to achieve an additional QALY using intervention A instead of B, an additional amount of 10,000 EUR has to be spent.

The threshold ICUR value was set at the level of 25,511 EUR (as for 2010), that is 3 times the gross domestic product (GDP) per capita. Higher costs would mean that the therapeutic strategy used in the case of Peter is not cost-effective. An increase in the annual cost of Peter's treatment as compared with John's treatment was also established for lowel thresholds (2000 EUR and 25,000 EUR).

The progression of the disease was simulated in a life-time horizon. Using the CORE model, we established the life expectancy of John and Peter, the number of QALY, and the costs associated with the treatment of diabetes and its complications. Clinical and economical results were

TABLE 1 Clinical characteristics of John

Parameter	Value
age[a], y	60
HbA_{1c}[b], %	7.08
SBP[a], mmHg	137
TC[b], mmol/l	5.40
HDL-C[b], mmol/l	1.06
LDL-C[b], mmol/l	3.49
TG[b], mmol/l	2.35
BMI[a], kg/m^2	30.6

a data from the ARETAEUS1 study
b data from the UKPDS study

Abbreviations: BMI – body mass index, HbA_{1c} – hemoglobin A_{1c}, HDL-C – high-density lipoprotein cholesterol, LDL-C – low-density lipoprotein cholesterol, SBP – systolic blood pressure, TC – total cholesterol, TG – triglycerides

discounted with the annual rates at the levels of 3.5% and 5%, respectively.[15] We considered only the direct costs, because both John and Peter were near the retirement age and the indirect costs should not have any significant effect on the results of the analysis, especially that severe complications should be expected only after a few years since the onset of diabetes.

Sensitivity analyses were performed to establish the effect of baseline patient characteristics and proportions of patients on hypotensive and hypolipemic agents on the results of the analysis.

CORE model The CORE model is an interactive, Internet-based tool to determine the long-time outcomes of type 1 and type 2 diabetes treatment.[14] The progression of the disease, including diabetic complications (e.g., cardiovascular, neurological, and renal disorders, eye diseases), is simulated based on the results from numerous recent studies on diabetes. The model has been widely validated,[16] and it is constantly developed and updated as new data become available.

The CORE model is used mainly in economic analyses. A vast number of the implemented parameters makes it possible to accurately define the patient cohort, to assess the effect of treatment on the disease course, and to include country-specific conditions (for example, by assigning appropriate cost to a simulated event). The outcome includes the clinical results (life expectancy, QALY, development of complications) and the economic results (direct and indirect cost of diabetes, including the cost of therapy and the cost of complications).

John and Peter John and Peter are hypothetical patients diagnosed with type 2 diabetes at the age of 60. In terms of clinical characteristics and medical history, they represent the population of Polish patients with newly diagnosed type 2 diabetes. The characteristics were established on the basis of 2 clinical studies: the main source of data was the ARETAEUS1 study on the Polish population,[17,18] and additional data (e.g., hyperlipidemia or HbA_{1c} levels) were obtained from UKPDS (United Kingdom Prospective Diabetes Study).[19] The effect of hyperlipidemia on the results was assessed using the sensitivity analysis. The mean HbA_{1c} level in newly diagnosed patients was 7.08% in UKPDS. This level seems to be similar to that in the ARETAEUS1 study (only median was reported). The parameters are presented in TABLE 1. A history of acute coronary syndrome was reported in 10% of the patients, stroke in 4%, nephropathy in 7%, and retinopathy in 17%.

TABLE 2 Diabetes control in Peter throughout the disease course

Parameter	Value
HbA_{1c}, %	7.0
SBP, mmHg	140
TC, mmol/l	4.5
HDL-C[a], mmol/l	1
LDL-C[b], mmol/l	2.6
TG, mmol/l	1.7

a in the Polish population, 50% of the newly diagnosed patients are women; mean value was taken to adjust for sex
b due to lack of data about ischemic heart disease, the value for patients without the disease was considered

Abbreviations: see TABLE 1

Effectiveness of treatment Clinical results describing the progression of the disease in John reflect the mean changes in health parameters observed in patients with type 2 diabetes (according to the assumptions of the CORE model). In the simulation of Peter's disease, it was assumed that the treatment allowed to achieve therapeutic goals defined in the guidelines over the entire course of the disease (control of glycemia, blood pressure, and lipid metabolism; the assumed values are presented in TABLE 2).

Cost analysis Cost data are one of the main elements of the CORE model that have to be adapted to the conditions specific for the Polish health care system. There are 2 general categories: costs associated with interventions and costs associated with the treatment of complications.

The mean cost of pharmacotherapy per patient (oral antidiabetics, insulins) depends on disease duration. In the population of newly diagnosed patients, 64% use metformin, 47% – sulfonylurea derivative, 11% – insulins, and 7% – other medications.[18] Data from the Improvement of Glycaemic Control (Poprawa Kontroli Glikemii), a Polish study that involved patients irrespective of the time from diagnosis, indicated that metformin is used by 71% patients, sulfonylurea derivative – 62%, insulin – 37%, and acarbose – 9%.[20] The mean annual cost of pharmacotherapy is about

TABLE 3 Cost of complications

Event	Cost in the first year (EUR)	Cost in subsequent years (EUR)
myocardial infarction	2300	690
coronary artery disease	974	974
cardiac failure	808	808
kidney transplantation	19,445	5818
hemodialysis	17,385	16,685
peritoneal dialysis	20,969	20,235
stroke	3434	1764
neuropathy	1447	312

Perspective of the public payer; use of resources based on the expert view; prices for the year 2011.

TABLE 4 Results of the threshold analysis

Increase in the annual cost (EUR) of Peter's treatment (compared with John's treatment)	ICUR (EUR)
102	2500
171	5000
240	7500
309	10,000
378	12,500
447	15,000
516	17,500
584	20,000
653	22,500
722	25,000[a]

a utility threshold in Poland equivalent to 3 GDP per capita is 25,511 EUR

Abbreviations: GDP – gross domestic product, ICUR – incremental cost utility ratio

125 EUR per patient in the population of newly diagnosed patients and almost 250 EUR per patient in the general population of patients with type 2 diabetes (from the perspective of a public payer and patients; medication cost based on the order of Minister of Health for December 30, 2010). These costs (125 EUR and 250 EUR) constitute 1% and 2%, respectively, of the average annual pay in Poland and 2% and 5% of the average annual pension. To calculate the mean costs, we assumed that insulins are administered at a dose of 45 IU/day, and antidiabetics at a dose equal to the defined daily dose.

The following conditions and treatments, together with associated costs, are included in the model: myocardial infarction, coronary heart disease, heart failure, kidney transplantation, hemodialysis, peritoneal dialysis, stroke, neuropathy, peripheral artery disease, limb amputation with or without prosthesis, treatment of necrosis, treatment of infected and noninfected ulcers, blindness, laser therapy, cataract operation, and others (e.g., severe hypoglycemic episode, ketoacidosis, lactic acidosis, the cost of screening programs).

Estimation of costs associated with the above events was performed in 2 stages: first, data concerning the use of resources was collected (data not published, obtained from Novo Nordisk Pharma); second, costs were estimated based on the prices of medical services established by the National Health Fund (Narodowy Fundusz Zdrowia – NFZ). The perspective of a public payer (NFZ) was considered.

The use of medical resources was estimated based on extensive consultations with experienced experts in the fields of diabetology, cardiology, neurology, nephrology, ophthalmology, and transplantology or based on expert panel consensus statements. The data were then validated with the published data derived from expert databases and with the opinions of independent experts.

The identified resources were assigned points based on the system of diagnosis-related groups or other appropriate legal acts. Points associated with given services were derived from the NFZ information brochure about the contracts signed in 2010. Cost of medications was established on the basis of the appropriate regulation of the Minister of Health.

The cost of selected treatments is presented in TABLE 3.

RESULTS In a life-time horizon and after discounting, the life expectancy of John was 11.1 years and of Peter – 11.5 years (15.6 and 16.3 years, respectively, without discounting). Quality-adjusted life expectancy was 8.1 QALY for John and 8.4 QALY for Peter.

Direct cost of treatment of diabetes complications in the case of John would be 5950 EUR in a life-time perspective, and in the case of Piotr it would be lower by about 400 EUR (5550 EUR).

Considering the difference in the cost of complications and the difference in QALY of 0.3, it can be calculated that if the treatment of Peter was more expensive by 250 EUR per year on average compared with the treatment of John, it would be cost-effective and the cost of additional QALY gained would be 7500 EUR. If the treatment of Peter was more expensive by 450 EUR compared with the treatment of John, the ICUR would be 15,000 EUR. In terms of the cost-effectiveness ratio as defined by the Agency for Health Technology Assessment in Poland (Agencja Oceny Technologii Medycznych), additional costs of Peter's therapy would be justified in light of additional clinical effects, if the costs would not exceed 725 EUR per year (expenses of the public payer and patients). This amount constitutes 7% of the average annual pay in Poland and 13.5% of the average annual pension (for the year 2011). For an increase in costs of 725 EUR per year, the ICUR would be almost equal to the cost-effectiveness threshold in Poland (TABLE 4). Because cost-effectiveness threshold is correlated with the GDP, it can be assumed that the threshold will increase over the next years, and thus it will be possible

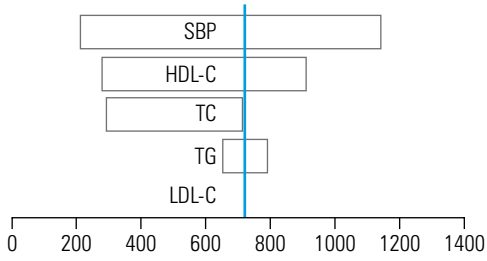

FIGURE Results of sensitivity analysis. Results were analyzed for the change of parameters related to systolic blood pressure and lipidemia ±10%. Better health status of patients at diagnosis means lower maximum increase of expenditures for the treatment of Peter. Abbreviations: see **TABLE 1**

to consider higher expenditure associated with intensive diabetes treatment as cost-effective.

Sensitivity analysis showed that better health condition of the patients at diagnosis decreases the maximum cost-effective level of expenditure associated with intensive treatment of diabetes in Peter. The results seem to be most affected by blood pressure and HDL cholesterol (**FIGURE**). Changes concerning the use of hypotensive and hypolipemic treatment did not significantly affect the results.

DISCUSSION Diabetes may be considered a civilization disease due to high morbidity and the increasing cost of treatment, which becomes a considerable burden for the health care system. In Poland, the total value of covered drugs for diabetes was almost 250 million EUR in 2010, and the reimbursement cost was 172 million EUR. Kidney replacement therapy in diabetics costs about 63 millions EUR per year (based on the contracts signed by the NFZ; diabetic nephropathy, observed in about 25% of dialysis patients, is the most common cause of end-stage renal failure).[21,22] Other costs are associated with the treatment of numerous diabetic complications, with outpatient care (primary care for patients with diabetes was estimated at 75 EUR per year and specialized outpatient care at 150 EUR per year)[22-24], and with diabetes education. It is estimated that the total cost of diabetes treatment in the European Union countries constitutes from 5% to 10% of the total health care expenditure.[25]

Due to an alarming increase in morbidity and expenditures associated with diabetes, it is necessary to devise most effective ways of using the available resources to treat diabetes and its complications. Target treatment (i.e., according to the guidelines of Diabetes Poland) involves tight control of the results achieved in patients and the optimal adjustment of the management scheme so that patients reach treatment goals. Such treatment may require higher financial expenses compared with less intensive therapy, which allows a certain level of uncontrolled metabolic parameters. Treatment according to the guidelines will require full involvement of the patient and physicians of various specialties (primary care physicians, diabetologists, cardiologists, and others). However, our analysis shows that the change in treatment standards is beneficial and is therefore worth all the cost and effort. Effective treatment allows to avoid or delay diabetes complications and thus considerably minimizes the expenses. But, more importantly, effective treatment allows patients to live longer and better quality lives. The awareness that therapeutic decisions made today will have a long-term effect on the quality of life and the cost of treatment should change the way we look at diabetes treatment. The added value of effective type 2 diabetes treatment seems to justify the implementation of demanding and expensive treatment regimens in urgent cases. Delay in the decision to introduce intensified treatment may only seemingly be cost-effective and convenient for the patient.

The cost of treatment optimization, as estimated in the threshold analysis, may be considered feasible in the Polish setting and seems to allow to introduce effective diabetes treatment according to the guidelines of Diabetes Poland. Assuming a very low cost-effectiveness threshold of 2500 EUR/QALY, an increase in the cost of treatment of about 100 EUR per year would be cost-effective. Assuming the cost-effectiveness threshold of 25,000 EUR/QALY (as used in the cost-effectiveness analyses in Poland), the acceptable increase of expenditures for diabetes treatment may be almost 725 EUR per year. This amount enables for example to introduce an additional antidiabetic agent or to increase the number of visits to a diabetes clinic.

In our analysis, we made a simplifying assumption that treatment goals are constant in the analysis horizon. In reality, the standards of management may change, but because we are not able to define the dynamics of these changes, it is impossible to use these variables in the analysis. Therefore, the results of the analysis should be interpreted in the context of the current (2011) guidelines on diabetes treatment.

Our simulation of the disease course in a patient treated according to the guidelines shows the ideal parameters of metabolic control, which is the main limitation of the study. In reality, fluctuations in clinical results during the course of the disease are unavoidable. Even tight control of the parameters and appropriate adjustment of treatment regimens in subsequent stages of the disease do not allow to achieve perfectly stable results.[26] Moreover, it may be more difficult (more expensive) to achieve the recommended values of the parameters with time. Clinical studies have shown that HbA_{1c} tends to increase with time, despite pharmacological treatment.[19]

Nevertheless, the assumed "ideal" course of the disease in a diabetic patient has an information value and may be used as reference when predicting the results of treatment.

This study is not a typical pharmacoeconomic analysis because it does not compare different therapeutic options and thus the results do not provide a clear answer as to the cost-effectiveness of a given modality. However, our aim was not to compare between specific treatment regimens, but to indicate the scope of a possible

improvement in the standards of diabetes treatment. This scope can be limited – among others – by the amount of expenditures that are cost-effective in the context of clinical results achieved in a patient. We did not compare specific therapeutic options because we are convinced that appropriate health effects can be achieved using different modalities and, additionally, treatment regimens can be modified during the course of the disease. In particular, to achieve better glycemic control and other key parameters, it is not always necessary to introduce more expensive and more demanding treatment. Sometimes it is enough to slightly modify the current regimen and, more importantly, to improve cooperation between the patient and the physician as well as to improve compliance. Such modifications do not require high expenditures, while the effects, both clinical and economic, should be noticed in a short time horizon.

The results of our study may be a useful point of reference and may facilitate decision making in the case when higher expenditures are required to improve the effectiveness of treatment. In the threshold analysis, we established an increase in the cost of diabetes treatment that allows to consider a modification in the therapeutic management as cost-effective and thus to introduce significantly higher (if not ideal) treatment standards. Assuming a very low willingness to pay for clinical effects (2500 EUR/QALY), an accepted increase in the cost of treatment is about 40% of the cost of treatment of an average patient with type 2 diabetes. Assuming that the utility threshold is near the standard ceiling value used in pharmacoeconomic analyses (25,000 EUR/QALY), the cost of treatment of an average diabetic patient may increase 4-fold and it will still be cost-effective.

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Analiza ekonomiczna realizacji standardów wyrównania cukrzycy typu 2 opracowanych przez Polskie Towarzystwo Diabetologiczne

Jaki wzrost kosztów jest uzasadniony przez wyniki kliniczne?

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SŁOWA KLUCZOWE

cukrzyca, opłacalność, wytyczne

STRESZCZENIE

WPROWADZENIE Zalecenia dotyczące terapii cukrzycy typu 2 opracowało Polskie Towarzystwo Diabetologiczne (PTD). Leczenie zgodne z wytycznymi wymaga większych nakładów finansowych i zaangażowania pacjenta niż obecna praktyka kliniczna.

CELE Celem badania było określenie, o ile większy mógłby być koszt terapii cukrzycy typu 2 prowadzonej zgodnie z wytycznymi w porównaniu z kosztami aktualnego leczenia, żeby realizacja zaleceń była opłacalna w polskich warunkach.

PACJENCI I METODY Zdefiniowano dwóch hipotetycznych pacjentów: Jana i Piotra, odpowiadających populacji nowo zdiagnozowanych pacjentów z cukrzycą typu 2. Symulowano rozwój choroby przy założeniu, że Jan jest leczony zgodnie z obecną praktyką, natomiast terapia Piotra prowadzi do osiągnięcia i utrzymywania celów PTD. Do symulacji wykorzystano model CORE, zbudowany i zwalidowany na podstawie opublikowanych dowodów naukowych, uwzględniający kilkanaście powikłań cukrzycy. Model pozwala na wiarygodne oszacowanie kosztów i efektów klinicznych związanych z cukrzycą. Parametry modelu dostosowano do polskich warunków. Analizę przeprowadzono w horyzoncie dożywotnim, uwzględniono dyskontowanie kosztów/efektów, przyjęto próg opłacalności 25 511 EUR/QALY (ilość lat życia skorygowana jakością – *quality-adjusted life-year*).

WYNIKI Oczekiwane przeżycie Jana skorygowane jakością będzie o 0,3 mniejsze niż oczekiwane przeżycie Piotra. Leczenie powikłań cukrzycy u Jana będzie o 400 EUR droższe niż u Piotra. Jeżeli przyjmie się gotowość do płacenia na poziomie 7500 EUR/QALY, koszty terapii cukrzycy u Piotra mogą być o 250 EUR większe w porównaniu z kosztami terapii Jana. Dla progu 15 000 EUR/QALY różnica w kosztach może wynieść 450 EUR, a dla progu 25 000 EUR za QALY – 725 EUR rocznie.

WNIOSKI Leczenie zgodne z zaleceniami PTD może być opłacalne, o ile dodatkowe koszty związane z intensyfikacją terapii nie przekroczą 725 EUR rocznie.

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