A Method to Measure Quality of Diabetes Treatment: Results from an Outpatient Clinic

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It is essential for patients, hospital staff and hospital administrators to know the quality of hospital care. We have developed a system to evaluate the quality in an outpatient clinic. The aims of this study are: to develop a system for quality monitoring of outpatient diabetes care, to evaluate the effectiveness of this system and to develop procedures for feedback to the patients and the staff.

In this paper we report on the results related to the first two aims. The metabolic control of diabetes mellitus is evaluated by measurement of serum HbA1c, serum triglyceride, serum total cholesterol, body weight and blood pressure, and the result is used in the calculation of a metabolic score. Diabetic nephropathy and retinopathy are evaluated once a year according to international classifications. The data were collected from 1 January to 31 December 1991.

We were able to collect data on HbA1c in 94% of the diabetic patients, but we obtained data in only 46-75% of the patients for all other parameters. Concerning glycemic regulation, 52.3% of the insulin-dependent diabetes mellitus patients and 41.5% of the non-insulin-dependent diabetes mellitus patients had poor regulation. The results for the other parameters included in the metabolic score were more satisfactory. There was a significant correlation between the number of days the patients were in hospital and the HbA1c value.

In conclusion, the system enables us to determine the degree of metabolic regulation and regular evaluation of diabetic late complications. Through the measurement of outcome parameters we have discovered failure in process quality in our hospital department.

Key words: Diabetes mellitus, quality measurement.

INTRODUCTION

In clinical practice there has been a long tradition of using clinical research results as recommendations for treatment and investigations. Up until now doctors have not routinely verified optimal investigations and good treatment, but assumed that they were providing good clinical practice. There has not been a tradition for continuous registration of investigation and treatment data to ensure that the recommendations were followed, or to document the effectiveness of treatment. It is essential for patients, hospital staff and hospital administrators to know the quality of hospital care. The patients have to be sure that they receive optimal care, the professionals must be informed about the results of their effort in order to develop their skills further and the hospital administrators have to know what quality of care they obtain for the taxpayers’ money.

Diabetes mellitus is a chronic disease. It is a growing health problem affecting about 2–5%
TABLE 1. Definition of metabolic regulation as good, acceptable or poor

<table>
<thead>
<tr>
<th></th>
<th>%</th>
<th>Good</th>
<th>Acceptable</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (arb.)</td>
<td>50</td>
<td>≤0.08</td>
<td>&gt;0.08–≤0.09</td>
<td>&gt;0.09</td>
</tr>
<tr>
<td>Diastolic blood pressure (mm Hg)</td>
<td>20</td>
<td>≤90</td>
<td>&gt;90–≤100</td>
<td>&gt;100</td>
</tr>
<tr>
<td>S-total cholesterol (mmol/l)</td>
<td>10</td>
<td>≤5</td>
<td>&gt;5–≤7</td>
<td>&gt;7</td>
</tr>
<tr>
<td>S-triglycerides (mmol/l)</td>
<td>10</td>
<td>≤2</td>
<td>&gt;2–≤5</td>
<td>&gt;5</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>10</td>
<td>≤25</td>
<td>&gt;25–≤30</td>
<td>&gt;30</td>
</tr>
</tbody>
</table>

The % indicates the weight of the parameter by calculation of the metabolic score.

The % indicates the weight of the parameter by calculation of the metabolic score.

of the adult population [1]. Complications of diabetes mellitus are the leading cause of blindness among adults, many of those on dialysis or with a kidney transplant are patients with diabetes, 30% of lower limb amputations are due to diabetes, and diabetes mellitus doubles the risk of heart disease or stroke. The life expectancy for a diabetic patient is reduced in comparison with the rest of the population [1]. Optimal metabolic control of diabetes is of great importance in avoiding the development of diabetic late complications [2,3]. A randomized trial in the USA [The Diabetes Control and Complications Trial (DCCT) (unpublished data)] recently showed that good metabolic control drastically reduced the development of diabetic late complications.

The aims of this study are:
— to develop a system for monitoring quality of outpatient diabetes care;
— to evaluate the effectiveness of this system;
— to develop procedures for feedback to the patients and the staff.

In this paper we report on the results related to the first two aims. We have developed a method for continuous registration of metabolic parameters and late complications in our outpatient diabetes clinic. We present the data collected during the first year of the project from 1 January to 31 December 1991.

MATERIALS AND METHODS

In 1991, at the Department of Internal Medicine and Endocrinology at Odense University Hospital, 1122 diabetic patients attended the outpatient diabetes clinic. The patients were divided into three groups according to the type of diabetes: 636 patients with insulin-dependent diabetes mellitus (IDDM), 438 patients with non-insulin-dependent diabetes mellitus (NIDDM) and 48 patients with secondary diabetes mellitus.

IDDM is defined by a fasting C-peptide ≤0.03 nmol/l, a glucagon stimulation test with a value ≤0.6 nmol/l, or if the patient at the time of diagnosis has a body mass index (BMI) less than 25 kg/m² and an age less than 40 or if there are clinical signs showing that the patient had IDDM [4].

Patients with NIDDM are defined by normal or high insulin production at the time of diagnosis, a BMI >25 and over 40 years of age at the time of diagnosis, a fasting C-peptide >0.3 nmol/l, and a glucagon stimulation test with a value >0.6 nmol/l. Secondary diabetes is caused by external factors such as pancreatitis, or steroid treatment.

Definition of quality

We have defined quality at two levels:
— Short-term quality: normal metabolic regulation for the patients.

Metabolic control

We chose to include five parameters in the determination of the metabolic control. These parameters are used to calculate a metabolic score. The parameters are: HbA1c, which gives an impression of the mean glucose level for up to 3 months [5–7], diastolic blood pressure, serum total cholesterol, serum triglyceride and BMI. BMI is calculated as the body weight in kilograms, divided by the square of the height in meters. For each parameter, the mean of the data values collected is used for evaluation. From these parameters, we have defined three levels of metabolic control: good, acceptable and poor (Table 1). The parameters have differ-
ent values in the calculation of the metabolic score. HbA1c counts 50%, diastolic blood pressure counts 20% and S-total cholesterol, S-triglyceride and body weight count 10% each. The metabolic score is the sum of the scores. For every patient a metabolic score between 0 and 2 is calculated using the data in Table 1. Good quality scores 0, acceptable quality scores 1 and poor quality scores 2. S-total cholesterol and S-triglyceride are measured only in patients below the age of 60 years.

**Diabetic late complications**

There are four different kinds of diabetic late complication: nephropathy, retinopathy, angiopathy and neuropathy. Nephropathy is evaluated once a year in all patients by the measurement of U-albumin excretion and in patients with albuminuria by determination of creatinine clearance. For evaluation of renal failure the results are divided into four groups [8,9]: No renal affection (U-albumin < 20 μg/min), microalbuminuria (U-albumin ≥ 20 μg/min < 200 μg/min), albuminuria (U-albumin ≥ 200 μg/min) and uraemia (creatinine clearance < 10 ml/hr).

Retinopathy is evaluated by an ophthalmologist once a year. Retinopathy is classified as non-proliferative retinopathy, proliferative retinopathy and macular involvement [10]. Visual acuity is measured and social blindness is defined as visual acuity less than 0.167 [11]. For analysis the most affected eye is considered. Angiopathy and neuropathy were not properly examined in this part of the project.

**Collection of data**

To retrieve information on treatment quality it was necessary to introduce structured data collection. We have developed two data sheets. The first sheet contains data on metabolic regulation (HbA1c, blood glucose, blood pressure, body weight and, for patients with nephropathy, S-creatinine and U-albumin). The sheet also contains the information on prescriptions for insulin, oral antidiabetic treatment, other medication and finally 8 cm² per visit for remarks. The second sheet contains all the information about the annual status. This sheet contains information from the ophthalmologist (the degree of retinopathy and the visual acuity). It also contains information on renal affection (U-albumin and, in the case of nephropathy, S-creatinine and creatinine clearance), information concerning neuropathy and angiopathy and information on the lipid status of the patient (S-total cholesterol, S-triglycerides, high density lipoprotein-cholesterol and low density lipoprotein-cholesterol).

These data sheets are an integral part of the patient’s medical record. They give the physician an overview of the condition of the patient. When a patient visits the department, the data collected are written on the sheet. After the visit, the data are entered into a computer system. The results from the Department of Clinical Chemistry are transferred electronically. When the data are collected and verified by the physician, the computer produces a printout with all the relevant data of the visit for the patient’s general practitioner.

**Computer equipment**

The project has grown from a little network with three computers to a network with 20 computers and six laser printers. There is a 3270-gateway connecting the departmental network to the county’s mainframe computer. There are six laser printers, and a modem connection to the Department of Clinical Chemistry.

In July 1992 we transferred all the data from self-developed software to a commercial system for medical records (MEDEX®). The database has approval from the legal authorities.

**Statistics**

Group comparisons concerning differences between NIDDM and IDDM were analysed by the Mann–Whitney U-test. Correlations were analysed by the Spearman rank-correlation test.

**RESULTS**

The results are based on data collected from 1 January to 31 December 1991. In 1991, 1122 diabetic patients attended the outpatient clinic and these patients had 3806 contacts with a doctor. Seventy-seven patients were admitted
TABLE 2. Number of patients for whom Data were obtained for each of the parameters used

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>IDDM</th>
<th>NIDDM</th>
<th>Secondary</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>636</td>
<td>438</td>
<td>48</td>
<td>1122</td>
</tr>
<tr>
<td>HbA\textsubscript{1c}</td>
<td>595 (94)</td>
<td>402 (92)</td>
<td>46 (95)</td>
<td>1043 (93)</td>
</tr>
<tr>
<td>Diastolic blood pressure</td>
<td>555 (87)</td>
<td>366 (84)</td>
<td>45 (93)</td>
<td>973 (86)</td>
</tr>
<tr>
<td>S-total cholesterol*</td>
<td>278 (50)</td>
<td>167 (76)</td>
<td>25 (71)</td>
<td>470 (58)</td>
</tr>
<tr>
<td>S-triglyceride*</td>
<td>218 (39)</td>
<td>137 (63)</td>
<td>21 (60)</td>
<td>376 (46)</td>
</tr>
<tr>
<td>Body mass index</td>
<td>479 (75)</td>
<td>282 (64)</td>
<td>38 (79)</td>
<td>798 (71)</td>
</tr>
<tr>
<td>U-Albumin</td>
<td>349 (55)</td>
<td>224 (51)</td>
<td>30 (63)</td>
<td>603 (54)</td>
</tr>
<tr>
<td>Ophthalmologist</td>
<td>328 (52)</td>
<td>165 (38)</td>
<td>24 (50)</td>
<td>517 (46)</td>
</tr>
</tbody>
</table>

Percentages of the number of patients are in brackets.
*Only patients below the age of 60. No. of patients: IDDM 556, NIDDM 219 and secondary 35.

IDDM, insulin-dependent diabetes mellitus; NIDDM, non-insulin-dependent diabetes mellitus.

in 1991 with newly diagnosed diabetes. Seventy-five patients were discharged from the outpatient clinic in 1991. It was not possible with the data structure to obtain the exact number of patients that were transferred in 1991 from other clinics or from the general practitioner with diabetes onset before 1991.

Process quality

We have obtained HbA\textsubscript{1c} values for 94% of the IDDM patients (Table 2) and 92% of the NIDDM patients. An analysis of the patients with missing data shows that 12 patients were newly referred patients that had not seen a doctor in the outpatient clinic during the data sampling period. In 22 patients the patient had been in the outpatient clinic, but no data were obtained. The remaining were patients that failed to appear for their scheduled appointments. We obtained U-albumin data on 55% of the IDDM patients and on 50% of the NIDDM patients. We received data from the ophthalmologist on 38% of the NIDDM, and on 52% of the IDDM patients.

S-total cholesterol was obtained in 58% of the patients. Concerning BMI, it was possible to calculate a value for 479 IDDM patients (75%) and for 282 IDDM patients (64%). A height was not recorded in 199 cases (17%) where body weight was recorded.

It was possible to calculate a metabolic score in only 327 patients (192 with IDDM, 118 with NIDDM and 17 with secondary diabetes).

There was no difference in the indicators (HbA\textsubscript{1c}, diastolic blood pressure, S-total cholesterol, S-triglyceride and BMI) between patients where a metabolic score could be calculated and the patients where this was not possible. An exception was BMI in IDDM patients ($p = 0.0046$) and diastolic blood pressure in NIDDM patients ($p = 0.0223$).

Outcome quality: metabolic control

The mean HbA\textsubscript{1c} in all diabetic patients was $0.090 \pm 0.017$ (SD). The mean value among the IDDM patients was $0.092 \pm 0.016$. More than half the IDDM patients had poor glycemic regulation (Table 3). Glycemic control was better among the NIDDM patients, with a mean at $0.088 \pm 0.017$. 34.3% of the NIDDM patients had good glycemic regulation, and 41.5% had poor glycemic regulation.

The patients with secondary diabetes were the patients with the best glycemic regulation with a mean HbA\textsubscript{1c} of $0.083 \pm 0.015$. Of the patients in this group, 50.0% had good glycemic regulation and only 28.3% had poor glycemic regulation.

Only 0.9% of the IDDM patients had poor diastolic blood pressure. Among the NIDDM patients, there were more patients with poor diastolic blood pressure, but more than 95% of the NIDDM patients had good or acceptable regulation of their diastolic blood pressure. The measurement of S-total cholesterol and S-
Quality of Diabetes Treatment

TABLE 3. Number of patients grouped under good, acceptable and poor regulation

<table>
<thead>
<tr>
<th></th>
<th>Good IDDM</th>
<th>Good NIDDM</th>
<th>Secondary</th>
<th>Acceptable IDDM</th>
<th>Acceptable NIDDM</th>
<th>Secondary</th>
<th>Poor IDDM</th>
<th>Poor NIDDM</th>
<th>Secondary</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c</td>
<td>139(595)</td>
<td>138(402)</td>
<td>23(46)</td>
<td>145(595)</td>
<td>97(402)</td>
<td>10(46)</td>
<td>311(595)</td>
<td>167(402)</td>
<td>13(46)</td>
</tr>
<tr>
<td>Diastolic blood pressure</td>
<td>91.5%</td>
<td>82.5%</td>
<td>73.3%</td>
<td>42(555)</td>
<td>47(366)</td>
<td>9(45)</td>
<td>5(555)</td>
<td>17(366)</td>
<td>3(45)</td>
</tr>
<tr>
<td>S-total cholesterol</td>
<td>508(555)</td>
<td>302(366)</td>
<td>33(45)</td>
<td>120(278)</td>
<td>43.2%</td>
<td>24.0%</td>
<td>165(402)</td>
<td>24.1%</td>
<td>12.8%</td>
</tr>
<tr>
<td>S-triglycerides</td>
<td>508(555)</td>
<td>302(366)</td>
<td>33(45)</td>
<td>120(278)</td>
<td>43.2%</td>
<td>24.0%</td>
<td>165(402)</td>
<td>24.1%</td>
<td>12.8%</td>
</tr>
<tr>
<td>Body mass index</td>
<td>338(479)</td>
<td>74(282)</td>
<td>25(38)</td>
<td>127(479)</td>
<td>63.8%</td>
<td>26.5%</td>
<td>13(479)</td>
<td>35.1%</td>
<td>10.5%</td>
</tr>
</tbody>
</table>

Each parameter is included in the metabolic score. The number in brackets is the total number of data obtained in IDDM, NIDDM and secondary diabetes. Percentages of data obtained are also shown.

IDDM, insulin-dependent diabetes mellitus; NIDDM, non-insulin-dependent diabetes mellitus.

triglyceride revealed that more than 90% of the IDDM patients had good or acceptable values.

The mean BMI value was for IDDM patients 23.9 ± 3.0 kg/m². For NIDDM patients the mean BMI was 28.7 ± 5.6 kg/m²; 35.1% of the NIDDM patients had an unacceptably high body weight (BMI >30) and 26.2% of the NIDDM patients had a normal weight (BMI <25). The metabolic score for IDDM patients was 0.77 ± 0.42, and for NIDDM patients 0.83 ± 0.43.

Diabetic late complications

Retinopathy. Results from ophthalmological examination were only recorded in 328 of the 636 IDDM patients. One hundred and sixty-seven of these 328 patients (51.2%) showed no signs of retinopathy. Non-proliferative retinopathy was found in 122 patients (37.2%), proliferative retinopathy was found in 28 patients (8.5%) and 11 patients (3.3%) had macular involvement. Sixteen patients had a visual acuity of less than 16% (6/36). From 446 patients with NIDDM data were recorded in 165 patients. Eighty-five patients (51.5%) had no sign of retinopathy; non-proliferative retinopathy was found in 55 patients (33.3%), proliferative retinopathy in five patients (3.0%) and macular involvement in 20 patients (12.1%). Seven patients had a visual acuity of less than 16%.

Renal problems. From 636 patients with IDDM, data on renal affection were obtained in 349 patients: 324 patients (74.9%) had no renal affection (U-albumin excretion <20 μg/min), 65 patients (16.2%) had microalbuminuria (U-albumin excretion ≥0 μg/min and <200 μg/min) and 37 patients (9%) had albuminuria (U-albumin excretion ≥200 μg/min). Among the NIDDM patients data on renal affection were obtained in 224 of 438 patients: 163 patients (54.0%) had no renal affection, 81 patients (30.8%) had microalbuminuria and 35 patients (15.2%) had albuminuria. None of the patients had uraemia.

Angiopathy and neuropathy. Neuropathy and angiopathy were not evaluated properly in 1991. In our 1992 programme structured registration was initiated.

Resources used

A proper cost analysis of the treatment has not been performed, but some results are available. In 1991, the 1122 patients had 3806 contacts with doctors in the outpatient clinic. There is no significant difference between the type of diabetes and the number of contacts with a doctor (p = 0.55). Admission of diabetic patients to the hospital is a substantial part of the total cost of treatment, and it is integrated in the cost of treatment for the department. In 1991, the daily cost for one hospital bed was approxi-
FIGURE 1. The admission time (days as a function of HbA1c (arb.)). The correlation between admission time and HbA1c is significant ($p < 0.0001$).

Another basic requirement is structured data collection. Without this data retrieval is practically impossible. The introduction of the data sheets lead to discussions in the department about the necessity for more than 8 cm² free text. The impression is that free text outside the data sheet is a necessity in only about 10% of the patients.

Data collection has to be an integral part of the daily work. If not, data entrance will require extra resources. The data have to be used for a practical purpose to increase the interest in data and optimize data collection. In our outpatient clinic, the computer writes the correspondence to the general practitioner. This correspondence is revised by the physician.

It is normal procedure to divide quality assessment into assessment of the structure, the process and the outcome of care [12]. It is generally accepted that health care quality should be evaluated from outcome measurement [13,14]. When looking at the outcome parameters, we discovered that the percentage of data obtained was unacceptably low. The problem of obtaining data can be divided into three general problems:

— the investigation is not prescribed. This problem is one of planning and automating the prescription of the investigation;
— the patient has been told to have an investigation, but doesn't. This problem is one of patient compliance. To solve a problem on patient compliance it is necessary to inform the patients about the importance of the screening procedures, and the consequences of untreated late complications;
— the investigation is done, but the result is not entered into the database. This problem can again be divided into two separate ones: (A) the investigation has been performed and there is access to the data, but they are not entered into the database; (B) the investigation has been performed, but the investigator is not aware of the importance of giving us the result. In (A) it is a problem of the internal procedures in the Department. In (B) it is a problem of cooperation between the different parts of the health service system.

An acceptable recording rate was obtained only for HbA1c (93%). It should be possible to get higher rates than 93%. In 1992 we have started to include the laboratory results from
the admissions, and we hope that this will lead to a higher rate of HbA\textsubscript{1c} values obtained.

The recording rate of the diastolic blood pressure ought to be higher than 86%. It ought to be at least at the level recorded for HbA\textsubscript{1c}. There seems to be a failure in the process in the outpatient clinic. Therefore, instructions have been given that blood pressure measurement should be performed in all patients at least once a year. There are two possible reasons for failure to obtain data on S-total cholesterol and S-triglyceride. The doctor did not prescribe the tests, or the test was prescribed during admission, and the data were not transferred to the database. Measures to solve these problems have been taken. S-total cholesterol and S-triglyceride are now part of a screening procedure performed once a year and since 1 January 1992 all laboratory results have been transferred electronically to the database.

Calculation of BMI data was obtained in 71% of the patients, and in 18% of the patients the height was missing, though a body weight was recorded. This is solely a question of procedures in the outpatient clinic, and measures have been taken to ensure that the data are collected.

Urine albumin was recorded in only 54% of the patients. There are three possible reasons for not collecting data on urine albumin: lack of doctor’s compliance, i.e. the doctor did not prescribe the test; poor patient compliance, i.e. the patient did not bring a urine sample; or the test was carried out during admission and the data were not transferred. This test is now a part of the annual screening, and the results from tests carried out during admission are transferred electronically.

The lack of results obtained from the ophthalmological examination could have several causes: lack of doctor’s compliance, i.e. the doctor does not tell the patient to visit the ophthalmologist; lack of patient compliance, i.e. the patient is told to see the ophthalmologist but fails to go; communication failure, i.e. the patient does not tell the ophthalmologist that he/she has diabetes, or the ophthalmologist is not aware that the information has to be sent to the Department. The actions taken are: clear instructions when to tell the patient to see the ophthalmologist, a better follow-up on the patients who failed to see the ophthalmologist and cooperation with the ophthalmologists in the county. We hope that these actions will give us better process data in the future.

We have chosen five indicators of metabolic control for calculating a metabolic score: one parameter designating blood glucose control, and four essential predictors for the development of diabetic late complications. The limits for good, acceptable and poor control are chosen arbitrarily. Good control should at least be within the normal range, and poor control is outside the normal range.

In the metabolic score, the five indicators are of differing importance. In the light of the development of diabetic late complications glicemic regulation is very important [8]; for that reason, the HbA\textsubscript{1c} level counts 50% in the metabolic score. The diastolic blood pressure has a substantial influence on the development of nephropathy and retinopathy [9], and therefore it is given the value of 20%. The remaining indicators have less influence on the development of late complications.

International classifications have been used for the definitions of late complications [8–10]. No patient with uraemia was seen. The reason might be that all patients who require dialysis are transferred to the Department of Nephrology.

The division of metabolic control into good, acceptable and poor regulation has the advantage that it is easy to understand, easy to explain to the patient and easy to evaluate the results. The disadvantage is that it reduces flexibility in interpreting the results. Because of the variety in the patient population, it is not realistic to get good or even acceptable quality in all patients.

Since 1 June 1992 we have given every patient an individual goal for every parameter in the metabolic score. This goal is the milestone for the patient to reach within the next year. The year after, the next goal should be closer to the ideal goal.

We have shown that it is possible to develop a computer-based system to measure the quality of outpatient diabetes care. Through the measurement of outcome data, we discovered that we had problems in process quality.

REFERENCES
1. WHO, Diabetes care and research in Europe: an action programme for the implementation of the


