

Quality Control in Diabetes Mellitus

Doctoral Theses

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Introduction

Under the auspices of the World Health Organization and the International Diabetes Federation with the participation of European health care authorities, diabetes patient organizations, diabetes health care providers, and the press a meeting was organized in St. Vincent, Italy in 1989. The then approved St. Vincent Declaration emphasized the public health importance of diabetes mellitus, and urged the development of practice recommendations and standards. It also aimed at the reduction of diabetes related morbidity and mortality.

One of the main targets of the action programme was to develop a quality control system for the care of diabetic patients. After a thorough international consensus and debate process the working group arranged the Basic Information Sheet, a form that includes the most important questions and indicators related to diabetes care. It includes only essential parameters that should be collected on all levels of diabetes care. A software version of the Basic Information Sheet was also developed and implemented in several European countries including Hungary.

In the United States, where medical care is market oriented, quality assurance has deeper traditions. As a consequence of the market induced changes in the health care system quality assurance emerged as a major topic of clinical science.

In 1998 the American Diabetes Association introduced the Diabetes Quality Improvement Project that includes similar quality variables to the Basic Information Sheet. That could lead to easier international comparisons of patient care.

During the process of quality assurance several aspects of patient care might be examined, such as **structure** and **process** of health care, complications, risk factors (**outcomes**), and quality of life and patient satisfaction.

The **structure of health care** includes the entirety of financial, human and intellectual resources. During the structural examinations of patient care several studies compared the care provided by diabetes specialists and general practitioners. It was proven that diabetologists were more active in ordering the necessary examinations for their patients. It should be mentioned, however, that cardiovascular prevention was performed more frequently by the general practitioners.

The **process of health care** could be easily examined, since several of these data are collected for administrative and financial purposes. Larger patient populations, representative samples could thus be analyzed. During analysis the frequency of these processes are examined. They could be used for objective comparisons since process indicators should not be influenced by case-mix measures. Using this method could lead to the determination of several insufficiencies, though its role in positive conclusions is debatable.

Different studies agree that while the frequency of blood pressure, body weight, blood sugar, blood lipids, and ECG determination are acceptable (> 70%), the frequency of ophthalmological, foot, and dental examinations, dietary education, HbA1c and urinary albumin tests are lower than desirable.

A prerequisite of the **outcome indicators** analysis is their acceptable completeness. The *true outcome indicators* represent the end-stages of diabetes complications (end-stage renal failure, blindness, lower extremity amputations, myocardial infarction, and stroke). Their development is a long term process of years/decades, thus their analysis requires long term follow-up. Since their prevalence is very low (0,5-2%), their examination is advised only on large, population-based samples. The latter also requires the knowledge of the exact background population.

The *intermediate outcome indicators* represent the different pathologies lying on the pathological pathway towards end-stage complications: several alterations of the eyes, feet, microalbuminuria, elevated serum creatinine,

metabolic parameters, and macrovascular risk factors. Additional therapies, number of insulin injections, self-monitoring, and diabetes education should also be classified here. For the comparison of intermediate outcomes their exact definition should be stated and used.

Quality improvement methods may target different components of the health care system. Traditionally they mostly **target health care professionals**. These interventions might include different educational meetings, treatment guidelines based on local consensus, reminders and summaries of patient records, and decision support tools.

Patient related interventions include those aiming at increasing financial interest and knowledge of the patients related to their disease.

The different structural interventions try to modify the professional roles, to reorganize the information system, and to improve the patient follow-up,

Disease management is a combination of interventions that aims the improvement of the treatment and care of patients suffering from chronic diseases. These complex systems mostly improved processes.

Aims

There is a worldwide gap between the efficiency of diabetes care in clinical practice and the efficacy attainable in clinical trials. There is no wide-scale quality control data on diabetes care from larger populations in Hungary.

In the present study using the data collected during the voluntary DiabCare Hungary Programme (a quality control and patient management programme approved by a wide European consensus) our aim was to

- describe the level of diabetes care before intervention,
- to compare the participants data using bench-markings and national averages,
- to examine the applicability of the whole programme, and the validity, and usability of the data during a pilot study,

- to develop a valid method for the comparison of centres caring for different patient populations (standardization),
- to examine the development of quality indicators during the project,
- to perform international comparisons of processes and intermediate outcomes using the standardized indicators,
- to assess the applicability of the quality control data for epidemiological analysis. For this purpose the risk factors of erectile dysfunction were analyzed in a cross-sectional study.

Methods

We used the **software version** (ProDiab 1.5, later DiabCare for Windows) of the WHO/IDF approved **Basic Information Sheet** (BIS) for data collection purposes. The BIS includes different characteristics of diabetic patients for the last 12 months. The programme is freely available and can be downloaded free of charge. All versions include a detailed user's guide. Both the user's guide and the data entry form were translated into Hungarian.

The BIS includes several *demographical data* of the patients: sex, age, diabetes duration, type of diabetes. The next section includes data on *treatments*. These are followed by *laboratory results*. The user's guide gives recommendations for the acceptable methods. Both the incidence and prevalence of *end-stage complications* may be recorded. These are followed by the results of the *eye and foot examinations*. *Symptoms and complaints related to diabetes* help to describe diabetes complications. Smoking and alcohol consumption are collected as *lifestyle factors*. *Diabetes-related education* means at least 45 minutes of teaching on specified topics in the last 12 months.

The parameters were analyzed according to 2 aspects of care. First the **completeness** was described, then with the help of the previous data, the **patients were divided** into groups **using international recommendations**. The true **interventional value** of the DiabCare Hungary programme lies in the activities organized and performed by the evaluation centre.

Data sent for the centre **were immediately evaluated** using an automated evaluation software. These results were mailed in a few days to the centre.

Once a year all data collected were analyzed as a whole and by centre. These results were also published in a book. Using the bench-marking one can identify his/her own practice. Yearly **meetings** were organized to present the collected data, where the most active centres also had the opportunity to introduce their activities. By the request of certain centres **specific analysis were also carried out**.

Between 1994 and 2000 altogether 24 accredited diabetes care centres and 2 general practitioners participated in the DiabCare Hungary Working Group. The participation was voluntary and no financial support was provided to the group members. During the study period 11,291 patient records were entered into the database. This represents 13% of the diabetes population of the counties represented by the programme. The DiabCare cohort similarly represents 59% of type 1 diabetes patients.

In the **pilot study** 3,835 records from 19 care centres were analyzed collected between 1994 and 1996. This also includes 2 general practices.

For **the comparison of care centres with different patient populations** we compared the data of 2403 patients provided by 20 care centres between 1995 and 1997 to the results of 5 larger centres.

In the **longitudinal analysis** we evaluated the data collected from accredited care centres between 1994 and 2000, who had known type 1 or type 2 diabetes mellitus (n = 2,675 / 4,470).

Into the **international comparison of process indicators** two separate databases were included. The first represents the care of non-insulin treated

type 2 diabetes patients, and includes data collected by the general practitioners of Csongrád in 1996 (n = 763). The second represents the care of type 1 diabetes patients derived from the data sent by the accredited care centres by the end of 1997 (n = 4,362). These were compared to the 1994 Behavioral Risk Factor Surveillance System data.

For the **international comparison of outcome indicators** we selected those type 1 diabetes patients who were diagnosed under the age of 17. The thus selected 405 patients represent 86% represents of the whole (matching the above criteria) cohort. As a comparator patients from the Epidemiology of Diabetes Complications (EDC) Study were used, who are representative of the cohort of childhood-onset type 1 diabetic patients.

When the **risk factors of erectile dysfunction** were evaluated, those males were selected from 1994-1998, who had recorded information on impotence in the database.

Descriptive statistics are presented as mean \pm standard deviation or percentages. During the comparison of different care centres indirect standardization was used. For the longitudinal analysis of risk factor, continuous variables were evaluated using parametric correlations (Pearson), categorical variables using khi2 for trend analysis, For categorical outcomes khi2 test, for continuous outcomes t-tests and ANOVA were performed. To adjust for the effect of different covariates we used multiple logistic regression for categorical and multiple linear regression for continuous outcomes. Variables were log-transformed as required.

Results

Pilot Study

Forty-three percent of the patients were male. The completeness of the demographical data is good, the date of birth, sex, year of diagnosis, type of

diabetes, and the mode of therapy is known for 94% of the patients. Sixty-four percent of the patients received insulin as a part of their antidiabetic treatment, 52% performed self-monitoring of blood glucose. The completeness of risk factors is also good (~90%). The completeness of glycated hemoglobin and triglyceride values increased after the first year. The completeness of albuminuria examination was acceptable only in the second year. The distribution of centres according to the prevalence of HbA1c/HbA1c above 8% was very wide: 20-75%. There was a decreasing trend of smoking and alcohol consumption in the years evaluated. Sixty-two percent of the patients had any retinopathy, 7% of them proliferative.

Standardization – a Method for Comparison of Centres Caring for Different Patient Populations

According to their *demographical data* the evaluated centres are very different, the prevalence of males is between 27 and 63%, >15 years of diabetes duration is found in 14-50%, the prevalence of type 1 diabetes is 0-80%. The *completeness of demographical data* is 93% countrywide. In the 5 selected centres it varies between 78-99%, affected only partially by standardization.

There is no data available on 20% of the patients related to *diabetic eye disease*. The corresponding data for the selected centres is 2-72%. Diabetic retinopathy was found in 19-72% of the patients examined. The order of the centres was not significantly affected by standardization. The *completeness of risk factors* (glycated hemoglobin, triglycerides, blood pressure, smoking, alcohol consumption) was acceptable (>80% except for centre 3), which was only nonsignificantly affected by standardization. The completeness of albuminuria was 55%.

The *proportion of patients in the risk group* was 43% according to glycated hemoglobin (>8%), somewhat lower in centre 3 (2%) and centre 5 (29%), and higher in centre 5 (50%). Elevated triglycerides (> 2 mmol/l) were

found in 33% of the patients nationwide. This proportion was lower in centre 5 (17%). Elevated blood pressure value ($> 160/95$ mmHg) was reported in 15% of the patients. The prevalence was lower in centre 2 (2%). The higher prevalence in centre 3 was largely reduced by standardization (from 23 to 19%). The frequency of self-monitoring and severe hypoglycemia was related to the relative weight of type 1 diabetes in the given centre. If it increased during standardization the respective frequencies would rise.

Longitudinal Analysis of Quality Control Indicators

During 1994-2000 the yearly averages of both systolic and diastolic *blood pressure* decreased **in type 1 diabetic patients**. From 1994-1997 to 1998-2000 blood pressure values decreased by $7/3$ mmHg. The proportion of patients with pathological values decreased similarly. During the examined 7 years the treatment of *dyslipidemia* tripled, although mean LDL levels only minimally decreased. The proportion of *acceptable* blood pressure *treatment* ($<130/85$ mmHg) was found in 11-33% of hypertensive patients, linearly increasing throughout the study period. The prevalence of acceptable dyslipidemia treatment also showed some improvement (0-6%), however the target value was reached only by a minority of patients.

During 1994-2000 a decreasing trend was observed for both systolic and diastolic *blood pressure* values **in type 2 diabetic patients**. The difference reached $9/4$ mmHg between the first and last years of the study. The frequency of antihypertensive treatment increased similarly. The treatment of *dyslipidemia* tripled, and mean LDL levels significantly decreased. The proportion of *acceptable* blood pressure *treatment* ($<130/85$ mmHg) was found in 11-44% of hypertensive patients, linearly increasing throughout the study period. The prevalence of acceptable dyslipidemia treatment also showed improvement (4-43%), and the target value was reached by almost half of the patients by the end of the study.

International Comparison of Process Indicators

Hundred percent of Hungarian patients and 89% of American patients had health care insurance. In accordance to the data collection method all Hungarian patients had a visit to their diabetes health care provider in the previous year.

First *insulin users* and *nonusers* were compared within each database. Insulin users performed self-monitoring more frequently, and had HbA1c measured more often. In the care centres insulin users had higher rates of feet and eye examination than nonusers.

Among type 1 diabetes patients eye examination and HbA1c determination was done more frequently in the DiabCare database than in the American study ($P < 0.0001$). There was no other significant difference between the studies.

Insulin users in Hungary perform significantly more self-monitoring and HbA1c measurements ($P < 0.0001$) than their American counterparts. Regarding other ADA standards, insulin users get better care in specialist care centres in Hungary than in general practice in Hungary or in the US ($P < 0.0001$).

Insulin nonusers perform less self-monitoring and get fewer HbA1c measurements in Csongrád than in the US ($P < 0.0001$)

International Comparison of Outcome Indicators

Regarding general health care characteristics we can find that DiabCare patients were treated more frequently by a diabetologist or endocrinologist. Almost all Hungarian patient and 75% of the Pittsburgh cohort performed self-monitoring of blood glucose. More DiabCare patients received diabetes education in the year prior data collection. While most of the Hungarian patients received intensified insulin regimens, most of the American patients used conservative insulin treatment. Eye examinations were

documented also more frequently in the DiabCare database. Hypoglycemic emergencies were reported more often in the DiabCare database.

Glycated hemoglobin levels were lower among DiabCare patients compared to the Americans. Microvascular complications (proliferative retinopathy, blindness, albuminuria, end-stage renal failure, symptomatic neuropathy) were found more often in the EDC study. There was no difference in the prevalence of the macrovascular complications, while hypertension was found more often among the Hungarian patients.

Cross Sectional Risk Factors of Erectile Dysfunction

The prevalence of erectile dysfunction was 14.4% among 188 type 1, and 18.9% among 475 type 2 diabetes patients.

Type 1 diabetes patients with erectile dysfunction were older, had longer diabetes duration, had higher systolic blood pressure, albumin excretion rate, they had higher rates of micro- and macrovascular complications, higher rates of hypertension and higher rates of subjects on antihypertensive medication. Using logistic regression diabetic nephropathy was the only independent covariate of erectile dysfunction.

Type 2 diabetes patients with erectile dysfunction were older, had longer diabetes duration, they had a tendency for worse metabolic control, consumed more alcoholic beverages, they had more frequently proliferative diabetic retinopathy and diabetic neuropathy. Antihypertensive treatment and increased alcohol consumption increased the risk for erectile dysfunction. Using logistic regression the presence of neuropathy, increased alcohol consumption, proliferative retinopathy, and the presence of macrovascular complications increased the risk of erectile dysfunction.

Novel Findings and Conclusions

1. Our group was the first that used the quality control system developed under a European consensus for the examination of ambulatory diabetes care in Hungary. During the programme adaptation we translated the whole system including the whole software and the user's guide. According to the pilot results we found the system applicable for quality control purposes.
2. The voluntary multicentre group including diabetes care centres and general practices performed well as a quality control system. The observed results provided data on the status of the ambulatory care before intervention, and correlated well with the European and American literature.
3. During our analyses we proved that general patient data may deeply affect outcome indicators. Direct comparisons thus might be performed only between centres that care for similar patient populations.
4. According to our results direct standardization may be applicable for comparison of different care centres. We performed and automated such standardization for diabetes care centres. We proved that the main barrier to multi level standardization is the required large number of patients in the given centres (in our study it was set to 150 subjects). Using only one or two parameters (such a stype of diabetes) smaller centres could be compared and the method may be used also for general practices.
5. Using data from the accredited care centres of DiabCare Hungary from 1994-2000 we found **in a longitudinal analysis** significantly improving blood pressure values both in type 1 and type 2 diabetes patients
6. The antilipemic treatment tripled in both type 1 and type 2 diabetes patients. The LDL levels decreased markedly and significantly in type 2 patients in the examined period, while there was only a minimal (not significant) improvement among type 1 patients.
7. The observed 7/3 mmHg decrease of blood pressure might improve the micro- and macrovascular risk by 20%, while the 0,4 mmol/l LDL decrease has similar macrovascular risk reduction. Both of these finding may have significant public health importance.

8. In **the international comparison of process indicators** we proved that insulin users perform self-monitoring more frequently, and they have more often HbA1c examinations. Insulin users generally have better care results in Hungary (self-monitoring, HbA1c), although the best care is provided to patients in the accredited care centres. The care of insulin nonusers at general practices lack behind the care received by American patients.

9. Our study of **an international comparison on outcome indicators** was the first that published data on the effect of centralized or decentralized health care system on diabetes care using both process and outcome indicators.

10. Our data supports that in Hungary (where type 1 diabetes patients receive centralized, specialized care) patients had lower glycosylated hemoglobin levels, were more frequently treated by diabetologists, performed self-monitoring more often, used intensive insulin regimens more frequently, and the prevalence of severe hypoglycemic events was higher.

11. In the Hungarian cohort the risk of microvascular complications (retinopathy, cataract, blindness, albuminuria, and end-stage renal failure) was decreased, while the risk of hypertension was increased.

12. In the current cross-sectional study the prevalence of **erectile dysfunction** was 14% in type 1 diabetes and 19% in type 2 diabetes.

13. In both patient populations erectile dysfunction was tightly linked to age, diabetes duration, blood pressure lowering medications, and the presence of micro- and macrovascular complications. In addition we found an association of erectile dysfunction with hypertension in type 1 diabetes, and with alcohol consumption and metabolic control in type 2 diabetes. Our results further confirm the associations of previously described risk factors and erectile dysfunction.

14. Our result clearly demonstrate that data collected for quality control purposes may be used to describe with epidemiological methods the natural

history and risk factors of diabetes related questions if a rigorous methodological construction is applied.

Publications Relevant to the Current Work

Book Chapter

1. Tabák GyÁ, Kerényi Zs, Tamás Gy. Minőségbiztosítás, minőség-ellenőrzés diabetes mellitusban. In Diabetes mellitus: elmélet és klinikum. Halmos T, Jermendy Gy (eds). Medicina Könyvkiadó, Budapest, 2002, pp 767-784

Peer Reviewed Papers

Impact factor of the peer reviewed papers (7 papers) relevant to the current work: **10,076**

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Impact factor of the other peer reviewed papers (34 papers) relevant to the current work: **35,121**

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